Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Abbott Diagnostics Division, Abbott Laboratories	Full	14	5	NICE have recommended only NT-proBNP and not recommended BNP. This should be reconsidered. Recommending only NT-proBNP and not BNP may well have severe financial implications for some laboratories (or commissioning groups), as NT-proBNP in some cases might cost ten times or more the cost of BNP assays. This may result in slower uptake of this guideline or undue limitations in the number of patients that can be tested. Financial considerations have been partly the cause of the slow uptake of the 2010 and 2003 versions of this guideline and of the AHF 2014 guideline. Other guidelines including the ESC 2016 guideline rate BNP and NT-proBNP as equally clinically useful (Ponikowski et al; European Heart Journal 2016; Thygesen et al European Heart Journal (2012) 33, 2001–2006).	Thank you for your comment. The committee discussed the optimum natriuretic peptide biomarker to use in diagnosis and monitoring of heart failure. It noted differences in stability, variances, potential confounding and extent of clinical data available with the different peptides. The committee noted the lack of a validated inter-conversion algorithm between BNP and NT-proBNP concentrations as a number of different diagnostic thresholds were investigated. The committee considered that NT-proBNP is widely used and will not have a significant resource impact.
Abbott Diagnostics Division, Abbott Laboratories	Full	23	38	For research and possible future utility, data concerning BNP as well as NT-proBNP should be investigated.	Thank you for your comment. The committee did not add BNP to the research recommendation as, even with further research, the issues of stability and interference of Sacubitril Valsartan on BNP physiology would still remain. Any further research that is undertaken on the utility of cardiac biomarkers in heart failure (including BNP) will be assessed in future iterations of this guidance.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Abbott Diagnostics Division, Abbott Laboratories	Full (Short)	27 (19)	35 (6)	**"Though current practice favours the use of biomarkers for diagnosis rather than monitoring their future use cannot be predicted."** This revision only recommends "consider" (Short Guideline page 19, line 6) the measuring of NT-proBNP as part of treatment optimisation in a specialist care setting for people aged over 75 with HFrEF and an eGFR >60, so for the vast majority of patients tested the clinical performance of BNP and NT-proBNP would be equivalent.	Thank you for your comment. The committee and evidence review did identify situations in which monitoring of natriuretic biomarkers did provide benefit however there was some uncertainty in this and therefore the committee agreed to make a 'consider' recommendation. The committee felt that the simplest biomarker profile was likely to be the easiest for organisations to adopt.
Abbott Diagnostics Division, Abbott Laboratories	Full	27	39 - 42	"***the GDG decided that NT-proBNP should be the favoured biomarker as it was more commonly used, more stable, did not require additional laboratory specimens for ideal performance and did not suffer from potential interference by novel therapies (e.g. sacubitril-valsartan)"*** **Comment 1:** Many labs run BNP, (from the latest UKNEQAS for Cardiac Markers dist 239 20th April 2018, 53 labs run BNP and 123 labs run NT-proBNP), so yes NT-proBNP is more commonly used but a significant fraction of labs would have to change assays with costs of change, financial costs (higher test price of NT-proBNP over BNP of potentially 10 fold) and clinical considerations. **Comment 2**: "Stability"; If samples are kept at 2-8 degrees, then BNP is stable for 24 hours, whether with sample is spun or unspun, which is adequate for	Thank you for your comment and the information provided. Comment 1: The unit costs of natriuretic peptide testing were identified from a number of hospital trusts during development and have now been added to the evidence report. Data from three trusts gave an average cost for BNP of £21.69. Data from five trusts gave an average cost for NTproBNP of £26.07. The committee were reassured that the average cost difference between the two tests was only around £4, admittedly with some uncertainty due to the limited sample size, although there was some overlap where NTproBNP was less expensive than BNP. The committee also mentioned that the purchase of new equipment for analysing NTproBNP is not necessary as there are kits available for all main systems. Therefore did not consider that there would be further cost

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				routine use. Reference: Abbott ARCHITECT BNP pack insert (Instructions For Use). **Comment 3**: It is generally thought that in renal failure NT-proBNP is more affected than BNP (whre eGFR <30, see Thygesen et al European Heart Journal (2012) 33, 2001–2006 and Van Kimmenade et al, JACC 2009). Also, additional cut-offs may be required depending on the patient's age for NT-proBNP which are not required for BNP. For example: "NT-proBNP results > 125.0 pg/mL for patients younger than 75 years old and > 450.0 pg/mL for patients 75 years and older were considered abnormal and suggestive of patients with HF". (McCullough P., et al., Open Heart Failure Journal, 2009, 2, 6-17) **Comment 4:** "interference by novel therapies (e.g. sacubitril-valsartan)" This is not analytical interference. The mode of action of sacubitril is thought to reduce the breakdown of BNP. As these drugs are likely to only be prescribed to a small proportion (HFrEF, not in AHF) of patients with known HF, the utility of BNP and NT-proBNP in the diagnostic pathway for CHF is likely to remain similar. If patients are known to be on sacubitril-valsartan and monitoring of NT-proBNP is desired then NT-proBNP should be recommended over BNP only for that utility.	implications beyond those reflected in the costs above. The committee were also aware that NTproBNP is due to come off patent in the next couple of years and therefore expect the cost of NTproBNP to decrease. Furthermore, the committee noted that as NTproBNP overall had a higher sensitivity compared to BNP, there is potential for some offset of the current higher cost of NTproBNP due to reduced number of false negative results for people being tested with NTproBNP compared to BNP. A false negative result would either require re-testing, or could result in hospitalisation if an acute episode occurred prior to diagnosis. They therefore considered that taking into consideration that the majority of labs now run NTproBNP, some of them teaching hospitals which receive a high volume of tests, that only recommending NTproBNP would not have a substantial resource impact for the NHS in England. Comment 2: The availability of refrigeration in primary care and along transport pathways is unclear. It may have other significant confounding effects on other biochemical analyses relevant to heart failure e.g. potassium concentrations. Comment 3: The evidence for the effects of significant renal impairment on the diagnosis of

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				However, doubts remain as to whether this proposed mechanism of action of sacubitril represents an oversimplification, considering the highly complex nature of the NP system. Neprilysin is a ubiquitous enzyme involved in the breakdown of not just NPs, but of multiple vasoactive peptides, such as endothelin-1, angiotensin II, adrenomedullin and bradykinin. Its inhibition should result in elevated levels of beneficial substances, such as BNP, that work to prevent adverse processes in HF (such as sodium retention, remodeling and vasoconstriction). However, since NPs were discovered more than 20 years ago, the complex interactions between NPs and neprilysin have not been fully elucidated. Firstly, though we know that neprilysin is involved in BNP metabolism, it has been shown to have less affinity for BNP relative to other NPs, such as atrial natriuretic peptide.(Pankow K, Schwiebs A, Becker M, Siems WE, Krause G, Walther T. Structural substrate conditions required for neutral endopeptidase-mediated natriuretic peptide degradation. J Mol Biol. 2009;393:496-503). Secondly, recent evidence shows that, at high levels (>916 pg/ml), immunoreactive BNP may, in fact, act as a neprilysin inhibitor.(Vodovar N, Seronde MR, Laribi S, et al. Elevated plasma B-type natriuretic peptide concentrations directly inhibit circulating neprilysin	heart failure was reviewed for both BNP and NT-proBNP. Insufficient evidence was found and a research recommendation has been made. Comment 4: Analytical interference is a recognised specific term. 'Interference'- a more general term- has been amended to 'confounding of interpretation' as a potential problem. The committee considered that the potential necessity to run 2 natriuretic peptide biomarker assays for heart failure would introduce complexity, additional costs and potentially induce confusion amongst users. The committee reviewed the evidence for natriuretic peptide monitoring in heart failure and made recommendations on this topic. The effect of biotin interference is well recognised in clinical biochemistry laboratories. This specific topic is outside the scope of this guideline.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				activity in heart failure. J Am Coll Cardiol HF. 2015;3:629-636). Adding to this conundrum is the fact that commercially available BNP assays do not measure bioactive (1-32) BNP alone, but also measure proBNP and several BNP breakdown fragments.(Miller WL, Phelps MA, Wood CM, et al. Comparison of mass spectrometry and clinical assay measurements of circulating fragments of B-type natriuretic peptide in patients with chronic heart failure. Circ Heart Fail. 2011;4:355-360). A recent publication further highlights the fact that BNP and proBNP differ in their susceptibility to cleavage by neprilysin. The authors stated: "… in contrast to BNP, both forms of proBNP were resistant to degradation by neprilysin" and that "one may suggest that NT-proBNP … should be used as a HF biomarker, rather than BNP, along with LCZ696 therapy. However this hasty suggestion is based on an overly simplified model of a complex biological phenomenon. Undoubtedly, more clinical data are needed." Furthermore, if this potentially oversimplified mechanism of action were true, it could also be concluded from the limited data presented that NT-proBNP is unsuitable for monitoring HF patients treated with ACE inhibitors, as the observed NT-proBNP levels do not appear to significantly decrease over time for	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				patients on ACE inhibitors, according to the PARADIGM data (7Packer M, McMurray JJ, Desai AS, et al. Angiotensin receptor neprilysin inhibition compared with enalapril on the risk of clinical progression in surviving patients with heart failure. Circulation. 2014). Lastly, none of the publications to date demonstrate any direct correlation between a change in biomarker levels and patient outcomes. The effect of LCZ696 on neprilysin activity, as well as on proBNP and BNP fragments, has not yet been documented. Data to support the mechanism stated above have not been published, and further research in the area is urgently needed.(Bayes-Genis A. Neprilysin in heart failure: from oblivion to center stage. J Am Coll Cardiol HF. 2015;3:637-640; Dec GW. LCZ696 (sacubitril/valsartan): Can we predict who will benefit? J Am Coll Cardiol. 2015;66(19):2072-2074.:Jaffe AS, Apple FS, Mebazaa A, Vodovar N. Unraveling N-terminal pro-B-type natriuretic peptide: another piece to a very complex puzzle in heart failure patients. Clin Chem. 2015;61:1016-1018.) **Comment 5**: re Line 42 "interference". It has been demonstrated that assays using streptavidin-biotin capture/binding as part of the assay format may suffer interference from biotin present in patient samples (see	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				for example Trambas et al Ann Clin Biochem 2018, for example with one NT-proBNP assay "with a reduction in measured results of more than 95%"). Biotin interference as a potential issue was highlighted in a recent FDA safety warning where a death was associated with biotin interference with a laboratory test. https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586641.htm Note as well that the 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis (Ross et al. American Thyroid Association Guidelines; 2016; Thyroid;26(10): 1343-1421) note the possibility of biotin interference with testing and give advice on how to reduce risk. NICE in this guideline should recommend to use BNP or NT-proBNP assays which are robust or immune to biotin interference (do not use streptavidin-biotin binding/capture assay formats) and/or provide instructions on how to reduce the risk of biotin interference.	
Abbott Diagnostics Division, Abbott Laboratories	Full	27	43	**"The GDG also noted the lack of large-scale data to derive interconversion algorithms for BNP and NT-proBNP and thus decided to base its decision making solely on NT-proBNP."** The current (2010) version of the CHF guideline used cut-offs for both BNP and NT-proBNP. As literature and guidelines up to now have suggested equal clinical utility for BNP and NT-proBNP why is there a need for a conversion	Thank you for your comment. This sentence has been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				algorithm between BNP and NT-proBNP? If there is a need for a conversion algorithm and there isn't an algorithm why is BNP not recommended and NT-proBNP is? Please remove this statement.	
Action on Smoking and Health (ASH)	Full	15	34-41	**Explicit guidance on smoking cessation** *"For guidance on smoking cessation refer to the following NICE guidance…"* Overwhelming evidence demonstrates the damage done by smoking on chronic heart failure patients. Behavioural risk factors are responsible for 80% of all diagnoses of coronary heart disease and cerebrovascular disease.[1] Although unhealthy diet, physical inactivity and harmful use of alcohol play a role, smoking is by far the leading behavioural risk factor of CVD: it has been attributed to account for 14% of deaths from heart and circulatory disease.[2] ASH therefore welcomes the reference made to NICE Guidance PH45 on smoking harm reduction, PH10 on smoking cessation services and PH1 on interventions and referral for smoking cessation in primary care and other settings. ASH would like to flag that PH1 and	Thank you for your comment. We have updated the NICE guidance listed to include NG92. As NICE has issued comprehensive guidance on smoking cessation services and interventions we think this provides health professionals with guidance applicable to people with heart failure and separate recommendations are not necessary.

[1] Global status report on non-communicable diseases 2010. Geneva, World Health Organization, 2011
[2] Health and Social Care Information Centre (HSCIC), Lifestyles Statistics. Statistics on Smoking: England, 2012.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				PH10 have now been largely superseded by the New Guideline NG92. However, given the significant risk posed by smoking and exposure to secondhand smoke to people with chronic heart failure, ASH believes the NICE guidance would be improved by explicitly requiring health and care practitioners to: (1) Identify patients exposed to (secondhand) smoke (2) Issue brief advice and refer patients (and carers) to stop smoking services	
Action on Smoking and Health (ASH)	Short	4	10-12	**<u>(2) Issuing brief advice and referring patients (and carers) to stop smoking services</u>** "*The specialist heart failure MDT should directly involve, or refer people to, other services, including rehabilitation services, and tertiary and palliative care, as needed.*" This statement outlines the expectation that the specialist heart failure MDT should work with other health and care practitioners in managing chronic heart failure, and provide patients with guidance on where to seek the necessary support throughout their recovery.	Thank you for your comment. As NICE has issued comprehensive guidance on smoking cessation services and interventions we think this provides health professionals with guidance applicable to people with heart failure and separate recommendations are not necessary. A link to NICE guidance on smoking cessation has been provided in the guideline.

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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				However the guidance does not explicitly reference the need to provide adults with chronic heart failure support in adopting smokefree lifestyles. All healthcare professionals need to be prompting quit attempts through the delivery of cessation advice at every opportunity, and be connecting patients with the right network of smoking cessation services. Providing this advice is key to achieving NICE's ultimate aim of increasing the length and quality of life for people with heart failure. This is also crucial to reducing health inequalities. Higher smoking prevalence is associated with almost every indicator of deprivation or marginalisation. For example, compared to the population as a whole, smoking is more common among people with a mental health condition, the unemployed, homeless people, those who receive welfare benefits, and members of the LGBT community. Since smoking is so harmful, this difference in smoking prevalence translates into major differences in death rates and illness (including chronic heart failure). ASH therefore recommends that the NICE guidelines explicitly encourage the specialist heart failure MDT to offer brief advice and connect patients (and their carers) with smoking cessation services, to support them in quitting smoking and remaining smokefree.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Action on Smoking and Health (ASH)	Short	6	2-8	**(1) Identifying patients exposed to (secondhand) smoke** *"The specialist heart failure MDT should write a summary for each person with heart failure that includes…social circumstances, including carers' needs."* ASH welcomes this guidance, which encourages the specialist heart failure MDT to summarise their patient's diagnosis, medicines, social care needs and broader social context (as well as that of their carers'), when compiling the care plan. However, ASH believes this summary could be improved if practitioners were explicitly encouraged to use this summary as an opportunity to identify patients (and carers) who smoke. Smoking and passive smoking harms patients with chronic heart failure. Evidence shows that: • Following surgery, it is essential that smokers are supported to remain smokefree, since research has found that smokers who quit smoking after coronary surgery had significantly better outcomes, including lower	Thank you for your comment. The recommendation outlines the key areas to include within a care plan and is not intended to be a definitive list. As NICE has issued comprehensive guidance on smoking cessation services and interventions we think this provides health professionals with guidance applicable to people with heart failure and separate recommendations are not necessary. A link to NICE guidance on smoking cessation has been provided in the guideline.

Chronic heart failure in adults: diagnosis and management

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				risk of repeat coronary procedures than those who return to smoking.[3] • For those who have a heart attack, the risk of death is greater among current smokers: there is a 62% increased rate of death from heart attacks among smokers compared to lifelong non-smokers, and a 32% increased risk of death compared to former smokers.[4] • Within a year of giving up smoking, the risk of a heart attack halves compared to that of an active smoker and declines gradually thereafter.[5] • Exposure to second-hand smoke is a cause of heart disease, with an increased relative risk of about 25%.[6] • Exposure to secondhand smoke can increase the risk of CHD by 50% to 60%.[7]	

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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				• After the introduction of smokefree legislation in England in 2007, emergency hospital admissions for myocardial infarction (heart attack) fell by 2.4% (equivalent to 1200 fewer admissions).[8] ASH therefore recommends NICE explicitly advises the specialist heart failure MDT to include in the care plan a record of their patients smoking habit and whether they are exposed to second hand smoke.	
Alliance for Heart Failure	Full	General	General	At 515 pages in length the guidance is impractical and unreadable, especially for the non-expert for whom Guideline documents have the greatest day-to-day value. Some of the most useful parts such as the treatment algorithm are hidden at the back.	Thank you for your comment. The algorithm has been moved to an earlier section of the guideline. The full guideline is lengthy because of the large scope and number of evidence reviews conducted; however there is a short version containing just the recommendations.
Alliance for Heart Failure	Full	General	General	The NICE draft Guideline for the management of chronic heart failure contains a number of recommendations which are not supported by evidence from clinical trials and which, in some cases, may increase the risk of adverse outcome for patients with heart failure, particularly those with left ventricular systolic dysfunction.	Thank you for your comment. The protocols were agreed by the committee and all the identified studies that met the inclusion criteria were included in the evidence reviews. The protocols provide further detail about the inclusion and exclusion criteria. The committee made their decisions based on the best clinical and cost effectiveness evidence available and

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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				Some of the following points represent specific instances where the draft Guideline directly either fails to recommend the implementation of the results of well-conducted clinical trials, or makes recommendations based upon post-hoc analyses, the results of which are not accepted as being evidence-based by the vast majority of specialists in heart failure management. Moreover, in many cases the recommendations contradict those in Guideline documents from international specialist societies, in particular the European Society of Cardiology (ESC).	where the evidence was lacking the committee used their clinical experience and consensus.
Alliance for Heart Failure	Full	20	38-41	The Alliance for Heart Failure welcomes the changes to the guideline with the recommendation for use of NT-ProBNP and the removal of BNP based on the evidence available. The removal of the "Previous MI" caveat is welcomed as this previous recommendation was based on limited evidence.	Thank you for your comment.
Alliance for Heart Failure	Full	126	30	'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia. [2018]': There is no *a priori* evidence to support this recommendation but only a secondary analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				outcome studies and all other recent national and international heart failure guidelines.	recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Alliance for Heart Failure	Full	126	60	The evidence for this recommendation was taken from sub-analysis of original studies to set out to determine this. This goes against all previous RCT evidence for beta-blockers that did show a mortality improvement. Also, since increasing the prescribing of these data from the National Heart Failure Audit has seen an improvement in mortality rates. The Alliance for Heart Failure is concerned that this would be detrimental to patient care.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Alliance for Heart Failure	Full	170	2	IV iron – No recommendation. The Alliance for Heart Failure agrees there is no evidence for mortality and hospital admission. However, there is some information regarding quality of life and hence its inclusion into ESC Heart failure guidelines. It could be included as an option for those patients on maximum tolerated treatment who meet criteria for iron deficiency for symptomatic benefit.	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The committee have taken into account your comments but are not convinced that the high (and low quality) evidence on quality of life alone was enough to support a recommendation when taking into account the evidence on the other outcomes. The linking evidence to recommendations section outlines the committee's rationale for their decision that

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.
Alliance for Heart Failure	Full	193	31	**'For people who have heart failure with reduced ejection fraction and chronic kidney disease treat according to eGFR (estimated glomerular filtration rate) as follows : eGFR 45 ml/min/1.73 m2 or more: offer the treatment outlined in treating heart failure with reduced ejection fraction, eGFR 30 to 44 ml/min/1.73 m2: consider the treatment outlined in treating heart failure with reduced ejection fraction, and all eGFR 30 to 59 ml/min/1.73 m2: consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. [2018]':** This recommendation is also contrary to evidence from the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to LVSD, and all other recent national and international heart failure guidelines. The recommendation in the current NICE draft Guideline has the clear potential to cause harm to patients, as it will encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), without evidence to support this action. Further, the thresholds which	Thank you for your comment. The committee agree the evidence is not robust and it has been graded from low to very low quality with the majority being rated as very low quality. The committee have outlined in detail the limitations of the subgroup analysis in the evidence to recommendations section. However the committee agreed that it was important to provide advice for this common subgroup of HFREF patients. Based on the evidence reviewed and the experience of the committee members, consensus was reached on the optimal treatment approach for patients with HFREF and CKD.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				appear in the recommendation are entirely arbitrary, for which there is no scientific evidence. Considering eGFR is an estimate based on a number of factors, and this is the most appropriate way to direct treatment. Renal physicians would use ACEI/ARBs for their renal protective properties while monitoring renal function. If heart failure teams liaised with renal consultants for all patients with an eGFR < 30 they would be inundated with heart failure patients, with the potential for reduction In or withdrawal of evidence-based treatments without good clinical evidence for so doing. The Alliance for Heart Failure agrees that patients with reduced kidney function should have careful titration and monitoring and that changes in eGFR should be evaluated against the likely benefit of ongoing treatment. The Alliance for Heart Failure is concerned that this will be detrimental to patient care with patients not receiving appropriate treatment. This recommendation should be removed.	
Alliance for Heart Failure	Full	197	6	Diuretics – treatment in preserved ejection fractions should be offered low to medium doses of loop diuretics. Is treating oedema different in this cohort of patients? Should it not be titrated up and down according to symptoms as with HFREF?	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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Alliance for Heart Failure	Full	200	21,22	**Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)c':** There is no justification for the NICE guideline to FAIL to show the recommendation for this treatment in detail, as it does with other pharmacological interventions. In an area of such clinical importance (i.e. mortality benefit) why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, the Alliance for Heart Failure believes that the recommendations from NICE Technology Appraisal Guidance 388 should be replicated verbatim in this guidance to make the document easier for the reader. Further we are unclear as to why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a first-in-class medication with clear evidence of improved outcomes for patients, we believe that practical recommendations regarding initiation and monitoring, 'similar to every	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have now been included in full.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				other medication with prognostic importance, should be displayed.	
Alliance for Heart Failure	Full	217	2	**Figure 5: Therapeutic algorithm:**. This algorithm is not consistent with other recent national and international heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388. The Figure is unclear and places available therapies in an inappropriate order. a. **Beta-blockers and AF:** as above b. **CKD recommendations:** as above c. **2nd line MRA advice:** 'mildly symptomatic' is ambiguous. This should be displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. d. **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation and ivabradine all have prognostic importance and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies should be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				displays this flow more appropriately. The Alliance for Heart Failure sees no rationale for the NICE guideline to diverge from the Figure in the ESC guidelines. e. **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm.	arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
Alliance for Heart Failure	Full	223	Table 75	Typo in the column on 'no. of participants (studies) follow up': the 'exercise capacity – ISWT' outcome should read '30 (1 study) 2 months', rather than '161 (1 study) 2 months'.	Thank you for your comment. This has been amended.
Alliance for Heart Failure	Full	228	Recommendations	The inclusion of 'or device' within this table may lead to over-caution regards home exercise prescription in those with ICDs.	Thank you for your comment. The recommendation has been amended to remove any reference to devices.
Alliance for Heart Failure	Full	228	Recommendations	In line with BACPR Standards and Core Components, it would be pertinent to state that an appropriately qualified cardiac rehabilitation professional should perform the pre-exercise assessment and prescribe the home training programme.	Thank you for your comment. All interventions should be delivered by qualified health professionals with the necessary competencies to deliver care for patients with CHF; therefore we do not think it is necessary to specify it here.
Alliance for Heart Failure	Full	232	Other Considerations	Early results from an important study trialling an evidence-based home rehabilitation programme for those with HFPEF are now available. This paper -	Thank you for your comment. Lang et al (2018) was published after the cut-off date for the final searches and section 5.10 of Developing NICE

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				[http://bmjopen.bmj.com:/cgi/content/abstract/8/4/e019649?ct] - shows that the intervention was well-received by patients, carers and health professionals. This study should be highlighted to both clinicians and commissioners as full results will be disseminated soon.	guidelines: the manual states, 'If evidence is identified after the last cut-off date for searching but before publication, a judgment on its impact should be made by the Developer and NICE staff with a quality assurance role. In exceptional circumstances, this evidence can be considered if its impact is judged as substantial'. The committee did not consider this paper would have a substantial effect on the recommendations to include the data.
Alliance for Heart Failure	Full	265	14	**"The reduction in deaths & hospitalisation would be most significant for people in higher risk categories such as: Newly Diagnosed, a recent deterioration, require a medication titration".** The Alliance for Heart Failure supports the recommendation for the inclusion of the recommendation for monitoring patients using NT-ProBNP. The document however is very long and the recommendation is very specific. The details of specific patient groups that would benefit from monitoring could be made clearer as these are buried within the body of the text:	Thank you for your comment. . A short version of the guideline is available that provides a quick reference to the recommendations and has a section on monitoring as well as specific monitoring requirements for drug treatments.
Alliance for Heart Failure	Full	413	30, 31, 32, 34,35,36	Part of the role of the community team is to optimise treatment as part of the heart failure service. Is this suggestion that this should all be done in a secondary care setting? Are the community teams not able to optimise treatment and manage newly diagnosed patients? They currently do.	Thank you for your comment. No, the HF MDT would manage the person's care in collaboration with the primary care team. Configuration of services will vary but once discharged into the community the primary care team would manage the patient and ensure there are effective communication links between the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					different care settings and clinical services involved in a person's care to facilitate re-access to specialist HF services as required.
Anaemia Manifesto Steering Committee	General	General	General	The purpose of NICE's draft guidance was to assess chronic heart failure as a whole and the supplementation of people with iron deficiency as a subset, based on mortality, quality of life and unplanned hospitalisations, which we welcome. However, while the draft guidance recognises the high incidence of iron deficiency (ID) in chronic heart failure (CHF), it makes no recommendation for the diagnosis or treatment of iron deficiency in CHF, which we believe to be of critical importance. We understand that NICE may be unwilling to make this recommendation as they await the IRONMAN study to report, which is currently projected to be in 2022. However, we believe that in the interim, there are serious implications for the nearly 1 million heart failure patients in the UK who are living with potentially undiagnosed iron deficiency, which negatively impacts quality of life.[1] The panel have judged quality of life to be an important decision making-factor but have disregarded high-quality evidence demonstrating the benefits of intravenous iron treatment on quality of life. This oversight will have a severe impact on NHS providers as they struggle to accommodate increasing demand with fewer resources; IV iron therapy	Thank you for your comment. The committee reviewed all the available evidence and decided that in the absence of substantial effects on hard outcomes or hospitalisation that a clear statement about the benefits or harms of iron therapy could not be made. The committee noted that 2 large trials were underway that may answer this question. In addition the resource impact of any recommendation needed to be considered. It felt that making any definitive recommendation in this field was premature at this time.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				significantly reduces the rate of hospitalisations and improves symptoms, functional capacity, and quality of life for HF patients.[2] Finally, in assessing the same evidence, other, independent, guideline committees that have determined that IV iron treatment in CHF patients is clinically effective and meta-analyses support the conclusion that IV iron can improve symptoms, patient outcomes, exercise tolerance, quality of life and risk of hospitalisation. Eur J Heart Fail. 2016 Jul;18(7):786-95. doi: 10.1002/ejhf.473. Epub 2016 Jan 28. [2] Can J Cardiol. 2016 Feb;32(2):151-9. doi: 10.1016/j.cjca.2015.06.009. Epub 2015 Jun 21.	
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	20	10	'*should be preceded by an assessment to ensure that it is suitable for the person'* The word 'comprehensive' before assessment would improve this and inform on the detailed assessment necessary. Also adding that the assessment should be carried out by an ' appropriately qualified health professional'	Thank you for your suggestions. An appropriate assessment to determine whether a person is suitable for rehabilitation should be undertaken and the committee consider the current wording adequate. All recommendations should be carried out by health professional with the necessary qualifications and competencies and therefore we do not think it necessary to state this.
Association of Chartered Physiotherapi	Full	20	16 &17	Unclear what this sentence means ' *should be accompanied by information about support available from health care professionals when the person is doing the programme'*. I think it needs elaboration, Also	Thank you for your comment. The types of information and support provided to patients are outlined in the linking evidence to recommendations section of the review. What

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
sts in Cardiac Rehabilitation				I'm not sure about the phrase *'doing the programme'*, participating in the programme may be better	was provided varied between trials and therefore it was not possible to specify in a re commendation what this should comprise of.
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	218	12	Typo - heart is spelt incorrectly	Thank you for your comment, this has been corrected.
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	218	13	Typo - ischaemia is spelt incorrectly	Thank you for your comment, this has been corrected.
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	218	16	Typo - myocardial is spelt incorrectly	Thank you for your comment, this has been corrected.
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	228	General	Recommendation box …*'unless their condition is unstable or they have a condition or device that precludes such a programme.'* A device would not preclude such a programme and this could be misleading and give the wrong impression. Heart failure patients with traditional pacemakers, CRT, ICDs and LVADs access cardiac rehab routinely as per local arrangement. If there was an issue with the device then this would come under their condition being unstable	Thank you for your comment. The recommendation has been amended to remove any reference to devices.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	228	General	Recommendation box, same comment as comment 1 above	Thank you for your comment. The recommendation has been amended to remove any reference to devices.
Association of Chartered Physiotherapists in Cardiac Rehabilitation	Full	228	General	Recommendation box, same comment as comment 2 above	Thank you for your comment. The recommendation has been amended to remove any reference to devices.
Bayer plc	Short	19	5	Measuring NT-proBNP What appears to fall under the remit of the *'role of biomarkers (including natriuretic peptides)'* in *'monitoring heart failure'* as outlined in the scope for this guideline, but what is not covered in the draft guideline, is the value of the biomarker monitoring of patients who have experienced an acute decompensation/hospitalisation related to their chronic heart failure. Indeed it appears that the population for review question *"what is the clinical and cost effectiveness of biomarker-based monitoring, monitoring with cardiac MRI, and monitoring with repeated echocardiography in people with heart failure?"* as outlined in the PICO table (p234 full guideline) is limited to *"people diagnosed with heart failure in a community or outpatient setting",* which omits this important group. The importance of this group was previously	Thank you for your comment and the background references for this population. Acute episodes of heart failure are outside of the scope of this guideline as there is now an acute heart failure guideline. The protocol in the previous CHF guideline may have included a wider population because at that time the Acute HF guideline had not been developed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recognised in the current chronic heart failure clinical guideline in recommendation 1.4.3.1 *"Consider specialist monitoring of serum natriuretic peptides in some patients (for example, those in whom up-titration is problematic **or those who have been admitted to hospital)**."* We believe this omission is inappropriate and should be rectified. There is a large body of evidence showing that admission, discharge and change in BNP/NT-proBNP levels during admission because of acute decompensated heart failure and/or early post-discharge NT-proBNP trajectory are prognostic risk factors for readmission and mortality.[1-12] Therefore it has been suggested that objective data yielded by BNP/NT-proBNP and risk stratification during heart failure hospitalisation admission and/or early after discharge is important because it may help to select those patients in need of more intensive treatment, monitoring and follow-up.[2;13;14] We believe that according to the scope, the issue of monitoring natriuretic peptides in those who have been admitted to hospital should be covered by the guideline. It is not covered by the acute heart failure clinical guideline which only discusses NT-proBNP in the context of diagnosing HF in people presenting with new suspected acute heart failure, rather than a	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				decompensation or worsening of previously diagnosed chronic heart failure. **Reference List** (1) De Vecchis R, Ariano C, Giandomenico G, Di MM, Baldi C. Change of Serum BNP Between Admission and Discharge After Acute Decompensated Heart Failure Is a Better Predictor of 6-Month All-Cause Mortality Than the Single BNP Value Determined at Admission. *J Clin Med Res* 2016; 8(10):737-742. (2) Eurlings LW, Sanders-van WS, van Kraaij DJ, van KR, Meeder JG, Kamp O et al. Risk stratification with the use of serial N-terminal pro-B-type natriuretic peptide measurements during admission and early after discharge in heart failure patients: post hoc analysis of the PRIMA study. *J Card Fail* 2014; 20(12):881-890. (3) Greene SJ, Maggioni AP, Fonarow GC, Solomon SD, Bohm M, Kandra A et al. Clinical profile and prognostic significance of natriuretic peptide trajectory following hospitalization for worsening chronic heart failure: findings from the ASTRONAUT trial. *Eur J Heart Fail* 2015; 17(1):98-108.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(4) Leto L, Testa M, Feola M. The predictive value of plasma biomarkers in discharged heart failure patients: role of plasma NT-proBNP. *Minerva Cardioangiol* 2016; 64(2):157-164. (5) Minami Y, Kajimoto K, Sato N, Hagiwara N, Takano T, Mebazaa A. Heterogeneity of the prognostic significance of B-type natriuretic peptide levels on admission in patients hospitalized for acute heart failure syndromes. *Eur J Intern Med* 2016; 31:41-49. (6) Naffaa M, Makhoul BF, Tobia A, Jarous M, Kaplan M, Aronson D et al. Brain natriuretic peptide at discharge as a predictor of 6-month mortality in acute decompensated heart failure. *Am J Emerg Med* 2014; 32(1):44-49. (7) Omar HR, Guglin M. Discharge BNP is a stronger predictor of 6-month mortality in acute heart failure compared with baseline BNP and admission-to-discharge percentage BNP reduction. *Int J Cardiol* 2016; 221:1116-1122. (8) Omar HR, Guglin M. Rise in BNP despite appropriate acute decompensated heart failure treatment : Patient characteristics and outcomes. *Herz* 2017; 42(4):411-417. (9) Omar HR, Guglin M. Post-discharge rise in BNP and rehospitalization for heart failure. *Herz* 2018.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(10) Pereira-Barretto AC, Carlo CH, Cardoso JN, Ochiai ME, Lima MV, Curiati MC et al. Role of BNP levels on the prognosis of decompensated advanced heart failure. *Arq Bras Cardiol* 2013; 100(3):281-287. (11) Santaguida PL, Don-Wauchope AC, Oremus M, McKelvie R, Ali U, Hill SA et al. BNP and NT-proBNP as prognostic markers in persons with acute decompensated heart failure: a systematic review. *Heart Fail Rev* 2014; 19(4):453-470. (12) Scrutinio D, Guida P, Passantino A, Lagioia R, Pepe S, Catanzaro R et al. Amino-terminal pro-B-type natriuretic peptide for risk prediction in acute decompensated heart failure. *Congest Heart Fail* 2012; 18(6):308-314. (13) Bettencourt P, Azevedo A, Pimenta J, Frioes F, Ferreira S, Ferreira A. N-terminal-pro-brain natriuretic peptide predicts outcome after hospital discharge in heart failure patients. *Circulation* 2004; 110(15):2168-2174. (14) Salah K, Kok WE, Eurlings LW, Bettencourt P, Pimenta JM, Metra M et al. A novel discharge risk model for patients hospitalised for acute decompensated heart failure incorporating N-terminal pro-B-type natriuretic peptide levels: a European coLlaboration on Acute decompeNsated Heart Failure: ELAN-HF Score. *Heart* 2014; 100(2):115-125.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Betsi Cadwaladr University Health Board	Short	14	26	The recommendation will be challenging in practice, and the patient will have already been seen regularly for review whilst being titrated so if they are NYHA I, I do not see what benefit the additional monthly reviews would gain.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Betsi Cadwaladr University Health Board	Short	14	4	The recommendation will be challenging in practice, and the patient will have already been seen regularly for review whilst being titrated so if they are NYHA I, I do not see what benefit the additional monthly reviews would gain.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Betsi Cadwaladr University Health Board	Short	17	16	I am concern that this recommendation is contradictory to the statement below on page 17, line 20, where lower doses and slower titrations are suggested.	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

					agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.
Boehringer-Ingelheim	Short	General	General	We note that the guideline includes recommendations for heart failure (HF) patients with relevant co-morbidities including chronic kidney disease. With the increasing age and complexity of patients with HF we believe it would be useful to have specific guidelines for the management of HF in patients with type 2 diabetes. Type 2 diabetes and HF have significant and increasing association, particularly in patients with HFpEF where type 2 diabetes is a strong predictor[1]. Approximately 20% patients with HF have type 2 diabetes[2]. Indeed, type 2 diabetes is also a strong risk marker in HF, associated with significantly worse prognosis[3] and an increased risk of hospitalisation for HF (hHF) and death[4]. In addition, many therapeutic classes for glycaemic lowering in type 2 diabetes have particular importance to HF as they are either associated with fluid loss or retention and could thus affect HF symptoms and/or outcome. In the 2016 European Society of Cardiology guidelines for HF there is a section for diabetes, which includes	Thank you for your suggestion. At the time of considering the content for the update of this guideline the management of people with heart failure and type 2 diabetes was not highlighted as a high priority area. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				data and recommendations from the EMPA REG OUTCOME study[5]. This cardiovascular safety study in adults with type 2 diabetes showed that use of empagliflozin was associated with significant reductions in both hHF (HR 0.65 95% CI: 0.50, 0.85; p=0.002) and the composite of hHF and CV death (HR 0.66 95% CI: 0.55, 0.79; p<0.001) versus placebo. In the study 10.1% of patients had HF reported at baseline, with post hoc analyses showing that the risks of both hHF and the composite of hHF and CV death were consistent in patients with and without baseline HF[6]. **Summary** We believe that specific information about the management of HF patients with type 2 diabetes would be of particular relevance to clinicians. In addition, inclusion of information about HF outcomes associated with the use of empagliflozin would provide evidence based data to prescribers that could directly benefit patients and the NHS. 1. Ather S, et al. J Am Coll Cardiol 2012;59:998–1005. 2. Bertoni AG, *et al. Diabetes Care* 2004;27:699–703; 3. Varela-Roman A, et al. Eur J Heart Failure 2005;7:859–864	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				4. Aguilar D, et al. Am J Cardiol 2010;105:373–377 5. Zinman B, et al. N Engl J Med 2015;373:2117–2128. 6. Fitchett D, et al. Eur Heart J 2016;37:1526–1534	
Boston Scientific	Short	19-20	General	**We would ask NICE to consider the inclusion of the latest NICE Interventional procedure guidance (IPG603) published in December 2017: "Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death" under sub-heading Interventional Procedures since this has now moved into the category of Normal arrangements for the treatment of heart failure patients.**	Thank you. This information is not included in the short version of the guideline. It has been added to the full guideline see section 3.3.3.
Boston Scientific	Short	4	Line13	We would ask NICE to consider to include the following in the MDT tasks: MDT should check if the cardiac implantable electronic device (CIED) has an HF monitoring function, such as HeartLogic, and if that should be used in the specific patient.	Thank you for your suggestion but we feel this level of detail is not needed as the recommendation aims to provide a brief list of the core functions of the specialist HF MDT.
Boston Scientific	Short	4-5; 24	Page 4 line 2–20 Page 5 line 1–18	We are pleased to see that NICE is updating this guideline on Chronic Heart Failure in adults. We believe it is important to ensure high quality of care for patients with Heart Failure problems and for this reason we would like to emphasize the important role of the specialist heart failure multidisciplinary team (MDT) in the management of the patient pathway. The new draft recommendation suggests that the role of the	Thank you for your suggestion however This recommendation has been changed to clarify the specialist HF MDT would continue to manage the person's heart failure not the management of the interventional procedure and therefore a Electrophysiologist would not be require d as a core member of the MDT.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Page 24 line 12-15	specialist MDT should: 'manage care after an interventional procedure such as implantation of a cardioverter defibrillator, cardiac resynchronisation device or left ventricular assist device, or cardiac transplantation.' We would like NICE to include the Electrophysiologist (EP) in this MDT. The role of the EP has evolved with the inception of innovation technologies used in the management of Heart Failure. Historically the role was linked to complications that arise with the implantation of CRT and ICD devices e.g. battery and lead replacement. Today with the changing treatment landscape, the role of the Electrophysiologist within the MDT is also important during diagnostics and management of these patients, especially for patients with ICD and CRT devices.	
Boston Scientific	Short	27	Line 3-14	We would also like to suggest in "Recommendations for research" a multisensor algorithm to predict heart failure events in patients with implanted devices. This is important for the following reasons: • HF involves costly hospitalisations with adverse impact on patient outcomes. A diagnostic tool that is able to predict HF decompensation events before they happen may result in earlier intervention that reduces hospitalisation. The MultiSENSE (Multisensor Chronic Evaluation in Ambulatory Heart Failure Patients) study demonstrated that HeartLogic multisensor index and alert algorithm	Thank you for your comment. Research recommendations can only be made for questions that have been reviewed by the guideline and lack of evidence has been established.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				provide a sensitive and timely predictor of impending HF decompensation. (Evaluation of Multisensor Data in Heart Failure Patients with Implanted Devices [MultiSENSE]; NCT01128166).	
British Cardiovascular Society	Short	General	General	No comments to be made on most of the guidelines.	Thank you for your comment.
British Cardiovascular Society	Short	4-6	General	The detailed description of the MDT and its roles is good.	Thank you for your comment.
British Cardiovascular Society	Short	10	2-3	Re: 1.3.5 – clinic appointments "Offer people newly diagnosed with heart failure an extended first consultation, followed by a second consultation to take place within 2 weeks if possible." It would be helpful for consistency, planning clinic templates, and job planning for an approximate duration to be specified for these extended appointments - 30 minutes, for example?	Thank you for your comment. The committee made this recommendation in line with the Patient experience guideline (CG138), recommendation 1.3.4 'Allow adequate time so that discussions do not feel rushed.' The committee considered that keeping to a standard consultation appointment time was not generally long enough to allow for to this, and therefore made this recommendation. They did not consider that they could advise on how long this should be, as this would likely vary from patient to patient.
British Cardiovascular Society	Short	13	13-16	Re: 1.5.3 – use of beta-blockers in patients with AF "Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia. **[2018]"**	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This recommendation is based on a review of a meta-analysis of beta-blocker trials, with the conclusion that there is no clear harm or benefit for using beta-blockers in patients with AF. . Heart Failure specialists have been encouraging the use of beta-blockers in patients with left ventricular systolic dysfunction for many years. We are concerned that this guidance may confuse the message that beta-blockers are (mostly) helpful in this group of patients. This recommendation is also not specific regarding the type of AF to which it is referring – does it refer to patients with permanent AF only, or should beta-blockers be withheld from patients with LVSD and persistent AF, or paroxysmal AF?. Many patients with HFrEF and AF will need rate control and some will have previous MI so will have other indications for a beta-blocker. There is little economic argument for not giving a beta-blocker (drug costs are low compared to other heart failure treatment costs). So is it worth introducing potential confusion with this recommendation? We recommend that it is reviewed	potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
British Heart Rhythm Society	Full	General	General	The BHRS has read the new heart failure management guidelines in adults and wishes to give its comments. This is a good document but overlooks important evidence in the literature that we think should	Thank you for your comment. AF ablation and ablation of premature ventricular complexes were not identified by stakeholders as an area to include in the scope and as such we cannot evaluate the evidence in this area or make

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				significantly influence patient management. We accept that this guideline cannot possibly cover every aspect of heart failure management, nor can it be granular enough to directly guide the management of every heart failure patient but we do feel that some important aspects of heart failure management should be mentioned so that clinicians and patients reading the guidelines are aware of them and therefore are in a position to gain access to them if this is appropriate. Without mentioning them there is a serious risk of inequality of access such that only patients in teaching hospitals might be offered these treatments. 1) we would suggest that AF ablation should be *considered* in patients with heart failure. The 2014 AF management guidelines recommended this and so could be cross-referenced. Since then more evidence has been produced that demonstrate efficacy of AF ablation in heart failure that makes the case even more compelling, particularly for patients who have no other clear cause for their heart failure and the AF preceded or coincided with the heart failure. Studies demonstrating efficacy have included CAMTAF, AATAC and CAMERA MRI. These have now been superseded by CASTLE AF. 2) We would suggest that consideration should be given to ablation of premature ventricular complexes in a select group of patients with impaired LV systolic function and a PVC burden of 10-20% or over on	any recommendations in this area. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				ambulatory monitoring. Furthermore, in view of the adverse effects of most antiarrhythmic drugs in this group, catheter ablation be considered a first line therapy where there is a single or dominant morphology. The aetiology (idiopathic/ischaemic/nonischaemic) *per se* should not affect this recommendation. However, the electrophysiologist should weigh up the likelihood of success and complications based on the site of origin. We would be happy to furnish more data supporting our proposal if needed but wished to keep our response as brief as possible.	
British Society for Heart Failure (BSH)	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment. The full guideline is lengthy because of the large scope and number of evidence reviews conducted; however there is a short version containing just the recommendations.
British Society for Heart Failure (BSH)	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug
British Society for Heart Failure (BSH)	Full	14-25	General	On the full guideline there is a summary of all key recommendations. These will need to be changed based upon the incorporation of stakeholder comments.	Thank you for your comment. The summary has been updated to reflect any changes made to recommendations.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Full	15	13	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this. An explanation of the change is provided in the short guidance.
British Society for Heart Failure (BSH)	Full	23	36-42	We are concerned that 3 out of 6 research recommendations are about NT-proBNP – does this suggest the importance of this subject matter, or the research interests of the panel? Surely there are greater heart failure research questions requiring to be answered. Can these 3 recommendations on NT-proBNP be amalgamated into one (with stems)?	Thank you for your comment. The committee flagged a number of areas requiring further research throughout guideline development process. However, upon further discussion realised that many of these areas already had trials currently underway or that were planned to start in the near future. Therefore these areas were not prioritised as research recommendations.
British Society for Heart Failure (BSH)	Full	23	General	With the important findings of the DANISH study, which questioned the importance of defibrillator therapy in patients with heart failure of a non-ischaemic aetiology, we would like to suggest an additional research	Thank you for your comment. Research recommendations can only be made for topics in which the guideline has searched for the evidence and has established a gap in available

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommendation of: "The comparison of CRT-pacemakers with CRT-defibrillators in a prospective study in heart failure patients of any aetiology", assessing the efficacy (non-inferiority of CRT-pacemakers) and cost-effectiveness in a UK population. This is a particularly important question given the increasing numbers of these high value devices being implanted across the country.	evidence. The review question addressed in this guideline was specifically on the criteria to determine when to discuss deactivation of a defibrillator, and we are therefore not able to make a research recommendation as you suggest.
British Society for Heart Failure (BSH)	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
British Society for Heart Failure (BSH)	Full	103	3 (Algorithm)	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than "specialist clinical assessment and doppler echocardiography"	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at referral but could also be done in primary care. The algorithm has been updated to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from clinical trials. Such an approach would be consistent with all other recent national[1] and international[2,3] heart failure guidelines. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 3. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
British Society for Heart Failure (BSH)	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with prognostic importance follow thereafter. This is very strange prioritisation.	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Full	217	2	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** **Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include: ○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm displays this flow more appropriately.	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
British Society for Heart Failure (BSH)	Full	228	27	(Recommendation 7.1.6) We would recommend removal of 'devices' from the statement, 'unless their condition is unstable or they have a condition or device that precludes such a programme.' This may reduce the number of patients with implantable devices being offered rehabilitation unnecessarily.	Thank you for your comment. The committee agree the current wording may prevent people accessing rehabilitation programmes when they could derive benefit from participation. . The recommendation has been amended to clarify all people should be offered cardiac rehabilitation unless their condition is unstable,

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Full	377	10	The advice on writing a plan is clear and an important addition to the guideline.	Thank you for your comment.
British Society for Heart Failure (BSH)	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised to start with treatment for HF with reduced ejection fraction as this is a more logical order.
British Society for Heart Failure (BSH)	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
British Society for Heart Failure (BSH)	Short	5	27-29	There are also instances where the specialist heart failure MDT may need to continue to manage the patients, even after they have been stabilised and management has been optimised. This is in particular cases such as cardiac transplantation and LVADS. This section could be changed to include: There may be instances where the specialist heart failure team need to continue to manage heart failure patients such as post cardiac transplant and after implantation of Ventricular Assist Devices	Thank you for your comment. A recommendation has been made stating that the specialist HF MDT should continue to manage patients after an interventional procedure. Collaboration between primary care teams and the specialist HF MDT should ensure transfer of care is made at the appropriate time.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Short	7	1-29	We agree that NTproBNP is the ideal blood test to assist in the diagnosis of heart failure and we should encourage localities to make it readily available to GPs. However, many localities already have access to BNP (included in previous guidelines). Access to and the use of any natriuretic peptide test to assist in making the timely diagnosis of heart failure is preferable to no availability. As such it would be wrong for this guideline not to mention BNP and the relevant cut-offs.	Thank you for your comment. The committee considered that a number of factors would favour the use of NT-proBNP as outlined in the LETR. The committee was unable to locate data for BNP equivalent concentrations given biological variances in the recent evidence base as this was not measured simultaneously in the studies used to define this recommendation.
British Society for Heart Failure (BSH)	Short	7	7	We agree with NICE that the cut-offs for BNP and NT Pro-BNP should remain as described.	Thank you for your comment.
British Society for Heart Failure (BSH)	Short	9	16-26	We find the advice on giving information to people with heart failure extremely helpful and considered.	Thank you for your comment.
British Society for Heart Failure (BSH)	Short	10	1-11	Advice on first consultation is clear and useful.	Thank you for your comment.
British Society for Heart Failure (BSH)	Short	10	17	We like this wording (diuretics). Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	10	26-29	Calcium channel blockers. (Also full Page 197 Lines 10-12 'Calcium-channel blockers. Avoid verapamil, diltiazem and short-acting dihydropyridine agents in people who have heart failure with reduced ejection fraction. [2003, amended 2018]'). Why have you singled out one class of contraindicated medications only? What about NSAIDs, glitazones, anti-arrhythmics, moxonidine etc? The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This should be a section on contra-indicated medication and not simply calcium-channel blockers.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Short	11	1-8	Amiodarone. This would be better placed after treating heart failure with reduced ejection fraction section (section 1.5). The wording is appropriate.	Thank you for your comment. This has been moved to after treating heart failure with reduced ejection fraction.
British Society for Heart Failure (BSH)	Short	11	9-16	Anticoagulants. The wording is fine but as per comment directly above, this would sit better in a separate section after disease modifying drugs with prognostic benefit.	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF with reduced ejection fraction followed by the management for all types of heart failure.
British Society for Heart Failure (BSH)	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict? We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				judgement should be used to consider applying this on an individual patient basis'.	
British Society for Heart Failure (BSH)	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	13	13-16	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines. The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example,	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias. The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-blockers around the country. Withdrawal of beta-blockade is unsafe for heart failure patients[8,9]. Whilst these studies are small they are biologically plausible. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely. These comments also applies to Main Document P198 Lines 7-9 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
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Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and long-term metoprolol followed by withdrawal and re-administration of metoprolol. Circulation 1989;80:551-63 Morimoto et al. Can β-blocker therapy be withdrawn from patients with dilated cardiomyopathy? Am Heart J 1999;137:456-9	
British Society for Heart Failure (BSH)	Short	13	2	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains the importance of disease modifying medications on mortality and morbidity in HF-REF. Such a message is needed to reinforce the importance of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. Discussion on the importance of treatments is included in the full guideline.
British Society for Heart Failure (BSH)	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
British Society for Heart Failure (BSH)	Short	14	17	We feel that the example of 'dry cough' should be added, as essentially the side effect profile of ACEI and ARB are similar bar dry cough. This comment also applies to Main Document P199 Lines 5	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					change the wording to 'renal function profile' to reflect this.
British Society for Heart Failure (BSH)	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 8	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
British Society for Heart Failure (BSH)	Short	14	3-12	We think these recommendations are good and we fully agree with them	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
British Society for Heart Failure (BSH)	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
British Society for Heart Failure (BSH)	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 26	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
British Society for Heart Failure (BSH)	Short	15	2-4	We feel that this recommendation does not fit well at this stage (i.e. the prioritisation and it's stage in clinical reasoning) and that this recommendation should be moved to a later place in the document and amalgamated with the other statement on hydralazine-ISDN (i.e. Page 16 Line 20-24). Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines. This comment also applies to Main Document P199 Lines 15-18	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website **https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.** The ordering of the pharmacological section has been reviewed and revised to start with treatment

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m	for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.
British Society for Heart Failure (BSH)	Short	16	16-19	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)': In an area of such clinical importance (i.e. mortality benefit) and change from previous NICE heart failure guidelines, why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388[1] should be replicated verbatim in this guidance to make the document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have been included in full on publication of the guideline. As we are incorporating the recommendations made within the TA and not reviewing the evidence as part of the update of this guideline we are unable to advise on the monitoring of this medication.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, the Board of the BSH would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed. This comment also applies to Main Document P200 Lines 20-22 National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
British Society for Heart Failure (BSH)	Short	16	20-24	'Considerations' for both indications for hydralazine-ISDN should be displayed at this stage: - Hydralazine and isosorbide dinitrate may be considered in symptomatic patients with HFREF who can tolerate neither an ACEI nor an ARB (or they are contra-indicated) to reduce the risk of death.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				- Hydralazine and isosorbide dinitrate should be considered in black patients with LVEF≤35% or with an LVEF <45% combined with a dilated LV in NYHA Class III–IV despite treatment with an ACEI, a beta-blocker and an MRA to reduce the risk of HF hospitalization and death This comment also applies to Main Document P200 Lines 24-27	https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.
British Society for Heart Failure (BSH)	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
British Society for Heart Failure (BSH)	Short	17	1-3	Digoxin is recommended for worsening or severe heart failure with reduced ejection fraction despite first and second line treatment for heart failure: We feel that this should be re-worded to 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in…..' 'Severe heart failure' is also ambiguous (i.e. Severe LVEF? Severe symptoms?) and should be changed to 'patients with symptomatic heart failure with reduced ejection fraction' Digoxin is also only indicated in such patients with sinus rhythm.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The final wording should be 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in patients with symptomatic heart failure due to reduced ejection fraction in sinus rhythm' Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines and the evidence base[3]. This comment also applies to Main Document P200 Lines 31-33 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1997;336:525–533	
British Society for Heart Failure (BSH)	Short	17	13-22	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled, clinical trials, of benefits to patients in both life expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely. References 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf	limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m 3. Yancy C, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509	Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.
British Society for Heart Failure (BSH)	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
British Society for Heart Failure (BSH)	Short	18	1-3	(Section 6.1.3) The Board of the British Society for Heart Failure agrees with this recommendation	Thank you for your comment.
British Society for Heart Failure (BSH)	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				is to give the correct amount of diuretics. In advanced heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing risk of becoming dehydrated, which can lead to hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the necessary information (ie measuring urea as well as creatinine and eGFR).	guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
British Society for Heart Failure (BSH)	Short	18	4-7	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				renal physicians in patients showing "deterioration" in renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of deteriorating renal function, patients have better outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patients. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in	The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the doses of these medications. Advice on this is given in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014 Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
British Society for Heart Failure (BSH)	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read: 'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
British Society for Heart Failure (BSH)	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
British Society for Heart Failure (BSH)	Short	19	26	Section 1.8.3. Bullet point 2. It is unclear what is meant by the term 'partially deactivate'. The tachycardia treatment functions of a defibrillator are	Thank you for your comment. The committee agree the term is unclear and have revised this to remove fully and partially and have removed

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				either on or off. A reader might think the authors are advocating turning off ICD shocks but leaving on anti-tachycardia pacing – this is generally inadvisable because anti-tachycardia pacing may be pro-arrhythmic. If the authors are referring to deactivation of tachycardia treatment function of CRT-D devices, then this should be more clearly worded.	reference to potential harms of unnecessary shocks.
British Society for Heart Failure (BSH)	Short	19	29	Section 1.8.3. Bullet point 3. Unnecessary shocks is not a recognised term. One assumes that the authors are referring to appropriate shocks that occur in the minutes, hours or days before an expected death in a patient with heart failure. These might be better described as 'futile' shocks but this may only be apparent in retrospect.	Thank you for your comment. The committee agree this term is unhelpful and have removed this.
British Society for Heart Failure (BSH)	Short	20	26	Section 1.10.1. This statement may be mis-interpreted. It only applies to patients with advanced heart failure who do not have hypoxaemia. As discussed in the full version, there is clear guidance from the British Thoracic Society that home oxygen should be offered to patients with advanced heart failure who have symptoms and a low resting pO2.	Thank you for your comment. Whilst the Committee acknowledged the guidance made by the British Thoracic society, they made the recommendation based on the evidence reviewed for the guideline which did not demonstrate a benefit for the key pre-specified outcomes. However the committee did recognise there may be other comorbid conditions where people may benefit from oxygen therapy and the recommendation has been amended to state that long-term home oxygen therapy may be offered for people with comorbidities such as COPD and hypoxia. A reference to the NICE COPD guideline (CG101) has also been added.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Heart Failure (BSH)	Short	20	5	Section 1.8.4. There are two additional time points where the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure should be reviewed 1. After any appropriate or inappropriate ICD therapy 2. Before any planned replacement of the ICD pulse generator	Thank you for your comment. The focus of the review undertaken was specifically on discussing deactivation of ICDs with patients. Decisions around the management of ICDs is outside the scope of this guideline.
British Society for Heart Failure (BSH)	Short	21	1	Section 1.10.2. It would be useful for the reader to include positive guidance about how to decide which patients should be offered referral to palliative care services.	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
British Society for Heart Failure (BSH)	Short	21	10	Section 1.10.5. The NICE guideline does not specify that the patient must be in the last 2-3 days of life. We would suggest that the wording 'last 2-3 days of life' is replaced with 'last days of life' as per the NICE guideline	Thank you for your suggestion, however the guideline states it 'covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life'.
British Society for Heart Failure (BSH)	Short	21	3	Section 1.10.3. This section should be expanded to include clinical triggers for consideration of a palliative care referral, such as , 1. More than 3 unplanned hospital admissions in the last 12 months 2. Important therapies are being withdrawn in the face of worsening heart failure and renal function	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendations in this area other than general principles based on consensus opinion.
British Society for Heart Failure (BSH)	Short	25	14-15	The statement "Intravenous and subcutaneous diuretics need to be administered by nursing or healthcare staff, whereas oral formulations do not" is not true in that a self-adhesive subcutaneous pump has been developed to be self-administered by patients.	Thank you for your comment and this information. We have updated this statement to reflect this.
British Society for Heart Failure (BSH)	Short	27	3	We are concerned about the research question "Risk tools for predicting **non-sudden** death in heart failure". BNP/NT-proBNP are excellent markers of pump failure death. Predicting sudden death is far more of a challenge, and relevant when considering who to consider for expensive device-based therapies. Only one study found BNP to be predictive of sudden death (Berger *et al.* Circulation 2002;105:2392-7), a finding that has not been replicated. We would suggest that the question should then be "Risk tools for predicting **sudden and** non-sudden death in heart failure'.	Thank you for your comment. The question addressed by the guideline was to determine which are the most accurate prognostic risk tools at predicting patient mortality in the short term, to support decisions about involvement of palliative care services and the use of palliative care processes. The guideline did not consider tools to predict sudden death and therefore cannot widen the question.
Cardiomyopathy UK	SHORT	4	1.1.1	We welcome the statement on the specific personnel and skills which make up the multidisciplinary team (MDT), rather than it focussing solely on the cardiologist	Thank you for your comment.
Cardiomyopathy UK	SHORT	4	1.1.3	We feel the MDT should also consider the cause of the patients' heart failure and whether a referral to a cardiomyopathy specialist is required. The provision of high quality, easy to understand information for patients is an important component of their care.	Thank you for your comment. The recommendation provides guidance on the core areas the specialist HF MDT should cover it is not meant to be exhaustive. The quality of information provided for patients is important and

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				However, there are multiple information resources available with an inconsistent standard. We feel that there should be an agreed standard for written information and information resources provided to patients should be endorsed by NICE.	the principles are outlined in the giving information to people with HF section of the guideline with links to the Patient Experience guidance. Links to other reliable organisations providing information on the condition will be made available via the NICE website on publication.
Cardiomyopathy UK	SHORT	5	1.1.4	Whilst we welcome the recommendations for two week consultations and six month follow ups, along with the requirement for extended consultations, we see considerable challenges in service provision. A common difficulty occurs when patients are discharged into the care of their GP. When symptoms worsen there is often the need to seek another referral from the GP back to the cardiologist. This can cause considerable delay and distress. Whilst the document contains good information on the role of the Primary Care services we think a clear statement on the patients' ability to self-refer back to the cardiologist should be included.	The committee believe the number of consultations recommended is reasonable. It would be usual practice to have an extended consultation with a new diagnosed patient and to have a second consultation within 2 weeks. The 6 monthly follow up is already provided by GPs as part of a patient's long-term conditions review. The committee discussed re-accessing specialist HF services and have recommended close collaboration between the specialist HF MDT with the primary care team in order that information flows between the two and primary care have a mechanism with which to access specialist HF services when required. In addition a recommendation has been made for the care plan provided to the patient, to contain information on the process for accessing specialist HF services and a named co-ordinator.
Cardiomyopathy UK	SHORT	6	1.1.7	We welcome the provision of a care plan for each patient as way of ensuring good levels of communication and consistency in care. We believe that, where the underlying cause of the heart failure	Thank you for your comment. The list of what should be included in the care plan is intended to be the core information and other information could be added if it was considered appropriate.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				condition is possibly genetic, the care plan should include a family tree.	
Cardiomyopathy UK	SHORT	6	1.2.1	In diagnosing heart failure we feel there should also be a statement to consider a genetic cause.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Cardiomyopathy UK	SHORT	9	1.3.1	We endorse the need for additional training and support for staff providing information to patients and stress the need to be clear and concise in explaining heart failure terminology	Thank you for your comment.
Cardiomyopathy UK	SHORT	10	1.3.5	To ensure adequate support for the patient and to help with the understanding of information we feel there should be a clearer statement on encouraging family members or designated close friends to attend consultations.	Thank you for your comment. We think the wording is clear that family members or carers are to be included if the person wishes it.
Cardiomyopathy UK	SHORT	12	1.4.13	We welcome the clear statement given on salt and fluid restriction, as this is a persisting area of confusion for both patients and health professionals.	Thank you for your comment.
Cardiomyopathy UK	SHORT	20	1.9.1	We welcome the statements which enhance the availability of cardiac rehabilitation services for patients with heart failure conditions.	Thank you for your comment.
City Hospitals Sunderland	Full	Overall	General	This is a hefty document that isn't very user friendly. Some of the most useful parts such as the treatment algorithm are hidden at the back.	Thank you for your comment. The algorithm has been moved to an earlier section of the guideline.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
City Hospitals Sunderland	Full	126	60	Do not routinely offer a BB to threat HFREF to people who have AF. The evidence for this recommendation was taken from sub-analysis of original studies to set out to determine this. This goes against all previous RCT evidence for BBs that did show a mortality improvement. Also since increasing the prescribing of these drugs, data from the National Heart Failure Audit has seen an improvement in mortality rates. We are concerned that this would be detrimental to patient care. This advice is unclear. Please change this to include heart rate parameters where beta blockers should be prescribed or are contra indicated.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
City Hospitals Sunderland	full	170	2	IV iron – No recommendation. We agree there is no evidence for mortality and hospital admission. However, there is some evidence regarding quality of life and hence its inclusion into ESC Heart failure guidelines. It could be included as an option for those patients on maximum tolerated treatment who meet criteria for iron deficiency for symptomatic benefit.	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The committee have taken into account your comments but are not convinced that the high (and low quality) evidence on quality of life alone was enough to support a recommendation when taking into account the evidence on the other outcomes. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					underway and hope this will aid evidence based decision making on iron supplementation.
City Hospitals Sunderland	Full	193	31	This recommendation is confusing to say the least. There are 2 ranges of eGFR that give the same advice and a 3rd covering the same ranges to consider lower doses and slower titration. This could be clearer if thought necessary. Considering eGFR is an estimate based on a number of factors is this the most appropriate way to direct treatment. Renal physicians would use ACEI/ARBs for their renal protective properties and monitor the effects on renal function. This seems more sensible. If Heart failure teams liaised with renal consultants for all patients with an eGFR < 30 they would be inundated with heart failure patients. We agree that patients with reduced kidney function should have more careful titration and monitoring but that it should be evaluated against this monitoring and treatment effect. We are concerned that this will be detrimental to patient care with patients not receiving appropriate treatment. We recommend that you either completely remove this advice or give clear indications as to when to initiate and when to discontinue medication that will blockade the renin angiotensin system.	Thank you for your comment. The committee have revisited the evidence and wording of the recommendations and have updated the recommendations to make them clearer. The updated recommendations are: For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m^2 or above: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.
City Hospitals Sunderland	Full	197	6	Diuretics – treatment in preserved ejection fractions should be offered low to medium doses of loop diuretics. Is treating oedema different in this cohort of patients? Should it not be titrated up and down according to symptoms as with HFREF.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
City Hospitals Sunderland	Full	200	20	Sacubitril valsartan should have the same information from the NICE TA included in the document as Ivabradine. We feel that Sucubitril and Valsartan should be more prominent in the recommendation for treatment.	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have now been included in full.
City Hospitals Sunderland	Full	217	Algorithm	Clarify the definition of wide QRS for CRT devises. Can the therapeutic algorithm match the ECS guidelines? NICE guidelines are from 2014 and evidence for CRT with a QRS less than 130ms has been shown not to be beneficial (ECHO CRT trial)	Thank you for your comment. This is explained in TA314. The algorithm has been updated to say 'Cardiac resynchronisation therapy (CRT-P/D or implantable cardiac defibrillators (ICD) in accordance with TA314'.
City Hospitals Sunderland	Full	217	Algorithm	Clarify where it is appropriate for consideration for ICD.	Thank you for your comment. Links to the ICD and cardiac resynchronisation therapy for

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It is very time consuming to keeping looking though lots of sets of guidelines	arrhythmias and heart failure technology appraisals are provided in the short version and from the NICE CHF pathway.
City Hospitals Sunderland	Full	217	Algorithm	The algorithm recommending treatment is unclear and inconsistent. The advice on renal disease should be removed. Sacubatril/Valsartan should be recommended earlier. We recommend NICE adopt the ESC Heart failure guidance algorithm.	Thank you for your comment. The format and order of the algorithm has been revised. The algorithm reflects the recommendations made by the guideline committee for the update of the NICE CHF guideline and cannot refer to algorithms provided in other publications.
City Hospitals Sunderland	Full	413	30, 31, 32, 34,35,36	Part of the role of the community team is to optimise treatment as part of the heart failure service. Is this suggestion that this should all be done in a secondary care setting??? Are the community teams not able to optimise treatment and manage newly diagnosed patients? They currently do.	Thank you for your comment. No, the HF MDT would manage the person's care in collaboration with the primary care team. Configuration of services will vary but once discharged into the community the primary care team would manage the patient and ensure there are effective communication links between the different care settings and clinical services involved in a person's care to facilitate re-access to specialist HF services as required.
Cochrane Heart	Full	132	2	Why is TOPCAT not included in the analysis for all-cause mortality (dichotomous)?	Thank you for your comment. Time to event data is always extracted from a study in preference to dichotomous data.
Cochrane Heart	Full	219	3-5	Please add a citation/reference to the mentioned Cochrane review as this is where the data originate from: Anderson L, Sharp GA, Norton RJ, Dalal H, Dean SG, Jolly K, Cowie A, Zawada A, Taylor RS. Home-based versus centre-based cardiac rehabilitation. Cochrane Database of Systematic	Thank you for your comment. The reference has been added.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				Reviews 2017, Issue 6. Art. No.: CD007130. DOI: 10.1002/14651858.CD007130.pub4.	
Coventry and Warwickshire Cardiac Network	General	General	General	The heart failure service in Coventry and Warwickshire feel that Entresto should be considered alongside MRA and in some cases ahead of MRA (based on clinical judgement) . We, in Coventry, have used Entresto a lot and have robust data to support the efficacy of this medication used both prior to, after, in conjuction with and in some cases in the absence of MRA. The way it is now suggested in new guidelines raises concern that if Entresto is suggested after MRA, patients may not be able to receive this medication (ie hyperkalaemia caused by MRA). We would like to see it ahead of an MRA or in conjunction with MRA based on clinical judgement.	Thank you for your comment. The review on Sacubtril valsartan was conducted by the Technology Appraisal programme and recommendations and its place within the treatment regime for CHF was determined by this committee. The guideline has incorporated these recommendations but as we have not reviewed the evidence we are unable edit or change these.
Dorset HealthCare University NHS Foundation Trust	Full	17	1.6.1	This recommendation has the potential to cause harm and is likely to lead to under prescribing of 1st line treatments for heart failure. The evidence taken from sub group analysis is poor.	Thank you for your comment. The committee agree the evidence is not robust and it has been graded from low to very low quality with the majority being rated as very low quality. The committee have outlined in detail the limitations of the subgroup analysis in the evidence to recommendations section. However the committee agreed that it was important to provide advice for this common subgroup of HFREF patients. Based on the evidence reviewed and the experience of the committee members, consensus was reached on the optimal treatment approach for patients with

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					HFREF and CKD and have revised the recommendation to offer treatment for patients with CKD and eGFR of 30ml/min/1.73m^2 or above and consider lower doses and/or slower titration for people with eGFR 45 ml/min 1.73^2 or below.
Dorset HealthCare University NHS Foundation Trust	Full	217	6.3.31	The algorithm should define 'mildly' symptomatic in relation to adding MRA. The algorithm should also add 'discussion with heart failure MDT were patients with severe refractory symptoms despite optimum drug treatments. Explore advanced heart failure therapies, transplant assessment	Thank you for your comment. The term 'mildly' has been removed from this recommendation as we agree that this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class.
Dorset HealthCare University NHS Foundation Trust	Short	13	1.5.3	This recommendation is too simplistic and will cause confusion given the seminal beta-blocker trials that have supported guidelines. The recommendation needs to specific relating to the prognostic benefit alone or when Beta-blockers are used for rate control strategy in AF.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Dorset HealthCare University	short	16	17	Sacubitril/Valsartan recommendation should be included in full with advise on starting and monitoring	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS Foundation Trust				as this drug is increasingly being used in the management of patients with heart failure	the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations has been included in full on publication of the guideline.
Fresenius Medical Care	Short	17	23,24,25	Question 3: The best practice exchange between a renal physician and cardiologist should be highly promoted, especially as many of the hospitalizations in heart failure are related to congestion/fluid overload. For example some specific seminars could be held on the different treatment options for patients with heart failure and chronic kidney disease e.g. diuretics, ultrafiltration etc.	Thank you for your comment.
Fresenius Medical Care	Short	18	4,5,6	Question 2: The best practice exchange between a renal physician and cardiologist should be highly promoted, especially as many of the hospitalizations in heart failure are related to congestion/fluid overload (Costanzo et al., 2017; Tavazzi et al., 2006; Gheorghiade et al., 2006; Parissis et al., 2010). A further deterioration in kidney function should be avoided as much as possible due to the long-term cost associated with kidney failure and therefore all possible treatment options should be discussed to avoid future cost implications. Question 3: The negative effect on kidney function due to heart failure medicines should be fully known and aligned with a renal physician in order to pre-empt any future negative effects.	Thank you for your comment. The committee agree liaison between the heart failure specialist and the renal physician is important where indicated.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Fresenius Medical Care	Short	25	3,4,5	Question 3: According to the 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure, fluid overload should always be treated as first-line therapy with loop diuretics. However, as is also highlighted in this section on "recommendations for research", some patients might fail such a treatment and are recommended in a second-line be treated with ultrafiltration (removal of plasma water across semipermeable membrane). A clear pathway for patients with fluid overload should be defined for first and second-line therapy. Question 2: After such a patient pathway has been defined the resource utilisation associated with this pathway should be measured in order to identify the most optimal and cost-effective pathway for heart failure patients with fluid overload. As mentioned the cost-effectiveness of loop diuretics is so far unknown, however in general the cost-effectiveness of treating patients with fluid overload are so far unknown. Therefore, this research should be conducted more holistically including first and second-line therapy options for patients with congestion/fluid overload as this remains the main cause of hospitalization for heart failure patients.	Thank you for your comment. The committee consider the key question is the most clinically and cost effective routes of administration for diuretic therapy.
Hertfordshire Community NHS Trust	General	General	General	I would like to add my support to the comments submitted by the BSH in regards to the draft NICE guidance. I feel strongly that their recommendations should be incorporated into the new NICE guidance.	Thank you for your comment. A short version of the guideline is available that provides a quick reference to the recommendations. The order of the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				I would like to also add that the guidance is extremely difficult to navigate and the lack of guidance for EF in HFrEF/HFpEF is unhelpful when attempting to ensure the best evidenced treatment options.	pharmacological sections has been revised to provide greater clarity.
Imperial College Healthcare NHS Trust	Full	19	26-35	This recommendation is contrary to evidence from the *a priori* trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to LVSD, and all other recent national[1] and international heart failure guidelines. The recommendation in the current NICE draft Guideline has the clear potential to cause harm to patients, as it will encourage a conservative approach to the use of disease modifying therapies, in particular ACE inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are comparable to most common cancers. Further, it appears that the thresholds chosen in the recommendation are entirely arbitrary, for which there is no scientific evidence. We believe this recommendation should be removed entirely.	In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows:

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m^2 or above: • offer the treatment outlined in section 1.4 and • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin.
Imperial College Healthcare NHS Trust	Full	217	algorithm	We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national and international heart failure guidelines. The recommendation is also overly simplistic and could therefore be harmful in many cases. For example, does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Should patients already on beta-blockers have these agents discontinued if they are in AF, or go on to develop AF? Beta-blockers are also a class of	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. There is evidence that certain non-selective beta-blockers, such as carvedilol, reduce mortality in patients with heart failure and atrial fibrillation. Others have recently also cast doubt on the findings of the secondary analysis which NICE have used to underpin the recommendation to avoid beta-blockade in patients with heart failure and AF. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed in its entirety.	
Imperial College Healthcare NHS Trust	Full	217	algorithm	In an area of such clinical importance (i.e. >20% mortality benefit) and change from previous NICE heart failure guidelines, we are curious as to why the draft guideline does not actually display these recommendations in their text. Instead they leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388 should be replicated verbatim in this guidance to make the	Thank you for your comment. The recommendations are not given in full because any subsequent updates carried out by the TAs would render the recommendations out of date in the guideline; therefore we provide links to the ICD and cardiac resynchronisation therapy for arrhythmias and heart failure and sacubitril valsaratan technology appraisals in the short version and from the NICE CHF pathway. The TA on Ivabradine has been incorporated into the guideline and will be updated as part of future updates to the guideline; therefore the recommendations are included in full. TA388 has also now been incorporated into the CHF

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, we would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed.	guideline and the recommendations included in full for publication. The scope of this guideline included the incorporation of the recommendations from the TA for sacubitril/valsartan which we are required to do without making any changes. We have not reviewed the evidence for this drug and we are unable to provide any guidance on monitoring.
Imperial College Healthcare NHS Trust	Full	217	algorithm	There are multiple problems with this figure, two of which are identified above, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national and international heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388. Problems include: f. **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				classifications (i.e. NYHA II – IV) in keeping with the evidence base. g. **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm displays this flow more appropriately. **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm.	This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Imperial College Healthcare NHS Trust	General	General	General	The decision to make no recommendation on IV iron is contrary to other recent national and international heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity, quality of life and readmission. In a clinical syndrome with such a high negative impact on quality of life, we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival and as such its impact on this outcome is currently unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: Such an approach would be consistent with other recent national and international heart failure guidelines. Further; if NICE is happy to recommend treatment with no known mortality benefits i.e., digoxin, then NICE need to apply the same standard/criteria to all recommendations, including IV iron.	Thank you for your comment. The committee reviewed all the available evidence and decided that in the absence of substantial effects on hard outcomes or hospitalisation that a clear statement about the benefits or harms of iron therapy could not be made. The committee noted that 2 large trials were underway that may answer this question. In addition the resource impact of any recommendation needed to be considered. It felt that making any definitive recommendation in this field was premature at this time.
Imperial College Healthcare NHS Trust	General	General	General	**Care plan:** the use of a 'dry' weight measurement is not stipulated in the care plan, and this is a useful tool in monitoring fluid status in heart failure patients to help prevent both sudden and gradual deteriorations. This	Thank you for your comment. The care plan outlines the key areas to include and is not meant to be exhaustive. Other records may be added as determined locally.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				also helps the heart failure team in the virtual management of the patient. **Heart failure MDT**: The guidance covers what the specialist heart failure MDT should do. We use our heart failure MDTs to intermittently (once every two months) discuss admissions/deaths in known patients. This may reproduce work from the wider divisional M&M meeting but involves more of the relevant people, who could and should learn from and share these important outcomes. **Cardiac rehabilitation:** The guidance implies but does not stipulate this should be offered to both patients with reduced and preserved ejection fraction. We feel this added clarification would serve to widen the services and potentially target important pathophysiological mechanisms in this difficult to manage cohort.	The guideline outlines membership of the core MDT but may include other health professionals as required How the team operates would be determined according to local need. Cardiac rehabilitation should be offered to all CHF patients who are stable and able to participate. This recommendation does not change from the 2010 guideline and we think the wording is clear.
Imperial College Healthcare NHS Trust	General	General	General	o The ordering and prioritisation of the pharmacological section should be reconsidered as it follows no clear logical or clinical order. o The use of the word 'high' in 'reducing intake for people with high levels of fluid consumption' is ambiguous and could lead to differing advice to patients. The level of evidence for abandoning fluid restriction is 'very low' and based on two weak studies. One study of 21 patients where quality of life was looked at; quality of life would	Thank you for your comment. The order of the pharmacological recommendations has been revised to begin with treatment for heart failure with reduced ejection fraction. The committee consider the wording of the recommendation allows for a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be anticipated to be lower with fluid restriction but hospital admissions and morbidity over a longer period (than 6 months) would be likely lower. In the second study the oedema score is higher but again this is in 23 patients with a 3 month follow up. Confidence intervals were wide in both studies, and as you highlight of low weight. The bias in directing this statement to protect the older patients who drink less anyway is misleading, as anyone delivering a fluid restriction statement would qualify it. There are a significantly higher number of patients who do not fluid restrict or even drink more when they are on diuretics to compensate the effect, in whom fluid restriction is important. o The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. o In the section for diagnosing heart failure, please consider amending the wording for measure NT-proBNP to 'perform a contemporary measurement of NT-proBNP'. Some referral**s** are made based on historic measurements (>1 yr), and whilst these are helpful in the overall diagnosis, do not help in the triage process for acute referrals.	unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this. We think the wording 'measure NT-proBNP' means at this time and is clear.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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IND	General	General	General	I would like to register my concerns re the draft NICE guidance for heart failure. I have read the response from the British Society of Heart Failure and endorse their recommendations	Thank you for your comment.
Kings College Hospital Heart Failure Unit	Full	General	General	This document is much poorer than the previous guidance. It is out of line with other major ESC/ACC guidelines. This will limit its relevance. It is also full of typos and errors in legends, I presume that these will be corrected in the final version	Thank you for your comment. The guidance has been developed according to the clinical and cost effectiveness evidence available. The document has been proofread for errors prior to publication.
Kings College Hospital Heart Failure Unit	Short	7	1	1.2.2 Use of BNP in diagnosis should also be mentioned-there is plenty of evidence!	Thank you for your comment. The committee was aware of the data on the use of a variety of natriuretic peptides for diagnosis of heart failure. The primary evidence base for the diagnostic threshold was based on studies that measured NT-proBNP.
Kings College Hospital Heart Failure Unit	Short	7	3	The cut points chosen are too high and out of line with ESC guidance. They may be more cost effective but 1 in 5 people with HF will be missed!	Thank you for your comment. The model developed for this question took into consideration the consequences of those whose heart failure diagnosis was missed and found the threshold of 400ng/l to be the most cost effective, and was therefore recommended. The committee considered that assessing the cost effectiveness of different NTproBNP thresholds for referral to echocardiography to be of very high importance to help ensure limited resources are best allocated across the NHS to maximise health of the population.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Kings College Hospital Heart Failure Unit	Short	13	13	Re not offering patients with HFref and AF a BB. This is out of line with other guidance. There is no trial of stopping BBs in AF and HFrEF, .and there is no trial of BBs versus placebo in HFrEF patients with AF. There is plenty of evidence from real life registries that BBs do improve mortality unlike the meta-analyses that have been used to justify this comment. There is no evidence that they do any harm. Not using them will expose patients to other less evidence-based ways of rate control in AF and potentially subject them to harm. This recommendation will just be ignored.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Kings College Hospital Heart Failure Unit	Short	16	17	Sacubitril Valsartan should not be recommended at the same level as ivabradine, hydralazine etc as it reduces mortality. It should be after ACE/BB/MRA, if the patient remains symptomatic as per the HTA.	Thank you for your comment. The committee did not review the third line treatments in this guideline update and therefore have not compared these treatments to each other. However, the committee considered that each of these third line treatments could be an option if a patient remains symptomatic after treatment with BB, ACEI and MRAs, and that the choice of treatment should be considered after advice from a specialist depending on the individual's condition and symptoms.
Kings College Hospital Heart Failure Unit	Short/Full	General	General	There needs to be some recommendation about IV iron . This is out of line with other international guidelines and will affect the credibility and implemention of this guideline. The confusion from this is likely to result in	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				more harm than good. We agree that there is insufficient evidence for harder outcomes and cost-effectiveness but 'no recommendations' does not help guide clinicians	linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.
Medtronic Limited	Full	216	Section 6.3.2	As Ventricular Assist Device therapy is currently omitted from the guideline though this therapy is part of the Chronic Heart Failure patient pathway and is commissioned by NHS England we suggest the following additions to the guideline • After line 4 add heading line: "Mechanical circulatory support" • Add sub heading line: "Ventricular Assist Devices (VAD)" • Add lines: "Specialist referral for continuous flow Ventricular Assist Device (VAD) should be considered for patients with end-stage heart failure (of any aetiology) with a reduced ejection fraction and refractory heart failure."	Thank you for your comment. Ventricular assist devices were not included in the scope and we cannot therefore make any recommendations in this area.
Medtronic Limited	Full	217	6.6.31 2	Treatment algorithm, Figure 5: Therapeutic algorithm: In order to include Ventricular Assist Device therapy into the Therapeutic algorithm Medtronic ask an additional box is included at the bottom of the HFREF section (right hand side): "If end stage heart failure and	Thank you for your comment. Ventricular assist devices were not included in the scope and we cannot therefore make any reference to VAD.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				resistant symptoms consider Ventricular Assist Device (VAD) or Heart Transplantation"	
Medtronic Limited	Short	General	General	Medtronic would like to highlight section 1.8 on Interventional procedures as there is no reference to referral for Ventricular Assist Devices. This important interventional therapy is currently omitted from the Guideline, though access to VAD's is part of the patient pathway and NHS England commission the service for Ventricular Assist Devices https://www.england.nhs.uk/wp-content/uploads/2013/06/a18-vad-all.pdf We ask for this interventional therapy to be added to the Guideline and make the following suggestions in comment number 2, 3 and 4 below	Thank you for your comment. Ventricular assist devices were not included in the scope of this update and we are therefore unable to comment on their use. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Medtronic Limited	Short	5	11,12	Add " an annual ECG and assessment of LV function	Thank you for your suggestion but we feel this level of detail is not needed as the recommendation aims to provide a brief list of the core functions of the specialist HF MDT.
Medtronic Limited	Short	19	17	In order to inform patients, care givers and healthcare providers of Ventricular Assist Device therapy we suggest additional points are included in Section 1.8 Interventional Procedures: (page 19) • After the ICD and CRT section add heading line: "Mechanical circulatory support"	Thank you for your comment. Ventricular assist devices were not included in the scope and we cannot therefore make any recommendations in this area.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				• Add sub heading line: "Ventricular Assist Devices (VAD)" • Add: "Specialist referral for continuous flow Ventricular Assist Devices should be considered for patients with end-stage heart failure (of any aetiology) with a reduced ejection fraction and refractory heart failure."	
Medtronic Limited	Short	19	19	To increase awareness and improve accessible information for Health Care Professionals thus enabling them to more easily identify patients who will benefit from ICD and CRT therapy when reading this guideline, we suggest the chart below from TA314 is added after line 19	Thank you for your comment. The short guideline is intended as a quick reference to the recommendations only. A link has been provided to the TA where further information is available.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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<tr><th>Stakeholder</th><th>Document</th><th>Page No</th><th>Line No</th><th>Comments
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Please respond to each comment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Table 1 Treatment options with ICD or CRT for people with heart failure who have left ventricular dysfunction with an LVEF of 35% or less (according to NYHA class, QRS duration and presence of LBBB)

<table><tr><td></td><td colspan="4">NYHA class</td></tr><tr><td>QRS interval</td><td>I</td><td>II</td><td>III</td><td>IV</td></tr><tr><td><120 milliseconds</td><td colspan="3">ICD if there is a high risk of sudden cardiac death</td><td>ICD and CRT not clinically indicated</td></tr><tr><td>120–149 milliseconds without LBBB</td><td>ICD</td><td>ICD</td><td>ICD</td><td>CRT-P</td></tr><tr><td>120–149 milliseconds with LBBB</td><td>ICD</td><td>CRT-D</td><td>CRT-P or CRT-D</td><td>CRT-P</td></tr><tr><td>≥150 milliseconds with or without LBBB</td><td>CRT-D</td><td>CRT-D</td><td>CRT-P or CRT-D</td><td>CRT-P</td></tr><tr><td colspan="5">LBBB, left bundle branch block; NYHA, New York Heart Association</td></tr></table></td><td></td></tr>
<tr><td>Medtronic Limited</td><td>Short</td><td>20</td><td>5, 6, 7</td><td>"Review the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure at each sixth month review".
To review the potential harm of this high beneficial therapy at each sixth month review may cause unnecessary anxiety for people living with a</td><td>Thank you for your comment. The committee discussed any anxiety this may cause the patient but concluded this did not mean that a conversation had to take place with the patient about deactivation at each 6 monthly review, but</td></tr>
</table>

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				cardioverter defibrillator. Medtronic suggest this is modified to: "If there has been a change in clinical condition or where clinically indicated review the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure at each sixth month review"	it was important that the healthcare professional considered it.
Medtronic Limited	Short	20	8	Add an additional line to state "where clinically indicated"	Thank you for your comment. The health professional carrying out the review may not know if an ICD is clinically indicated if they are not specialists in this field, and so we do not think it appropriate to add this.
Mid Cheshire Hospitals NHS Foundation Trust	Full	88	20	This recommendation does not include the use of BNP as an alternative to NT proBNP. This is currently not used at our trust and surrounding CCGs as BNP is used and would therefore have a significant practical and financial cost to implement.	Thank you for your comment. The committee discussed that although the majority of areas have access to NT-proBNP, not all areas currently do and therefore there would be some resource implications of only recommending NT-proBNP. However they considered that NTproBNP was a better test to use over BNP for the following reasons: • The clinical review demonstrates that NT-proBNP has a greater sensitivity over a range of thresholds compared to BNP. • NTproBNP has a longer stability in blood samples than BNP • Sacubitril Valsartan interferes with BNP physiology (TA388), and as natriuretic peptides can also be used for monitoring

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					heart failure patients, it would be more useful to have NTproBNP as the baseline peptide in case monitoring was needed in a patient with heart failure who is subsequently treated with this drug. **The unit costs of natriuretic peptide testing were identified from a number of hospital trusts during development and have now been added to the evidence report. Data from three trusts gave an average cost for BNP of £21.69. Data from five trusts gave an average cost for NTproBNP of £26.07. The committee were reassured that the average cost difference between the two tests was only around £4, admittedly with some uncertainty due to the limited sample size, although there was some overlap where NTproBNP was less expensive than BNP. The committee also mentioned that the purchase of new equipment for analysing NTproBNP is not necessary as there are kits available for all main systems. Therefore did not consider that there would be further cost implications beyond those reflected in the costs above. The committee were also aware that NTproBNP is due to come off patent in the next couple of years and therefore expect the cost of NTproBNP to decrease. Furthermore, the committee noted that as NTproBNP overall had a higher sensitivity compared to BNP, there is potential for some offset of the current higher cost of NTproBNP**

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					due to reduced number of false negative results for people being tested with NTproBNP compared to BNP. A false negative result would either require re-testing, or could result in hospitalisation if an acute episode occurred prior to diagnosis. They therefore considered that taking into consideration that the majority of labs now run NTproBNP, some of them teaching hospitals which receive a high volume of tests, that only recommending NTproBNP would not have a substantial resource impact for the NHS in England.
Mid Cheshire Hospitals NHS Foundation Trust	Full	88	20	This recommendation does not include the use of BNP as an alternative to NT proBNP. This is currently not used at our trust and surrounding CCGs as BNP is used and would therefore have a significant practical and financial cost to implement.	The committee discussed that although the majority of areas have access to NT-proBNP, not all areas currently do and therefore there would be some resource implications of only recommending NT-proBNP. However, they considered that NTproBNP was a better test to use over BNP for the following reasons: • The clinical review demonstrates that NT-proBNP has a greater sensitivity over a range of thresholds compared to BNP. • NTproBNP has a longer stability in blood samples than BNP • Sacubitril Valsartan interferes with BNP physiology (TA388), and as natriuretic peptides can also be used for monitoring heart failure patients, it would be more useful to have NTproBNP as the baseline peptide in

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					case monitoring was needed in a patient with heart failure who is subsequently treated with this drug. This area has been noted with the business analyst to assess the resource impact of only recommending NT-proBNP. The unit costs of natriuretic peptide testing were identified from a number of hospital trusts during development and have now been added to the evidence report. Data from three trusts gave an average cost for BNP of £21.69. Data from five trusts gave an average cost for NTproBNP of £26.07. The committee were reassured that the average cost difference between the two tests was only around £4, admittedly with some uncertainty due to the limited sample size, although there was some overlap where NTproBNP was less expensive than BNP. The committee also mentioned that the purchase of new equipment for analysing NTproBNP is not necessary as there are kits available for all main systems. Therefore did not consider that there would be further cost implications beyond those reflected in the costs above. The committee were also aware that NTproBNP is due to come off patent in the next couple of years and therefore expect the cost of NTproBNP to decrease. Furthermore, the committee noted that as NTproBNP overall had a higher sensitivity compared to BNP, there is potential for some offset of the current higher cost of NTproBNP due

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					to reduced number of false negative results for people being tested with NTproBNP compared to BNP. A false negative result would either require re-testing, or could result in hospitalisation if an acute episode occurred prior to diagnosis. They therefore considered that taking into consideration that the majority of labs now run NTproBNP, some of them teaching hospitals which receive a high volume of tests, that only recommending NTproBNP would not have a substantial resource impact for the NHS in England.
Mid Cheshire Hospitals NHS Foundation Trust	Full	126	30	We are concerned that this recommendation would lead to a drop in the use of beta-blockers by non heart failure specialists who may interpret this as evidence of lack of efficacy of beta-blockers in heart failure. Whilst the IPG meta-analysis raises compelling questions about current routine practice in AF patients with chronic HF, it did not demonstrate harm and there are currently no other safer agents that are better used in managing chronic heart failure patients with AF.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Mid Cheshire Hospitals NHS	Full	126	30	We are concerned that this recommendation would lead to a drop in the use of beta-blockers by non heart failure specialists who may interpret this as evidence of lack of efficacy of beta-blockers in heart failure. Whilst	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Foundation Trust				the IPG meta-analysis raises compelling questions about current routine practice in AF patients with chronic HF, it did not demonstrate harm and there are currently no other safer agents that are better used in managing chronic heart failure patients with AF.	the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Mid Cheshire Hospitals NHS Foundation Trust	Full	170	2	We are surprised that no recommendation has been made in relation to the use of IV iron for HFREF patients given the evidence from more than one RCT showing reduction in HF hospitalisation and improvement in symptoms.	Thank you for comment. The protocol on iron supplementation was agreed by the committee and all the studies that met the inclusion criteria were included in the evidence review. The protocol provides further detail about the inclusion and exclusion criteria. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version. Following the methods set out in the NICE guidelines manual the committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee have taken into account your comments but are not

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					convinced that the evidence was enough to support a recommendation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.
Mid Cheshire Hospitals NHS Foundation Trust	Full	170	2	We are surprised that no recommendation has been made in relation to the use of IV iron for HFREF patients given the evidence from more than one RCT showing reduction in HF hospitalisation and improvement in symptoms.	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.
Mid Cheshire Hospitals NHS Foundation Trust	Full	200	10	This seems a confusing statement and we are unclear as to what the recommendation is in relation to the use of ivabradine.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Mid Cheshire Hospitals NHS Foundation Trust	Full	201	1	Give the evidence linking high digoxin levels to mortality, we are concerned that this recommendation would lead to excess digoxin toxicity and mortality. It is our current practice to routinely monitor levels at least once after initiation when stable state is reached or with subsequent uptitrations.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
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Mid Cheshire Hospitals	Full	217	2	Whilst we agree that sacubitril/valsartan and CRT are third line treatments after beta-blockers, ACE/ARB and	Thank you for your comment. The committee considered that further treatment should be

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS Foundation Trust				MRA, it appears very misleading from the flow chart to suggest that these treatments are on parity with ivabradine, digoxin and hydralazine/nitrates in terms of strengths of evidence and efficacy. It is our view that these treatments (sacubitril/valsartan and CRT) should be considered in preference to the others given the established symptomatic, and prognostic benefit including mortality.	decided by the specialist depending on the patient's condition and symptoms and therefore agreed that these treatments should be equal options.
Mid Cheshire Hospitals NHS Foundation Trust	Full	217	2	Whilst we agree that sacubitril/valsartan and CRT are third line treatments after beta-blockers, ACE/ARB and MRA, it appears very misleading from the flow chart to suggest that these treatments are on parity with ivabradine, digoxin and hydralazine/nitrates in terms of strengths of evidence and efficacy. It is our view that these treatments (sacubitril/valsartan and CRT) should be considered in preference to the others given the established symptomatic, and prognostic benefit including mortality.	Thank you for your comment. The comparative effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. The committee considered that further treatment should be decided by the specialist depending on the patient's condition and symptoms and therefore agreed that these treatments should be equal options.
Mid Cheshire Hospitals NHS Foundation Trust	Full	415	1	We would like to suggest the recommendation for consideration of the use of the Gold Standard Framework for patients with advanced heart failure who are not candidates for transplantation. We have found this useful in our practice to ensure patients receive better end of life care and are looked after at their preferred place of care.	Thank you for your suggestion, however as we have not considered the Gold standard Framework as part of a review we are unable to make any recommendations for its use.
Mid Cheshire Hospitals NHS	Full	415	1	We would like to suggest the recommendation for consideration of the use of the Gold Standard Framework for patients with advanced heart failure who are not candidates for transplantation. We have	Thank you for your suggestion, however as we have not considered the Gold standard Framework as part of a review we are unable to make any recommendations for its use.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Foundation Trust				found this useful in our practice to ensure patients receive better end of life care and are looked after at their preferred place of care.	
NHS England	Full	17	15	Duplication of point about treatment of women of childbearing potential (same point has been made on page 16 line 22) (MJ)	Thank you. We have removed the duplication.
NHS England	General	General	General	I note the likely increased demand on echocardiography services including specific reference to a group of patients who need this assessment within 2 weeks. This should be fed into the existing work programme looking to expand echo capacity 7/7 (CIC)	Thank you for your comment. The recommendation was originally made in 2010, but the committee acknowledged that not all areas have been able to ensure people receive an echocardiography within 2 weeks, due to the current strains on echocardiography services.
NHS England	Short	6	22	Sharing care plan with urgent care services would help improve provision of care of patients with cardiac failure if their condition rapidly deteriorates and usual MDT team is not available. (MJ)	Thank you for your suggestion. The patient and family/carers will hold a copy of the care plan and therefore this may be available.
NHS England	Short	6	4	It would be useful to add that written summary for each person with heart failure should include considerations about prognosis (in addition to including diagnosis and aetiology). (MJ)	Thank you for your comment. The list of what should be included in the care plan is intended to be the core information and other information could be added if it was considered appropriate
Novartis Pharmaceuticals UK Ltd	Long version	176	8-10	It is stated that no evidence was identified regarding the use of sacubitril valsartan in people with HF and CKD (Chronic Kidney Disease). However, two publication cover subgroup analysis of sacubitril valsartan in this population: McMurray et al (2014) N Engl J Med; 371:993-1004 and Damman et al. (2015) Eur Heart J; 36(Suppl 1):545. Additionally, the following manuscript was published on this subject during the	Thank you for your comment The protocols were agreed by the committee and all the identified studies that met the inclusion criteria were included in the evidence reviews The protocols provide further detail about the inclusion and exclusion criteria. McMurray et al (2014) was excluded the population does not meet the protocol population of 'adults with heart failure and chronic kidney disease (at least stage 3A /

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				consultation: Damman et al. (2018) JACC Heart Fail. doi: 10.1016/j.jchf.2018.02.004 [Epub ahead of print]	eGFR <60 mL/min), who are not on dialysis.'Damman et al (2018) was published after the cut-off date for the final searches and section 5.10 of Developing NICE guidelines:the manual states, 'If evidence is identified after the last cut-off date for searching but before publication, a judgment on its impact should be made by the Developer and NICE staff with a quality assurance role. In exceptional circumstances, this evidence can be considered if its impact is judged as substantial'. In this circumstance sacubutril-valsartan is out of outside the remit of this guideline as a new therapy. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388) is cross referred to in the short guideline.
Novartis Pharmaceuticals UK Ltd	Short version Long version Long version	15-17 116 148-153 217	5-27, 1-27, 1-10 11-14 39 2	We are supportive of the recommendations that patients with HFrEF who are symptomatic should be offered triple therapy (RAAS inhibition, beta-blockade, and mineralocorticoid antagonists (MRAs/aldosterone antagonists)) instead of MRAs being considered as an option only. The draft guidelines reflect the change in clinical practice that occurred in 2011 following publication of EMPHASIS-HF which was reflected in the 2012 National Heart Failure Audit that started to report on patients being discharged on triple therapy	Thank you for your comment. The Initiation and sequencing of pharmacological therapies is included in the Scope for this guideline and states this will incorporate and contextualise recommendations for Sacubitril valsartan. The committee were tasked with considering the sequencing of pharmacological therapies in light

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
	Long Version			(http://www.ucl.ac.uk/nicor/audits/heartfailure/documents/annualreports/hfannual11-12.pdf). We do not support the revision of the initiation and sequencing of all pharmacological therapies which a) was not within the scope of the update, b) is not based on a review of all evidence for each pharmacological therapy and c) conflicts with the NICE TA recommendations, specifically TA 388 for sacubitril valsartan. With respect to issue b), the only research question for this guideline update focusing on pharmacological therapies in HFrEF considers MRAs only and no other therapies i.e. 'What is the clinical and cost effectiveness of adding a mineralocorticoid receptor antagonist to existing standard first line treatment in people with heart failure with reduced ejection fraction?' Please note that both TA 388 and previous NICE guidelines refer to MRAs as aldosterone antagonists rather than MRAs. Our main concern is that the recommendations in the draft guidelines imply a different eligible patient population for sacubitril valsartan compared to TA 388 without considering any of the evidence on sacubitril valsartan. NICE TA388 does not stipulate an MRA has to be used before sacubitril valsartan and therefore the draft guideline algorithm on p217 is not congruent with TA388.	of new evidence for MRAs and the TA's 388 and TA 267. The use of sacubutril-valsaratan has to be considered in light of the TA appraisal and the clinical pathway followed in the PARADIGM-HF trial. In making a decision on the sequencing of treatments the committee took into consideration that the treatments were given in combination with standard care including beta blockers and MRAs, patients in the trial were younger than the general population seen in clinical practice and the recommendation for sacubitril valsartan to be initiated and supervised by a heart failure specialist. The new evidence for MRAs allowed a stronger recommendation to be made than in the previous guideline and the suggestion to seek specialist advice prior to introduction has been removed. The sequencing of treatments is also in line with the recommendations in the Acute Heart Failure guideline (CG187), from which many patients are likely to transition to chronic management.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• The evidence-based recommendation from TA 388 with regards to prior treatments only requires patients to be switched from a stable dose of ACEi/ARB (see comment 5 above). o The pivotal trial informing the recommendation of TA 388 was PARADIGM-HF, a randomised, double-blind, controlled, phase III trial comparing sacubitril valsartan (n=4,187) with enalapril (n=4,212). Both treatments were given in combination with standard care (including beta blockers and MRAs). At baseline, 93% of patients received beta blockers and 56% received MRAs (See TA 388, section 3.5). o The results of PARADIGM-HF showed an overwhelming morbidity and mortality benefit for sacubitril valsartan compared to enalapril leading to the trial being stopped early and sacubutril valsartan being the first non-oncology product to be granted promising innovative medicine (PIM) designation and early access to medicine scheme (EAMS) status in the UK (TA 388, Section 5.1). Sacubitril valsartan treatment reduced the risk of the primary composite endpoint (cardiovascular death and time to first HF hospitalisation) when compared with enalapril, independent of all predefined subgroups (TA 388, Section 3.8). These subgroup analyses include prior use of MRA and clinical and cost-effectiveness evidence on	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				this subgroup analysis was included in the company submission, although it was not specifically considered in the TA. The clinical trial data showed that independent of prior MRA use the primary endpoint was significant, and no difference was observed between the two groups i.e. with MRA vs. without MRA (p-value for interaction 0.10; McMurray et al (2014) N Engl J Med; 371:993-1004). The difference in the incremental cost-effectiveness ratio (ICER) for sacubitril valsartan vs. ACEi with or without prior use of MRA was less than £200 (Addendum to the company submission, Table 23, row 29-30, respectively). • Importantly, the PARADIGM-HF study design was adjusted for changes in clinical practice with regards to MRA usage based on publications since the 2010 NICE chronic heart failure guideline. The same evidence was the basis of the MRA research questions in this guideline update. TA 388, section 4.8: *'The committee heard from the company that improvement in clinical care, attributed to increased use of aldosterone antagonists, had reduced the baseline risk for cardiovascular mortality and hospitalisation. Therefore, the cut-off [for left ventricular ejection fraction] was lowered from 40% to 35% in the trial to offset this anticipated decrease in the event rates for the outcomes.*' Additionally, EMPHASIS-HF and	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				RALES, the key outcome trials used to make the updated recommendations in the draft guidelines, were considered in the systematic review of RCT evidence and network meta-analysis that was submitted to inform TA 388 (J-EMPHASIS-HF was identified but excluded because of population). No new outcomes evidence was identified during the guideline update that was not included in the company evidence submission for TA 388 and as a result different conclusions should not be made. ○ In contrast with the NICE draft guideline view that the evidence on mortality and hospitalisation rate for MRAs is of low or very low quality (Table 47 of draft guideline); the NICE technology appraisal committee considered PARADIGM-HF as a good quality trial (Section 4.4, TA 388). • The draft recommendation that all other treatments previously assigned as second-line therapy should now be a third-line option, including sacubitril valsartan and ivabradine which have had a published TA since the previous guideline, does not accurately reflect the evidence base. There are substantial differences in the clinical efficacy between these treatments. For example, hydralazine and nitrates have been shown to be inferior to enalapril in head-to-head trials (e.g., V-HEFT-I Cohn (1991); N Engl J Med;325:303-310, reviewed as part of previous NICE chronic heart	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				failure guidelines), while sacubitril valsartan was shown to be superior to enalapril in a head-to-head trial (see above). In conclusion, we support the aim that everyone should progress to triple therapy according to clinical need. However, based on the evidence reviewed in this draft guideline and in TA388, there is no justification to sequence sacubitril valsartan as a third-line therapy. This can be addressed by including the recommendations in TA 388 verbatim (see comment 5 above). Therefore, we propose the guidelines reflect that it should be a clinical decision whether a symptomatic patient should receive an MRA in addition to ACEi/ARB and beta blocker or, for sacubitril valsartan eligible patients, be switched from their ACEi/ARB to sacubitril valsartan first before an MRA is considered. **Based on the available evidence, both MRA and sacubitril valsartan should be listed as second-line options for eligible patients.** This would be aligned with the second line positioning in the dynamic NICE pathway on chronic heart failure which was updated following publication of NICE TA388 (https://pathways.nice.org.uk/pathways/chronic-heart-failure#path=view%3A/pathways/chronic-heart-failure/treating-chronic-heart-failure-due-to-left-ventricular-systolic-dysfunction.xml&content=view-node%3Anodes-second-line-treatment).	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Novartis Pharmaceuticals UK Ltd	Short version	4 5	2-20 1-18	We are supportive of the new recommendation for the primary care team to be an essential member of the heart failure (HF) multi-disciplinary team (MDT) to improve patient management and outcomes independent of where the patient's care is being delivered. Clarity could be added by being explicit as to when the guideline is referring to primary care in general versus the primary care team that is part of the HF MDT.	Thank you for your comment. These recommendations have been updated so that the primary care team is no longer recommended to be a member of the specialist heart failure MDT, but instead to work in collaboration with the MDT. The primary care team refers to those delivering care to patient with heart failure.
Novartis Pharmaceuticals UK Ltd	Short version	5	5-18	We are supportive of the new recommendation of a 6-monthly follow-up and review in primary care for all HF patients. Clarity could be added by being explicit as to when the guideline is referring to primary care in general versus the primary care team that is part of the HF MDT.	Thank you for your comment. These recommendations have been updated so that the primary care team is no longer recommended to be a member of the specialist heart failure MDT, but instead to work in collaboration with the MDT. The primary care team refers to those delivering care to patient with heart failure.
Novartis Pharmaceuticals UK Ltd	Short version	7 19	1-20 6	We are supportive of the new recommendation of NT-proBNP being the preferred test over BNP for patients with suspected heart failure because of higher sensitivity, NT-pro-BNP having a longer stability in blood samples than BNP and potential for monitoring independent of which treatments patients are prescribed if required (important because sacubitril valsartan affects BNP levels).	Thank you for your comment.
Novartis Pharmaceuticals UK Ltd	Short version	13	6-16	Further clarity could be added regarding beta blocker use in HFrEF. The first statement suggests ACEI and beta blockers should be offered to all HF patients with reduced ejection fraction (HFrEF) while two paragraphs	Thank you for your comment. This recommendation has been removed in light of stakeholder feedback.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				later, beta-blockers are no longer being recommended for some patients with atrial fibrillation.	
Novartis Pharmaceuticals UK Ltd	Short version Full version	16 14-23	16-19 N/A	The guidelines should include the NICE technology appraisal recommendation for sacubitril valsartan verbatim as this would be consistent with the approach adopted for other therapies included in the guideline that have technology appraisal recommendations (e.g. ivabradine). We propose it states the following: 'These recommendations are from NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388; TA 388). • Sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction, only in people: o with NYHA class II to IV symptoms and o with a left ventricular ejection fraction of 35% or less and o who are already taking a stable dose of ACE inhibitors or ARBs. • Treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults: management.'	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have been included in full for publication of the guideline.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In addition, there seems to be an omission of the insertion of the new TA for sacubitril valsartan in the full list of recommendations in the full version of the draft guideline whilst it does appear in the short version.	
Novartis Pharmaceuticals UK Ltd	Short version	19 20	17-29 1-10	Further clarity could be added as to who is recommended to be having discussion about implantable cardioverter defibrillators and cardiac resynchronisation therapy with patients as no specification is given as to whether this should only be appropriate specialists.	Thank you for your comment. This would be a person from the specialist heart failure MDT with the experience and competencies to discuss this topic with the patient.
Portsmouth Hospitals NHS Trust	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment The full guideline is lengthy because of the large scope and number of evidence reviews conducted, however there is a short version containing just the recommendations
Portsmouth Hospitals NHS Trust	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment. The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug
Portsmouth Hospitals NHS Trust	Full	14-25	General	On the full guideline there is a summary of all key recommendations. These will need to be changed based upon the incorporation of stakeholder comments.	Thank you for your comment. The summary has been updated to reflect any changes made to recommendations.
Portsmouth Hospitals NHS Trust	Full	23	36-42	We are concerned that 3 out of 6 research recommendations are about NT-proBNP – does this suggest the importance of this subject matter, or the	Thank you for your comment. The committee flagged a number of areas requiring further research throughout guideline development

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				research interests of the panel? Surely there are greater heart failure research questions requiring to be answered. Can these 3 recommendations on NT-proBNP be amalgamated into one (with stems)?	process. However, upon further discussion realised that many of these areas already had trials currently underway or that were planned to start in the near future. Therefore these areas were not prioritised as research recommendations.
Portsmouth Hospitals NHS Trust	Full	23	General	With the important findings of the DANISH study, which questioned the importance of defibrillator therapy in patients with heart failure of a non-ischaemic aetiology, we would like to suggest an additional research recommendation of: "The comparison of CRT-pacemakers with CRT-defibrillators in a prospective study in heart failure patients of any aetiology", assessing the efficacy (non-inferiority of CRT-pacemakers) and cost-effectiveness in a UK population. This is a particularly important question given the increasing numbers of these high value devices being implanted across the country.	Thank you for your comment. Research recommendations can only be made for topics in which the guideline has searched for the evidence and has established a gap in available evidence. The review question addressed in this guideline was specifically on the criteria to determine when to discuss deactivation of a defibrillator, and we are therefore not able to make a research recommendation as you suggest.
Portsmouth Hospitals NHS Trust	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Portsmouth Hospitals NHS Trust	Full	103	3 (Algorithm)	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than "specialist clinical assessment and doppler echocardiography"	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at referral but could also be done in primary care. The algorithm has been updated to reflect this.
Portsmouth Hospitals NHS Trust	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinical trials. Such an approach would be consistent with all other recent national[1] and international[2,3] heart failure guidelines. 4. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 5. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 6. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
Portsmouth Hospitals NHS Trust	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prognostic importance follow thereafter. This is very strange prioritisation.	
Portsmouth Hospitals NHS Trust	Full	217	2	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** **Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include: ○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				European Society of Cardiology (ESC) algorithm displays this flow more appropriately. The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
Portsmouth Hospitals NHS Trust	Full	228	27	(Recommendation 7.1.6) We would recommend removal of 'devices' from the statement, 'unless their condition is unstable or they have a condition or device that precludes such a programme.'	Thank you for your comment. The recommendation has been amended to remove any reference to devices.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This may reduce the number of patients with implantable devices being offered rehabilitation unnecessarily.	
Portsmouth Hospitals NHS Trust	Full	377	10	The advice on writing a plan is clear and an important addition to the guideline.	Thank you for your comment.
Portsmouth Hospitals NHS Trust	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised to start with treatment for HF with reduced ejection fraction as this is a more logical order.
Portsmouth Hospitals NHS Trust	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
Portsmouth Hospitals NHS Trust	Short	5	27-29	There are also instances where the specialist heart failure MDT may need to continue to manage the patients, even after they have been stabilised and management has been optimised. This is in particular cases such as cardiac transplantation and LVADS. This section could be changed to include: There may be instances where the specialist heart failure team need to continue to manage heart failure	Thank you for your comment. A recommendation has been made stating that the specialist HF MDT should continue to manage patients after an interventional procedure. Collaboration between primary care teams and the specialist HF MDT should ensure transfer of care is made at the appropriate time.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patients such as post cardiac transplant and after implantation of Ventricular Assist Devices	
Portsmouth Hospitals NHS Trust	Short	7	1-29	We agree that NTproBNP is the ideal blood test to assist in the diagnosis of heart failure and we should encourage localities to make it readily available to GPs. However, many localities already have access to BNP (included in previous guidelines). Access to and the use of any natriuretic peptide test to assist in making the timely diagnosis of heart failure is preferable to no availability. As such it would be wrong for this guideline not to mention BNP and the relevant cut-offs.	Thank you for your comment. The committee considered that a number of factors would favour the use of NT-proBNP as outlined in the LETR. The committee was unable to locate data for BNP equivalent concentrations given biological variances in the recent evidence base as this was not measured simultaneously in the studies used to define this recommendation.
Portsmouth Hospitals NHS Trust	Short	7	7	We agree with NICE that the cut-offs for BNP and NT Pro-BNP should remain as described.	Thank you for your comment.
Portsmouth Hospitals NHS Trust	Short	9	16-26	We find the advice on giving information to people with heart failure extremely helpful and considered.	Thank you for your comment.
Portsmouth Hospitals NHS Trust	Short	10	1-11	Advice on first consultation is clear and useful.	Thank you for your comment.
Portsmouth Hospitals NHS Trust	Short	10	17	We like this wording (diuretics). Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Portsmouth Hospitals NHS Trust	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	10	26-29	Calcium channel blockers. (Also full Page 197 Lines 10-12 'Calcium-channel blockers. Avoid verapamil, diltiazem and short-acting dihydropyridine agents in people who have heart failure with reduced ejection fraction. [2003, amended 2018]'). Why have you singled out one class of contraindicated medications only? What about NSAIDs, glitazones, anti-arrhythmics, moxonidine etc? The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This should be a section on contra-indicated medication and not simply calcium-channel blockers.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Portsmouth Hospitals NHS Trust	Short	11	1-8	Amiodarone. This would be better placed after treating heart failure with reduced ejection fraction section (section 1.5). The wording is appropriate.	Thank you for your comment. This has been moved to after treating heart failure with reduced ejection fraction.
Portsmouth Hospitals NHS Trust	Short	11	9-16	Anticoagulants. The wording is fine but as per comment directly above, this would sit better in a separate section after disease modifying drugs with prognostic benefit.	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF with reduced ejection fraction followed by the management for all types of heart failure.
Portsmouth Hospitals NHS Trust	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict? We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				judgement should be used to consider applying this on an individual patient basis'.	
Portsmouth Hospitals NHS Trust	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	13	13-16	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines. The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example,	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias. The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-blockers around the country. Withdrawal of beta-blockade is unsafe for heart failure patients[8,9]. Whilst these studies are small they are biologically plausible. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely. These comments also applies to Main Document P198 Lines 7-9 9. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 10. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 11. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 12. Kotecha D, et al. Efficacy of beta blockers in patients with heart failure plus atrial fibrillation: an individual-patient data meta-analysis. Lancet. 2014; 384(9961):2235-43 13. Swedberg K, *et al*. Prognostic relevance of atrial fibrillation in patients with chronic heart failure on long-term treatment with beta-blockers: results from COMET. *Eur Heart J* 2005;26:1303–1308 14. Joglar, J.A. et al. Effect of carvedilol on survival and hemodynamics in patients with atrial fibrillation and left ventricular dysfunction: Retrospective analysis of the US Carvedilol Heart Failure Trials Program. *Am Heart J;* 142 (3): 498-501 15. Cadrin-Tourigny J, *et al*. Decreased Mortality With Beta-Blockers in Patients With Heart Failure and Coexisting Atrial Fibrillation. *JACC: Heart Failure* 2017, 579; DOI: 10.1016/j.jchf.2016.10.015 16. Waagstein F et al. Long-term betablockade in dilated cardiomyopathy; effects of short-term	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and long-term metoprolol followed by withdrawal and re-administration of metoprolol. Circulation 1989;80:551-63 Morimoto et al. Can β-blocker therapy be withdrawn from patients with dilated cardiomyopathy? Am Heart J 1999;137:456-9	
Portsmouth Hospitals NHS Trust	Short	13	2	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains the importance of disease modifying medications on mortality and morbidity in HF-REF. Such a message is needed to reinforce the importance of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. Discussion on the importance of treatments is included in the full guideline.
Portsmouth Hospitals NHS Trust	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Portsmouth Hospitals NHS Trust	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
Portsmouth Hospitals NHS Trust	Short	14	17	We feel that the example of 'dry cough' should be added, as essentially the side effect profile of ACEI and ARB are similar bar dry cough. This comment also applies to Main Document P199 Lines 5	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					change the wording to 'renal function profile' to reflect this.
Portsmouth Hospitals NHS Trust	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 8	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
Portsmouth Hospitals NHS Trust	Short	14	3-12	We think these recommendations are good and we fully agree with them	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
Portsmouth Hospitals NHS Trust	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Portsmouth Hospitals NHS Trust	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 26	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
Portsmouth Hospitals NHS Trust	Short	15	2-4	We feel that this recommendation does not fit well at this stage (i.e. the prioritisation and it's stage in clinical reasoning) and that this recommendation should be moved to a later place in the document and amalgamated with the other statement on hydralazine-ISDN (i.e. Page 16 Line 20-24). Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines. This comment also applies to Main Document P199 Lines 15-18	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope. The ordering of the pharmacological section has been reviewed and revised to start with treatment

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m	for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.
Portsmouth Hospitals NHS Trust	Short	16	16-19	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)': In an area of such clinical importance (i.e. mortality benefit) and change from previous NICE heart failure guidelines, why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388[1] should be replicated verbatim in this guidance to make the document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations has been included in full on publication of the guideline. As we are incorporating the recommendations made within the TA and not reviewing the evidence as part of the update of this guideline we are unable to advise on the monitoring of this medication.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, the Board of the BSH would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed. This comment also applies to Main Document P200 Lines 20-22 National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
Portsmouth Hospitals NHS Trust	Short	16	20-24	'Considerations' for both indications for hydralazine-ISDN should be displayed at this stage: - Hydralazine and isosorbide dinitrate may be considered in symptomatic patients with HFREF who can tolerate neither an ACEI nor an ARB (or they are contra-indicated) to reduce the risk of death.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				- Hydralazine and isosorbide dinitrate should be considered in black patients with LVEF≤35% or with an LVEF <45% combined with a dilated LV in NYHA Class III–IV despite treatment with an ACEI, a beta-blocker and an MRA to reduce the risk of HF hospitalization and death This comment also applies to Main Document P200 Lines 24-27	https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.
Portsmouth Hospitals NHS Trust	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
Portsmouth Hospitals NHS Trust	Short	17	1-3	Digoxin is recommended for worsening or severe heart failure with reduced ejection fraction despite first and second line treatment for heart failure: We feel that this should be re-worded to 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in…..' 'Severe heart failure' is also ambiguous (i.e. Severe LVEF? Severe symptoms?) and should be changed to 'patients with symptomatic heart failure with reduced ejection fraction' Digoxin is also only indicated in such patients with sinus rhythm.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The final wording should be 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in patients with symptomatic heart failure due to reduced ejection fraction in sinus rhythm' Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines and the evidence base[3]. This comment also applies to Main Document P200 Lines 31-33 3. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 4. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1997;336:525–533	
Portsmouth Hospitals NHS Trust	Short	17	13-22	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled, clinical trials, of benefits to patients in both life expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely. References 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf	limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m^2 or above: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m 3. Yancy C, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509	For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.
Portsmouth Hospitals NHS Trust	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
Portsmouth Hospitals NHS Trust	Short	18	1-3	(Section 6.1.3) The Board of the British Society for Heart Failure agrees with this recommendation	Thank you for your comment.
Portsmouth Hospitals NHS Trust	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion is to give the correct amount of diuretics. In advanced heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing risk of becoming dehydrated, which can lead to hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the	urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				necessary information (ie measuring urea as well as creatinine and eGFR).	
Portsmouth Hospitals NHS Trust	Short	18	4-7	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of renal physicians in patients showing "deterioration" in renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of deteriorating renal function, patients have better outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patients. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4. The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the doses of these medications. Advice on this is given in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure. https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
Portsmouth Hospitals NHS Trust	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read: 'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
Portsmouth Hospitals NHS Trust	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Portsmouth Hospitals NHS Trust	Short	19	26	Section 1.8.3. Bullet point 2. It is unclear what is meant by the term 'partially deactivate'. The tachycardia treatment functions of a defibrillator are either on or off. A reader might think the authors are advocating turning off ICD shocks but leaving on anti-tachycardia pacing – this is generally inadvisable because anti-tachycardia pacing may be pro-arrhythmic. If the authors are referring to deactivation of tachycardia treatment function of CRT-D devices, then this should be more clearly worded.	Thank you for your comment. The committee agree the term is unclear and have revised this to remove fully and partially and have removed reference to potential harms of unnecessary shocks.
Portsmouth Hospitals NHS Trust	Short	19	29	Section 1.8.3. Bullet point 3. Unnecessary shocks is not a recognised term. One assumes that the authors are referring to appropriate shocks that occur in the minutes, hours or days before an expected death in a patient with heart failure. These might be better described as 'futile' shocks but this may only be apparent in retrospect.	Thank you for your comment. The committee agree this term is unhelpful and have removed this.
Portsmouth Hospitals NHS Trust	Short	20	26	Section 1.10.1. This statement may be mis-interpreted. It only applies to patients with advanced heart failure who do not have hypoxaemia. As discussed in the full version, there is clear guidance from the British Thoracic Society that home oxygen should be offered to patients with advanced heart failure who have symptoms and a low resting pO2.	Thank you for your comment. We think the wording of the recommendation is clear. Whilst the Committee acknowledged the guidance made by the British Thoracic society, they made the recommendation based on the evidence reviewed for the guideline which did not demonstrate a benefit for the key pre-specified outcomes. However the committee did recognise there may be other comorbid conditions where people may

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					benefit from oxygen therapy and this has been stated in the recommendation.
Portsmouth Hospitals NHS Trust	Short	20	5	Section 1.8.4. There are two additional time points where the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure should be reviewed 1. After any appropriate or inappropriate ICD therapy 2. Before any planned replacement of the ICD pulse generator	Thank you for your comment. The focus of the review undertaken was specifically on discussing deactivation of ICDs with patients. Decisions around the management of ICDs is outside the scope of this guideline.
Portsmouth Hospitals NHS Trust	Short	21	1	Section 1.10.2. It would be useful for the reader to include positive guidance about how to decide which patients should be offered referral to palliative care services.	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
Portsmouth Hospitals NHS Trust	Short	21	10	Section 1.10.5. The NICE guideline does not specify that the patient must be in the last 2-3 days of life. We would suggest that the wording 'last 2-3 days of life' is replaced with 'last days of life' as per the NICE guideline	Thank you for your suggestion, however the guideline states it 'covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life'.
Portsmouth Hospitals NHS Trust	Short	21	3	Section 1.10.3. This section should be expanded to include clinical triggers for consideration of a palliative care referral, such as , 1. More than 3 unplanned hospital admissions in the last 12 months	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Important therapies are being withdrawn in the face of worsening heart failure and renal function	committee were unable to make recommendations in this area other than general principles based on consensus opinion.
Portsmouth Hospitals NHS Trust	Short	25	14-15	The statement "Intravenous and subcutaneous diuretics need to be administered by nursing or healthcare staff, whereas oral formulations do not" is not true in that a self-adhesive subcutaneous pump has been developed to be self-administered by patients.	Thank you for your comment and this information. We have updated this statement to reflect this.
Portsmouth Hospitals NHS Trust	Short	27	3	We are concerned about the research question "Risk tools for predicting **non-sudden** death in heart failure". BNP/NT-proBNP are excellent markers of pump failure death. Predicting sudden death is far more of a challenge, and relevant when considering who to consider for expensive device-based therapies. Only one study found BNP to be predictive of sudden death (Berger *et al.* Circulation 2002;105:2392-7), a finding that has not been replicated. We would suggest that the question should then be "Risk tools for predicting **sudden and** non-sudden death in heart failure'.	Thank you for your comment. The question addressed by the guideline was to determine which are the most accurate prognostic risk tools at predicting patient mortality in the short term, to support decisions about involvement of palliative care services and the use of palliative care processes. The guideline did not consider tools to predict sudden death and therefore cannot widen the question.
Resuscitation Council	Full	General	General	To avoid unnecessary duplication of comments, please cross-reference all the above comments on the short version to the corresponding text in the full guideline.	Thank you for your comment.
Resuscitation Council	Short	19-20	25-29, 1-10	We welcome this section of the guidance, which helps to reinforce elements of our NICE-accredited guidance on this topic: Pitcher D, Soar J, Hogg K, et al. Cardiovascular implanted electronic devices in people towards the end of life, during cardiopulmonary resuscitation and after death: guidance from the	Thank you for your comment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Resuscitation Council (UK), British Cardiovascular Society and National Council for Palliative Care. Heart 2016;102: A1–A17 (http://heart.bmj.com/content/heartjnl/102/Suppl_7/A1.full.pdf). If followed widely and consistently, this section of the guidance could lead to delivery of much better person-centred care for this specific group. There may be resistance to implementation from some clinicians who prefer to avoid important conversations about topics that they think may be difficult to discuss.	
Resuscitation Council	Short	4-5	2 onwards	We welcome the emphasis on an MDT approach to the management of heart failure and on the importance of good communication. We believe that, implemented widely, this will have a major positive impact on quality of care.	Thank you for your comment.
Resuscitation Council	Short	6	22-24	We agree that sharing of information is an important factor in ensuring high-quality care, but health and care providers must also comply with the law and with the imminent implementation of the General Data Protection Regulation (GDPR), some reference to this would be helpful.	Thank you for your comment. Compliance with GDPR is the responsibility of service providers and outside of the remit of this guideline.
Resuscitation Council	Short	7 and in many other places	5 and in many other places	The word 'Doppler' should be spelled with an upper-case D, in line with accepted/usual UK and international practice in cardiology and imaging literature.	Thank you for your comment, this has been amended.
Resuscitation Council	Short	9	20-22	We welcome the emphasis on openness and honesty, and on the importance of helping a person to understand where there is uncertainty. When explaining uncertainty in this way, it is also crucial to	Thank you for your comment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				offer the person and their family/carers support in coping with that uncertainty.	
Resuscitation Council	Short	9	25-26	We welcome the recommendation about advanced communication skills training. This could also have a major positive impact on the delivery of high-quality person-centred care. Implementation may be challenging, partly because such training involves cost, and partly because some (perhaps more senior) health professionals may not perceive that such training, and the time commitment required, would enhance the quality of care that they deliver. If this could be implemented widely, some of other challenges (e.g. see comments 4 and 17) would be much more easily addressed.	Thank you for your comment. The committee discussed the potential costs of this recommendation, and this is why this was agreed to be a 'consider' recommendation.
Resuscitation Council	Short	10	8-9	We agree that it is important to address the risk of sudden death and to correct any misconceptions about it. We believe that it is also important to explore each person's wishes, in their individual situation, for the care and treatment that they would want to be considered in the event of a sudden emergency, including but not limited to cardiac arrest or sudden death. Health professionals should not assume that a person would want to receive all types of potential care and treatment, including but not limited to CPR, without first giving them an opportunity to express their informed wishes.	Thank you for your comment. We agree and these issues are explored in more detail in the LETR in the full guideline.
Resuscitation Council	Short	13	24-26	This recommendation (measuring serum sodium, potassium, creatinine and estimated glomerular filtration rate (eGFR) before and 1 to 2 weeks after	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				starting an ACE inhibitor, and after each dose increment) could have been amended much more effectively by including advice on how the results of these tests should guide further treatment. If there has been a sharp and substantial deterioration in renal function, this implies severe renovascular disease and a danger of rapid progression to sever renal failure if treatment is not stopped immediately. As worded, this element of the guidance is incomplete.	therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	13	27-28	This recommendation also omits to advise how to respond - to any change in blood pressure measurements. This is less critical than the point made in comment 7 above, as action would largely be driven by symptoms rather than by the blood pressure measurements alone.	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
Resuscitation Council	Short	14	19-20	Please see comment 7 above. A similar principle is involved here.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	14	25-27	Please see comment 10 above.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	14	3	The wording 'Once the target or maximum tolerated dose is reached' is potentially misleading. It would be better to state: 'Once the target **dose** or maximum tolerated dose is reached'. Elsewhere you have reduced confusion to a degree by using punctuation: 'Once the target, or maximum tolerated, dose is reached'. The use of the wording 'target dose' would be clearer.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	14	3	It would be helpful to refer clearly to the later explanation (section 1.7) of what is meant by 'monitor treatment'.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	14	6-8	Please see comment 8 above.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Resuscitation Council	Short	15	11-12	Please see comment 7 above. A similar principle is involved here.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Resuscitation Council	Short	15	13-14	Please see comment 8 above.	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Resuscitation Council	Short	15	17-19	Please see comment 10 above.	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Resuscitation Council	Short	29	General	We wish to suggest retention of '1.2.1.4 Be prepared to broach sensitive issues that are unlikely to be raised by the person with heart failure, such as sexual activity.' Although you state that this is now covered in the NICE guideline on patient experience in adult NHS services, we are not sure that the majority of readers will have the time or commitment to access a separate guideline and to find and read the relevant section.	Thank you for your comment. A link to the Patient Experience guideline is provided in the short version for ease of access and there will be a link to the relevant section from the CHF pathway via the NICE website.
Resuscitation Council	Short	29	General	As above, we suggest retention of '1.2.2.1 Dosing regimens should be kept as simple as possible, and the healthcare professional should ensure that the patient and carer are fully informed about their medication.'. Again, we are not sure that the majority of readers will have the time or commitment to access a separate guideline and to find and read the relevant section.	Thank you for your comment. A link to the Medicines adherence guideline is provided in the short version for ease of access and there will be a link to the relevant section from the CHF pathway via the NICE website.
Resuscitation Council	Short	30	General	Once again, we think that removing '1.4.1.5 When a patient is admitted to hospital because of heart failure, seek advice on their management plan from a specialist in heart failure.' represents the loss of an	Thank you for your comment. A link to the Acute Heart Failure guideline is provided in the short version for ease of access and there will be a link

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				important point from this guidance on **chronic heart failure**. You should not assume that all clinicians will refer to and/or extrapolate advice from a separate guideline on **acute heart failure**, even though that may contain similar advice.	to the relevant section from the CHF pathway via the NICE website.
Roche Diagnostics Limited	Economic Model	General	General	Access to the economic model accompanying the Guideline required the purchase of specialist software, which limited the opportunity to review. Furthermore, it was our experience that the file saved on the link provided did not open in the required software. Every effort should be made to create such models in readily available software to improve transparency of the economic analyses and conclusions derived.	Thank you for your comment. We apologise for the difficulties you experienced in accessing the economic model. TreeAge is commonly used software for developing economic models. Models developed in other software still require a specialist to fully understand, operate and edit, which is why we provide the detailed technical report explaining our data inputs and methods.
Roche Diagnostics Limited	Full	General	General	We recognise the significant effort and content of the full document however we are concerned that the recommendations are not clear enough to support clinicians given the volume of information provided. The explanations for certain recommendations are often buried in large bodies of text and could be more clearly made with formatting changes to the document. We suggest that the short version of the guideline is improved to offset against the volume of information within the full document.	Thank you for your comment. The short version of the guideline has been revised in light of stakeholder comments.
Roche Diagnostics Limited	Full	233-269	General	Monitoring - We would suggest that NICE's recommendation on monitoring using NT-proBNP is made clearer and the groups of patients recommended as suitable for testing are more easily identifiable. We believe that highlighting these groups as below in bullet point form would benefit the reader. The full guideline	Thank you for your comment. The committee considered the variation in the NP-guided treatment protocols made it difficult to specify a particular model of NP monitoring, however they consider the recommendation to be

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				suggests that the reduction in deaths and hospitalisation would be most significant for people in higher risk categories such as: ● Newly Diagnosed ● A recent deterioration Require a medication titration	clear and reflects the strength of the evidence found.
Roche Diagnostics Limited	Full	62-92	General	Diagnosis of Heart Failure - We would suggest that this section needs to clearly state that NICE no longer recommends BNP testing and only recommends the use of NT-proBNP for the diagnosis of heart failure. This section would also benefit from a clearer explanation of why the recommendation has been made by highlighting the main points i.e. in bullet points as shown below as opposed to in paragraphs of text which may not be clear. ● NT-ProBNP has greater sensitivity over BNP ● NT-ProBNP samples are more stable than BNP making it more suitable for Primary Care samples NT-ProBNP levels retain prognostic value in patients on Sacubitril/Valsartan	Thank you for your comment. The committee did not consider it necessary to state that BNP should not be used and did not consider the clinical evidence strong enough to support a do not use recommendation for BNP. NICE prefer not to include the rationale for a recommendation within the recommendation itself and therefore the recommendation remains unchanged. The committee considered it important that the reasons for recommending NT-proBNP be fully explained in the LETR. However the LETR has been edited to highlight these reasons by numbering them and then providing further explanation below.
Roche Diagnostics Limited	Full	84-96	General	We would recommend the inclusion of the reference listed below which supports the use of NT-proBNP in patients with renal dysfunction. Schaub et al. concludes that NT-proBNP retains diagnostic ability in patients with poorer renal function at a higher cut-off point. In terms of the prognostic ability of NT-proBNP, the pooled results between patients with preserved and	Thank you for your comment. Schaub et al (2015) is a systematic review. The inclusion criteria for this review does not match the protocol agreed by the committee to evaluate the diagnostic accuracy of BNP and NT-proBNP in diagnosis of heart failure in people with chronic kidney disease. The protocol provides further detail about the inclusion and exclusion criteria.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				diminished renal function were not significantly different. Schaub J. A., Coca S. G., Moledina D. G., Gentry M., Testani J. M., Parikh C. R. Amino-Terminal Pro-B-Type Natriuretic Peptide for Diagnosis and Prognosis in Patients With Renal Dysfunction. JACC: Heart Failure. 2015;3(12):977–89.	
Roche Diagnostics Limited	Full	234-246	General	We would suggest that the references listed below are considered as part of the clinical evidence section in the guideline. 1. Chow S. L., Maisel A. S., Anand I., Bozkurt B., Boer R. A. D., Felker G. M., et al. Role of Biomarkers for the Prevention, Assessment, and Management of Heart Failure: A Scientific Statement From the American Heart Association. Circulation. 2017;135(22). 2. Felker G. M., Anstrom K. J., Adams K. F., Ezekowitz J. A., Fiuzat M., Houston-Miller N., et al. Effect of Natriuretic Peptide-Guided Therapy on Outcomes in High-Risk Patients with Heart Failure and Reduced Ejection Fraction: A Randomized Clinical Trial. Journal of Cardiac Failure. 2017;23(11):830. 3. Gardner R. S., Chong V., Morton I., Mcdonagh T. A. N-terminal brain natriuretic peptide is a more powerful predictor of mortality than endothelin-1, adrenomedullin and tumour	Thank you for your comment. The references you have listed do not match the inclusion criteria in the protocol agreed by the committee to evaluate the diagnostic accuracy of BNP and NT-proBNP in diagnosis of heart failure in people with chronic kidney disease. The protocol provides further detail about the inclusion and exclusion criteria. Chow et al (2017) is a statement paper on biomarkers and does not have data that can be extracted for a review. Felker et al (2017) is included in the review on diagnostic accuracy. The populations in Gardner et al (2005) and Gardener et al (2007) are in a very specific population of people with heart failure waiting for a cardiac transplant, the population for this guideline is people with suspected heart failure in a community or outpatient setting. Arzilli et al (2018) was published after the finals searches for the guideline were conducted and did not evaluate the diagnostic accuracy of BNP and NT-proBNP.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				necrosis factor-α in patients referred for consideration of cardiac transplantation. European Journal of Heart Failure. 2005;7(2):253–60. 4. Gardner R. S., Chong K. S., Morton J. J., Mcdonagh T. A. A change in N-terminal pro-brain natriuretic peptide is predictive of outcome in patients with advanced heart failure. European Journal of Heart Failure. 2007;9(3):266–71. Arzilli C., Aimo A., Vergaro G., Ripoli A., Senni M., Emdin M., et al. N-terminal fraction of pro-B-type natriuretic peptide versus clinical risk scores for prognostic stratification in chronic systolic heart failure. European Journal of Preventive Cardiology. 2018.	
Roche Diagnostics Limited	Full	233	22-24	We believe that the wording of this statement regarding the measurement of natriuretic peptides in the management of heart failure remaining "uncertain" is not reflective of the evidence available and is not in line with the recommendations made within the guidance on monitoring heart failure patients using NT-proBNP.	Thank you for your comment. This question was reviewed as the optimal biomarkers for diagnosis of heart failure remain a topic of active research and there is uncertainty about the optimum diagnostic thresholds for natriuretic peptides.
Roche Diagnostics Limited	Full	233	23-26	Whilst Troponin may not be routinely used in Heart Failure, this is not reflective of the evidence which suggests that it does have utility in Heart Failure. We would suggest the inclusion of recommendations for the clinical use of Troponin in Heart Failure and specifically in certain subgroups. There are a multitude of references to support this, a few of which are listed below.	Thank you for your comment. Troponin is included in the review question ,'What is the clinical and cost effectiveness of biomarker-based monitoring, monitoring with cardiac MRI, and monitoring with repeated echocardiography in people with heart failure?'.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				1. Aimo A., Januzzi J. L., Vergaro G., Ripoli A., Latini R., Masson S., et al. Prognostic Value of High-Sensitivity Troponin T in Chronic Heart Failure. Circulation. 2018;137(3):286–97. 2. Mcevoy J. W., Chen Y., Ndumele C. E., Solomon S. D., Nambi V., Ballantyne C. M., et al. Six-Year Change in High-Sensitivity Cardiac Troponin T and Risk of Subsequent Coronary Heart Disease, Heart Failure, and Death. JAMA Cardiology. 2016;1(5):519. Gravning J., Askevold E. T., Nymo S. H., Ueland T., Wikstrand J., Mcmurray J. J. V., et al. Prognostic Effect of High-Sensitive Troponin T Assessment in Elderly Patients With Chronic Heart Failure: Results From the CORONA Trial. Circulation: Heart Failure. 2013;7(1):96–103.	The references you have listed are not included in this review for the following reasons: • Aimo et al (2018) was published after the cut-off date for the final searches and section 5.10 of Developing NICE guidelines: the manual states, 'If evidence is identified after the last cut-off date for searching but before publication, a judgment on its impact should be made by the Developer and NICE staff with a quality assurance role. In exceptional circumstances, this evidence can be considered if its impact is judged as substantial'. The committee did not consider this paper would have a substantial effect on the recommendations to include the data, in addition limitations based on the end points assessed, assay quality and heterogeneity were also noted. • Gravning, et al (2013). The population was limited to ischemic heart failure and comprised a clinical trial population selected for recruitment to the CORONA trial and is not representative of the wider heart failure population stated in the review protocol. • McEvoy, et al (2016). The population consisted of a general population cohort study (Atherosclerosis Risk in Communities and does not investigate the utility of

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					troponin measurement and effect on prognosis in patients with signs and symptoms of heart failure as specified in the review protocol.
Roche Diagnostics Limited	Full	233	26-28	We would suggest that the diagnosis and the monitoring of heart failure in patients with co-existing conditions such as chronic kidney disease (CKD) and atrial fibrillation (AF) are looked at separately in line with the other sections of the heart failure guideline. This is because there is evidence demonstrating that the prognostic value in monitoring is maintained in HF in both AF and CKD patients. Whilst we would agree that the diagnostic utility of NT-proBNP is affected by AF and CKD, we would suggest the wording of this statement is changed from "uncertain" to reflect the evidence listed below in monitoring of these patients. ***AF:*** 1. Kristensen S. L., Jhund P. S., Mogensen U. M., Rørth R., Abraham W. T., Desai A., et al. Prognostic Value of N-Terminal Pro-B-Type Natriuretic Peptide Levels in Heart Failure Patients With and Without Atrial Fibrillation. Circulation: Heart Failure. 2017;10(10). ***CKD*:** 1. Koratala A, Kazory A. Natriuretic Peptides as Biomarkers for Congestive States: The	Thank you for your comment. The committee reviewed the evidence for people with heart failure and CKD, and heart failure with atrial fibrillation for both the diagnostic and monitoring review questions as there was uncertainty about the utility of biomarkers when patients had comorbidities that would affect their clearance and the wording in the introduction reflects this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				Cardiorenal Divergence. Disease Markers. 2017;2017:1–9. Schaub J. A., Coca S. G., Moledina D. G., Gentry M., Testani J. M., Parikh C. R. Amino-Terminal Pro-B-Type Natriuretic Peptide for Diagnosis and Prognosis in Patients With Renal Dysfunction. JACC: Heart Failure. 2015;3(12):977–89.	
Roche Diagnostics Limited	Full	234	13-15	The guideline states that no relevant studies comparing usual care with Troponin or combinations of different biomarkers were identified. Evidence exists to suggest that both Troponin and Growth differentiation factor 15 (GDF-15) can be used similarly to NT-proBNP for biomarker testing. Please see comment 8 above for the supporting evidence for the inclusion of Troponin. The references below demonstrate that GDF-15 has prognostic utility in heart failure. 1. Anand I. S., Kempf T, Rector TS, Tapken H, Allhoff T, Jantzen F, et al. Serial Measurement of Growth-Differentiation Factor-15 in Heart Failure: Relation to Disease Severity and Prognosis in the Valsartan Heart Failure Trial. Circulation. 2010;122(14):1387–95. Kempf T., Vonhaehling S., Cicoira M., Ponikowski P., Filippatos G., Rozentryt P., et al. Prognostic utility of growth-differentiation factor-15 in patients with chronic heart failure. European Journal of Heart Failure Supplements. 2007;6(1):46–7.	Thank you for your comment. The protocol on to evaluate the clinical and cost effectiveness of biomarker-based monitoring, monitoring with cardiac MRI, and monitoring with repeated echocardiography in people with heart failure was agreed by the committee and all the identified studies that met the inclusion criteria were included in the evidence reviews. The protocols provide further detail about the inclusion and exclusion criteria. The reasons these two references did not meet the inclusion criteria are set out below. Anand. et al (2010) addresses the utility of serial measurements of GDF-15 in a subset set of patients with HFREF specifically recruited to the ValHEFT trial rather than a cohort of symptomatic patients with heart failure in the community as required in the scope of the review. Kempf et al (2007) addresses the prognostic utility of GDF-15 in patients selected to participate in cardiac biomarker study with left systolic dysfunction and HFREF. It is unclear how this

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					would translate to a general population with heart failure.
Roche Diagnostics Limited	Short	General	General	We believe that clinicians who are not experts in Heart Failure are most likely to consult this short document and are therefore concerned that the recommendations are not clear enough to support them. For example, we support the recommendation that NT-proBNP is measured in people with suspected heart failure (page 7 lines 1-2) however the short version should also state that NICE no longer recommends BNP testing and that the only NP recommended is NT-proBNP. We are concerned that this new recommendation is not clear enough given the terminology around NPs. Another example is that "BNP testing" is often used as an umbrella term for natriuretic peptide testing as a whole without distinguishing between assays. In the update information (pages 27 - 37), the short version of the document does not clarify the reason for the recommended removal of BNP testing and subsequent replacement with NT-proBNP. The full version suggests that the recommendations for NT-proBNP over BNP testing is due to: ● NT-ProBNP has greater sensitivity over BNP ● NT-ProBNP samples are more stable than BNP making it more suitable for Primary Care samples ● NT-ProBNP levels retain prognostic value in patients on Sacubitril/Valsartan	Thank you for your comment. The committee reviewed the data for natriuretic peptides based on prospective studies of their utility in the diagnosis of heart failure in primary care. It made recommendations about the optimal diagnostic threshold based on the data available, and the exact biomarker used in the key studies. It was aware that there was variation in NHS practice in the choice of natriuretic peptides and previous guidance that had cited thresholds for both principal natriuretic peptides.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				We would suggest that these points are highlighted in the short document as we believe that this clarification would benefit the reader.	
Roche Diagnostics Limited	Short	19	5-9	Measuring NT-proBNP - In practice, clinicians are more likely to consult the short version of the document, therefore we would suggest that there is a clear statement around the recommendation of NT-proBNP testing and which groups of patients the clinicians should "consider" NT-proBNP testing with. The recommendations of which patients to consider for NT-proBNP testing are currently listed in a large body of text in the long version (pages 233-269) however they are omitted in the short version. The full guideline suggests that the reduction in deaths and hospitalisation would be most significant for people in higher risk categories such as: ● Newly Diagnosed ● A recent deterioration ● Require a medication titration We would suggest that these groups are highlighted in the short guideline as well as in the full document.	Thank you for your comment. The categories you cite came from the discussion by the committee in their consideration of the evidence and are given as examples rather than recommendations. The Committee were unable to specify those at higher risk due to the variation in the NP-guided treatment protocols.
Royal College of General Practitioners	General	General	General	The RCGP welcomes that patients should be managed in primary care as soon as possible, once they are stable and to see the focus that this guideline has on communicating information about the condition to the patient and their carers.	Thank you for your comment.
Royal College of General Practitioners	General	General	General	The terminology used - the term 'Heart Failure' itself is a terrifying term for patients, and may not fully represent the nature of the disease	Thank you for your comment. The committee discussed the use of the term 'heart failure' and that it could be a frightening term for patients.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					Therefore the committee made a recommendation for the first consultation (where a diagnosis is given the committee) to ensure that heart failure terminology is explained.
Royal College of General Practitioners	General	General	General	No mention of the value for intravenous iron and potential value (of oral iron depending on trial results) if low iron/ferritin even if not anaemic	Thank you for your comment. The committee reviewed all the available evidence and decided that in the absence of substantial effects on hard outcomes or hospitalisation that a clear statement about the benefits or harms of iron therapy could not be made. The committee noted that 2 large trials were underway that may answer this question. In addition the resource impact of any recommendation needed to be considered. It felt that making any definitive recommendation in this field was premature at this time.
Royal College of General Practitioners	General	General	General	No mention about discontinuation of aspirin if no need for it (it is a NSAID like drug)	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal College of General Practitioners	Long and Short	General	General	There needs to be some mention of the current evidence of left ventricular assist device (LVAD) pump such as the HeartMate 3 (HM III). Stroke and right ventricle failure appear to continue to be problems with comparable rates compared with the HeartMate II.	Thank you for your comment. Ventricular assist devices were not considered as part of this update. For details on what areas are included in this update please refer to the NICE website

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Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				Several large studies in HFpEF failed to show improvement in outcomes and management continues to be geared towards lifestyle modification and symptom relief.	https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal College of General Practitioners	Short	General	General	Danger of capacity issues of heart failure team all get sent on advance communication skill courses and too much detail is required for care plans. There is already a 'gold service' for some and no service for most due to capacity problems	Thank you for your comment. The evidence reviewed highlighted the skills required by healthcare staff in communicating diagnosis and prognosis with HF patients. The committee acknowledged healthcare staff are required to deliver difficult or complex messages and supported the provision of advanced communication skills training. The committee consider the contents of the care plan has the key information required to be shared between the different care settings and clinical services providing care and is reasonable in order to ensure continuity of care.
Royal College of General Practitioners	Short	4	9	There needs to be a definition of "primary care team" in the context of a specialist heart failure multidisciplinary team. The recognition that primary care physicians can form an integral part of the MDT is welcome but due to current pressures in primary care it will not be practical for representation to occur. If it is an area then this needs to be stated along with who and what the clinical discipline might be. If "primary care team" throughout this document refers to the patient's GP, a 6-monthly review ***and*** written care plan would be an increase in workload.	Thank you for your comment. The exact arrangements vary across the NHS but the committee identified that practitioners with competencies in primary care are a key part of the MDT. The 6 month review may also be part of the long-term conditions review and so would not be additional.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Royal College of General Practitioners	Short	6	General	Care Plans- consider encouraging doctors and specialist nurses to adopt the practice of writing outpatient clinic letters directly to the patient Care plans have had had mixed success with other long-term conditions. There are problems of availability, recognition by health care professionals and being kept up to date. The RCGP Northern Ireland produced a universal health passport which could be used for a variety of long term conditions. http://www.rcgp.org.uk/rcgp-near-you/rcgp-nations/rcgp-northern-ireland/my-healthcare-passport.aspx The RCGP is working with other Royal Colleges to encourage doctors to adopt the practice of writing outpatient clinic letters directly to the patient, with a copy of the same letter being sent to the patient's general practitioner. The Academy of Medical Royal Colleges has adopted the 'Letters to Patients' initiative as part of its commitment to place patients at the centre of their care. It is aligned to Good Medical Practice (2013), which states: 'You must give patients the information they want or need to know in a way they can understand', and the NHS Constitution (2015), which states that patients 'have the right to be given information about the test and treatment options available to [them], what they involve and their risks	Thank you for your suggestion. The recommendations made throughout the guideline have promoted inclusion of patients and the sharing of information. They state that patients should be given copies of discharge summaries and healthcare plans. The principles of information giving and communication with patients as outlined in the Patient Experience guideline have also been cross referred to.

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and benefits' and have 'the right of access to [their] own health records and to have any factual inaccuracies corrected'. In addition it states that staff should aim to 'involve patients, their families, carers or representatives fully in decisions about prevention, diagnosis, and their individual care and treatment'	
Royal College of General Practitioners	Short	10	2	It is unclear here whether this extended appointment then subsequent follow-up is in general practice or within the MDT? If this is aimed at general practice, given the current capacity issues in general practice, it is unlikely many would have an "extended" appointment at short notice? If this is aimed at general practice "offer" should be changed to "consider" as it may be unrealistic for many parts of UK general practice. The ambiguous use of "primary care team" throughout this document needs to be clarified.	Thank you for your comment. The wording has been amended to make clear the extended appointment is with the specialist HF MDT rather than the primary care team. The composition of the primary care team would need to be determined locally depending on how services are configured, but would usually include a GP and HF nurse. Who this may typically include is provided in the glossary of the full guideline.
Royal College of General Practitioners	Short	16	37	Consider adding Angiotensin receptor -neprilysin inhibitor (ARNi) after Sacubitril Valsartan to develop understanding of this drug which is likely to be used more often in the future	Thank you for your comment. The wording used comes from the title used by TA388. A link is provided to more detailed information including a description of the drug.
Royal College of Nursing	General	General	General	This is to inform you that there are no comments to submit on behalf of the Royal College of Nursing to inform on the Chronic heart failure in adults: diagnosis and management Draft Guidance Consultation.	Thank you for your comment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Physicians	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by British Society for Heart Failure (BSH).	Thank you for your comment.
Royal College of Physicians of Edinburgh	Short	General	General	The Royal College of Physicians of Edinburgh generally welcomes this draft guideline and agrees that there are some commendable new evidence based recommendations, including defining the role of the specialist heart failure team and recommendations on a care plan.	Thank you for your comment.
Royal College of Physicians of Edinburgh	Short	4	9	The College notes that there needs to be careful two way communication with each patient's primary care team, but it would likely be challenging to include a member of each primary care team on the multidisciplinary team.	Thank you for your comment. These recommendations have been updated so that the primary care team is no longer recommended to be a member of the specialist heart failure MDT, but instead to work in collaboration with the MDT. The updated wording of the recommendation is: The core specialist heart failure multidisciplinary team (MDT) should work in collaboration with the primary care team, and should include: • a lead physician with subspecialty training in heart failure (usually a consultant cardiologist) • a specialist heart failure nurse • a healthcare professional with expertise in specialist prescribing for heart failure.
Royal College of Physicians of Edinburgh	Short	5	13	The patient should be recalled at least every six months and their care plan updated: there may need to	Thank you for your comment. The 6 monthly review may be part of the long-term conditions review and the committee have revised wording

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				be negotiation between primary and secondary care over responsibilities in this area.	of recommendation to updating the clinical record both of which reflect current practice for the primary care team.
Royal College of Physicians of Edinburgh	Short	7	11-16	The recommendations (1.2.5) on BNP need to emphasise more that a "high BNP is not heart failure" and echocardiography and clinical assessment is needed. The College highlights that a raised BNP can be due to multiple causes (eg. atrial fibrillation, age, CKD), not just heart failure.	Thank you for your comment. The committee recognised that biomarkers formed only part of the assessment. This is highlighted in the sections relating to the diagnostic pathway including other clinical investigations and potential diagnoses.
Royal College of Physicians of Edinburgh	Short	7	5	Having transthoracic doppler 2D echocardiography and specialist assessment within two weeks will be difficult to achieve without increase in echo facilities and staff. Resource implications should be recognised.	Thank you for your comment. This recommendation has been carried forward from the 2010 guideline update (CG108). The committee discussed the current capacity constraints on echocardiography services, but agreed that this should be maintained for those with very high levels of NTproBNP (>2,000ng/l) due to their greater risk of poorer prognosis.
Royal College of Physicians of Edinburgh	Short	8	13-17	The College notes that "*alternative methods of imaging the heart (for example, radionuclide angiography [multigated acquisition scanning], cardiac MRI or transoesophageal doppler 2D echocardiography) if a poor image is produced by transthoracic doppler 2D echocardiography. [2003, amended 2018]*" will require increased nuclear cardiology and MRI resourcing.	Thank you for your comment. This recommendation was originally made in 2003. Some minor wording edits were made in this guideline. Therefore we do not expect there to be an increase in resourcing.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Royal Devon and Exeter NHS Foundation Trust	Full	General	General	The GDG are to be congratulated for completing a huge amount of work and distilling a large amount of literature. Many of the guidelines are likely to have an on-going beneficial impact on the care of heart failure patients in the UK. It is disappointing however that a significant number of the planned review questions had insufficient evidence available to make a recommendation. The usefulness of researching an area with no evidence is debatable and could probably have been pre-empted.	Thank you for your comment. Stakeholder consultation on the scope of this guideline identified the key questions to be reviewed by the committee. The evidence reviews were based on these questions. The committee agree that the lack of good quality evidence in this area is disappointing. It is important that the gaps in the evidence are highlighted and where appropriate the committee have made research recommendations. The committee hope that this will support evidence based decision making in the future.
Royal Devon and Exeter NHS Foundation Trust	Full	General	General	The whole document would benefit from careful scrutiny for typographical errors. Some are pointed out below but there are many more.	Thank you for your comment.
Royal Devon and Exeter NHS Foundation Trust	Full	14	13	Guideline statement 4: Suggest changing units to ng/L.	Thank you for your comment. The units in the recommendation have been changed to ng/L. The units in the review remain as pg/ml, with a note added to the introduction explaining the 1:1 conversion of pg/ml to ng/L.
Royal Devon and Exeter NHS Foundation Trust	Full	14	16 and 26	Guideline statement 5 and 7: Both seem educational rather than a recommendation. Rather than take up valuable guideline space this information could reside within the information for guideline 2-4.	Thank you for your comment. The committee consider the recommendations provide helpful advice for health professionals and should be retained.

Chronic heart failure in adults: diagnosis and management

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13/03/2018 - 26/04/2018

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Royal Devon and Exeter NHS Foundation Trust	Full	14	39	Guideline statement 8: 1. Who is this guideline statement aimed at? 2. If all patients (with raised NTproBNP) are being referred for specialist assessment and echo, where does this statement fit in the pathway? Specialists know why to request echo. Better would be clarification of the role of echocardiography in the hands of the General Practitioner. Echocardiography is performed to identify many more potential abnormalities than are listed and there is no need to try and list them all here. The need for echocardiography is recommended clearly in the previous statements and I would now suggest removal of this.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	14	42	Guideline statement 9 and 10: 1. These statements essentially say the same thing and should be combined. 2. What are the relevant professional standards given the increase in different types of accreditation from a number of different national/international bodies?	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	14	9	Guideline statement 3: 1. Wording of guideline 3 – starting sentence with "Because" does not read well. 2. I do not think that anyone would now refer for echocardiography that did not have at least 2D	Thank for your suggestions. We think the wording is clear and the committee wished to highlight the poor prognosis and this is why the recommendation begins with this point. The terminology used for echocardiography was

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				capability/Doppler etc and this should be removed as unnecessary. 3. The units of NTproBNP do not match those used in the Acute Heart Failure guideline and there has been a move towards ng/L and not pg/ml. This should be harmonised. Suggestion: Refer people with suspected heart failure and an NTproBNP level greater than 2000 ng/L to have urgent specialist assessment and transthoracic echocardiography within 2 weeks.	carried over from the previous guideline and reference to Doppler 2D has been removed. The units have been harmonised throughout the guideline to ng/L.
Royal Devon and Exeter NHS Foundation Trust	Full	15	22	Guideline statement 13: 1. There are several conditions which may present in a similar manner as heart failure. Naming only one possibility in the guideline statement is not particularly helpful. 2. Equally the aim should be to definitively exclude alternative diagnoses, not 'try' to.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	15	27	Guideline statement 15: When all patients with an NTproBNP greater than 400 are being referred for specialist assessment, why is valve disease singled out from the myriad other causes?	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Devon and Exeter NHS Foundation Trust	Full	15	42	Guideline statement 19: Typo: 'Nice' should be NICE.	Thank you for your comment, this has been amended.
Royal Devon and Exeter NHS Foundation Trust	Full	15	9	Guideline statement 12: Would be better positioned just after the recommendation regarding a careful history?	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	16	9	Guideline statement 20: 1. This statement is based on trials combining only 63 patients in total. The uncertainty behind this recommendation (which is discussed in the full explanation) is not represented in the guideline statement, may confuse, and may also prevent a tailored approach in individual patients. Rephrasing may be possible to focus on a tailored approach whilst awaiting better evidence in either direction.	The committee considered the wording of the recommendation allows for a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that not routinely advising sodium restriction allowed flexibility unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.
Royal Devon and Exeter NHS	Full	17	23	Guideline statement 38: 1. What is the evidence base for this statement? 2. The majority of heart failure patients with common valve disease are likely to be	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Foundation Trust				improved by an ACE-I. Equally, patients with all but the most severe AS are likely to tolerate an ACE-I and it may actually be beneficial. Therefore the overall outcome from this statement could be harm. This appears to have been a consensus recommendation from the 2003 guideline but there is now more evidence available in this area. Consider further review or removal of this recommendation.	on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	17	26	Guideline statement 39: 1. The evidence for this significant shift in treatment approach is not definite. Before making such a fundamental change a contemporary RCT with this specific question in mind should be performed. Rate control in heart failure (and AF) is important and this may well discourage this – despite the second sentence.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Royal Devon and Exeter NHS Foundation Trust	Full	17	4	Guideline statement 33: Anticoagulation does not affect renal or liver function. Rather the type and dose of anticoagulation should be adjusted in the knowledge of the renal and liver function.	Thank you for your comment. This has been amended to: Be aware of the effects of impaired renal and liver function on anti-coagulant therapies.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Devon and Exeter NHS Foundation Trust	Full	18	12	Guideline statement 53 to 55: 1. These could be combined with statement 48 to 50 to avoid the repetition.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Royal Devon and Exeter NHS Foundation Trust	Full	19	26	Guideline statement 62: 1. This is confusing. There is likely to be more simple way to phrase the more cautious use of the same treatment regime in people with renal dysfunction.	Thank you for your comment. The committee have reconsidered the evidence and have amended the recommendation for further clarity to: For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m^2 or above: • offer the treatment outlined in section 1.4 and • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors or ARBs, mineralocorticoid receptor antagonists and digoxin.
Royal Devon and Exeter NHS Foundation Trust	Full	20	3	Guideline statement 66: 1. One can only offer coronary revascularisation to people with HFREF if they also have concomitant coronary artery disease and so this could be clarified. Given the evidence available the 'Do not routinely' appears too strong. In the STITCHES study, there are	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				definite groups of people who benefit. Therefore this option should be considered but discounted if not safe for a particular individual. If the evidence in this area is not robust enough then making no guideline may be better whilst other studies are awaited.	that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
Royal Devon and Exeter NHS Foundation Trust	Full	20	38	Guideline statement 73: The abbreviation of NT-proBNP is expanded in some recommendations but not others. Suggest harmonising this.	Thank you for your comment. Where the recommendations are grouped together in the diagnosis section it was felt only necessary to give the full name once and also in the monitoring section where the recommendation stands alone.
Royal Devon and Exeter NHS Foundation Trust	Full	20	42	Guideline statement 74: Typo: 'Corespecialist'	Thank you, this has been corrected.
Royal Devon and Exeter NHS Foundation Trust	Full	21	20	Guideline statement 77: 1. Who is the primary care team in this statement? Is this the usual GP or a community based HF nurse or someone else? 2. Typo: 'Specailsit' and 'receiving specialist heart failure' – needs clarification.	Thank you for your comment. The composition of the primary care team would need to be determined locally depending on how services are configured, but would usually include a GP and HF nurse. The transition of care between primary care and specialist HF MDT is described in the linking evidence to recommendations section of the guideline, but there may be periods when a patient would need to transfer back to the specialist MDT if they needed specialist care.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Devon and Exeter NHS Foundation Trust	Full	21	34	Guideline statement 78: No need to repeat Acute Heart Failure – suggest '….see NICE guideline 187'	Thank you for your comment. This wording is used as it has been transferred from the short guideline where a hyperlink is provided.
Royal Devon and Exeter NHS Foundation Trust	Full	22	31	Guideline statement 88: 1. The aim of this recommendation is important but the ability to provide an initial extended appointment and then a second appointment within 2 weeks is difficult. The challenge in implementation will largely be funding/capacity. It would be useful to clarify in the statement that this appointment may be with a different member of the MDT, not a second consultant appointment.	Thank you for your comment. The wording does specify to offer within 2 weeks if possible. The committee considered an appointment two weeks apart was reasonable but have clarified in the 'trade-off between benefits and harms' section of the LETR that this could be undertaken by any member of the specialist MDT.
Royal Devon and Exeter NHS Foundation Trust	Full	23	26	Guideline statement 94: 1. The heart failure risk scores reviewed have not been tested in their ability to help clinicians determine who may or may not benefit from palliative care services. To construct a guideline recommendation from the evidence reviewed would therefore not seem appropriate as this has not been tested. 2. The accuracy of an individual risk score in predicting individual outcomes may not be excellent in all situations; this does not mean they cannot help inform the clinician and patient discussion about therapeutic options,	Thank you for your comment. The committee are clear that the evidence for any of the risk tools did not support their use in identifying people at high risk of mortality and they were keen to ensure that these risk tools are not used in the wrong context to refer people to palliative services. The committee considered there was a serious risk of harm from the inappropriate use of risk tools in the palliative care context. For those reasons, the committee agreed to make an explicit recommendation that the tools should not be used to determine whether to offer referral to palliative care services.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				including access to specialist palliative care services. Clinicians should be able to consider using risk scores, in the knowledge of their limitations, to inform overall treatment discussions. 3. This recommendation appears to be a consensus agreement based on a different application of the risk scores than that intended by the authors of the studies. Better not to make a guideline recommendation but to recommend a research study in this area trying to answer the specific question. The research recommendation made appears to differ from the PICO question and also the actual question asked by the GDG.	The committee set out their rationale in detail in the evidence to recommendations section. NICE guidance does not override the responsibility of the clinician to make decisions appropriate to the individual patient. The committee noted that it is important that any treatment decision is made with the person. The protocol for this review states that the objective of the review was to determine which prognostic risk tools are the most accurate at predicting patient mortality, to support decisions about involvement of palliative care services and the use of palliative care processes. The key outcomes were: - Area under the ROC curve (AUC or c-statistic) - Sensitivity, specificity, negative predictive value, positive predictive value - Predicted risk versus observed risk (calibration) - Other outcomes e.g., D statistic, R2 statistic and Brier score - Reclassification The committee discussed the lack of studies reporting accuracy data (such as sensitivity, specificity and negative and positive predictive values) and therefore considered that this should be explicitly mentioned in the research

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendation. However, the PICO for the research recommendation matches that of the PICO for the original review.
Royal Devon and Exeter NHS Foundation Trust	Full	32	24	Why is the sacubitril/valsartan TA not referenced in any specific guideline statements?	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have now been included in full.
Royal Devon and Exeter NHS Foundation Trust	Full	32	6	States that guidance on valve disease will be removed but this does not seem to be case.	Thank you for your comment. The scope stated this would be removed but this decision was overturned at the request of the committee because they felt it was important to highlight that clinicians should seek specialist advice when treating this population. The scope has been revised.
Royal Devon and Exeter NHS Foundation Trust	Full	118	15	The decision to include the studies using the short acting metoprolol tartrate, even though it is not licensed for heart failure use in the UK, is interesting. The assumption of the 'similar overall effect' has not been definitively shown. Not having a licence in this area has previously been an exclusion for consideration within a UK NICE guideline.	Thank you for your comment**.** Prior to commencing the review, the committee noted that only bisoprolol, carvedilol, and nebivolol were licensed for use in heart failure in the UK. The committee discussed this issue in detail and concluded that all beta blockers were likely to have a similar overall effect despite some differences in pharmacokinetic properties. As the committee were evaluating the class effect and not the individual formulations it was appropriate to include all the identified beta blockers. In these circumstances drugs that are not licenced for a

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					specific indication but are commonly used in practice the UK can be included in a systematic review. This does not apply to drugs that do not have a licence for any indication.
Royal Devon and Exeter NHS Foundation Trust	Full	126	15	The beta-blocker trials included did not recruit and stratify originally according to atrial fibrillation or not and so this sentence is misleading. The subsequent meta-analysis, whilst rigorously performed, is not a contemporary randomised test of beta-blockers in heart failure and AF. The risk or benefit in different subgroups also remains to be determined. The strength of recommendation here does not reflect the uncertainty in the area.	Thank you for your comment. The committee acknowledge this is a post-hoc subgroup analysis using individual patient data from the original trials. The study investigators analysed people diagnosed with both CHF and AF, and split them into those randomized (in the original trials) to receive placebo or beta-blocker therapy, and analysed them. Baseline data for both groups is provided. However, the committee have reconsidered the evidence and the recommendation due to concerns of misinterpretation and potential unintended consequence of beta-blockers not being prescribed for this population. The recommendation has been removed and a research recommendation added to highlight the need for a prospective study to be undertaken.
Royal Devon and Exeter NHS Foundation Trust	Full	175	12	Heart failure medications are not really 'nephrotoxic' as in general they do not intrinsically harm the kidney. The change in perfusion state or fluid balance often results in the apparent deterioration in kidney function detected. This would benefit from correction/clarification.	Thank you for your comment. The committee reviewed the indications and harms associated with heart failure medications and was aware that disturbances in electrolyte balance and renal function were a consequence of many of them.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Devon and Exeter NHS Foundation Trust	Full	192	20	1. Only searching for evidence of an intervention against placebo is problematic here. With the newer medications used in heart failure it is unlikely to be ethical to compare to placebo and so are compared against the current standard of care instead. Therefore only using studies against placebo does not allow the potential beneficial effects of sacubitril/valsartan or other new agents to be discussed and weighed up. 2. The analysis of sacubitril/valsartan and renal outcomes has now been published and perhaps should be considered for review (Damman, K et al. JACC HF 2018)	Thank you for your comment. The protocol for this review listed the comparators to be against each other (class versus class and within class comparisons), against the same drug at a different dose, or against placebo. However, the majority of the literature found compared to placebo. Damman et al (2018) was published after the cut-off date for the final searches and section 5.10 of Developing NICE guidelines: the manual states, 'If evidence is identified after the last cut-off date for searching but before publication, a judgment on its impact should be made by the Developer and NICE staff with a quality assurance role. In exceptional circumstances, this evidence can be considered if its impact is judged as substantial'. In this circumstance sacubutril-valsartan is out of outside the remit of this guideline as a new therapy. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388) is cross referred to in the short guideline.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Devon and Exeter NHS Foundation Trust	Full	217	General	1. The new treatment algorithm seems to suggest that the level of evidence and benefit from adding sacubitril valsartan is the same as ISMN/hydralazine, ivabradine, digoxin. Whereas this is not the case and the algorithm would benefit from clarification to reflect this. The positioning of CRT-P/D also appears to be after having tried all the 3rd/4th line medical options whereas the evidence base would support its use earlier in the pathway.	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
Royal Papworth Hospital NHS Foundation Trust	Short	5	3	We are concerned that this recommendation implies that management of left ventricular assist device or heart transplant patients should be within the domain of any specialist heart failure MDT. This is wrong. Both of these procedures are highly specialised. This patient group has life-long follow-up at their advanced heart failure centre for management of their left ventricular assist device or cardiac allograft.	Thank you for your comment. We agree and have amended the wording to clarify the specialist HF MDT would continue to manage the person's heart failure not the management of the interventional procedure.
St George's University Hospitals	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment The full guideline is lengthy because of the large scope and number of evidence reviews conducted, however there is a short version containing just the recommendations
St George's University Hospitals	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment. The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
St George's University Hospitals	Full	15	13	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
St George's University Hospitals	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					change the wording to 'renal function profile' to reflect this.
St George's University Hospitals	Full	103	3 (Algorithm)	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than "specialist clinical assessment and doppler echocardiography"	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at referral but could also be done in primary care. The algorithm has been updated to reflect this.
St George's University Hospitals	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from clinical trials. Such an approach would be consistent	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				with all other recent national[1] and international[2,3] heart failure guidelines. 7. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 8. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 9. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
St George's University Hospitals	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prognostic importance follow thereafter. This is very strange prioritisation.	
St George's University Hospitals	Full	217	2	**THIS COMMENT IS IDENTIFIED AS A PRIORITY** **Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include: ○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC)	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				algorithm displays this flow more appropriately. The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
St George's University Hospitals	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					to start with treatment for HF with reduced ejection fraction as this is a more logical order.
St George's University Hospitals	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
St George's University Hospitals	Short	10	17	Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
St George's University Hospitals	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
St George's University Hospitals	Short	10	26-29	The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				should be a section on contra-indicated medication and not simply calcium-channel blockers.	with reduced ejection fraction followed by the management for all types of heart failure.
St George's University Hospitals	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.
St George's University Hospitals	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict? We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical judgement should be used to consider applying this on an individual patient basis'.	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
St George's University Hospitals	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
St George's University Hospitals	Short	13	13-16	**THIS COMMENT IS IDENTIFIED AS A PRIORITY** Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines. The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example, does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias. The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				blockers around the country. Withdrawal of beta-blockade is unsafe for heart failure patients[8,9]. Whilst these studies are small they are biologically plausible. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely.	
St George's University Hospitals	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
St George's University Hospitals	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
St George's University Hospitals	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
St George's University Hospitals	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be added. This comment also applies to Main Document P199 Lines 8	monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
St George's University Hospitals	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
St George's University Hospitals	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
St George's University Hospitals	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be added. This comment also applies to Main Document P199 Lines 26	monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
St George's University Hospitals	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
St George's University Hospitals	Short	17	13-22	**THIS COMMENT IS IDENTIFIED AS A PRIORITY** (Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction (LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled,	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinical trials, of benefits to patients in both life expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely.	population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					The committee considered eGFR to be the most appropriate way to direct treatment.
St George's University Hospitals	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
St George's University Hospitals	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion is to give the correct amount of diuretics. In advanced heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing risk of becoming dehydrated, which can lead to	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the necessary information (ie measuring urea as well as creatinine and eGFR).	
St George's University Hospitals	Short	18	4-7	**THIS COMMENT IS IDENTIFIED AS A PRIORITY** (Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of renal physicians in patients showing "deterioration" in renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4. The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				deteriorating renal function, patients have better outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patients. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				doses of these medications. Advice on this is given in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014 Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure. https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
St George's University Hospitals	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read:	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	morbidity in patients with HFREF. It also noted that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
St George's University Hospitals	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
The Great Western Hospitals NHS Trust	Short	16	16	Sacubitril / Valsartan is listed as 3rd line rather than 2nd line and may reduce the use of this NICE approved medication. PARADIGM-HF trial inclusion criteria only required ACEI and BB use and did not require AIIA prescription. Only 54% were taking an AIIA. The trial demonstrates that symptomatic patients on sufficient ACEI should be changed to Sacubitril/ Valsartan irrespective of MRA use for both symptomatic and prognostic benefits. Sacubitril / Valsartan gives the same prognostic benefit over ACEI that ACEI did when compared against placebo so it is important that eligible patients receive this medication.	Thank you for your comment. The guidance for Sacubitril Valsartan from TA388 still holds and can be prescribed according to the guidance. When discussing the therapeutic treatment pathway the committee discussed that MRAs are currently much less costly than Sacubitril Valsartan and are also likely to be more cost effective. Therefore the committee considered that MRAs should be offered to patients in addition to BB and ACEi (if tolerated) prior to commencing treatment with sacubitril valsartan.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
UK Clinical Pharmacy Association	Full	Overall	General	This is a large document (515 pages) that is not very user friendly. Some of the most useful parts such as the treatment algorithm are hidden at the back. We would suggest reformatting to prioritise the recommendations on the pharmacological treatments that have a prognostic benefit and then follow this with the recommendations on other treatments such as calcium channel blockers, amiodarone, anticoagulants, inotropes, contraception and vaccinations Make sure terminology is consist throughout the document –for example spironolactone should always be mineralocorticoid antagonists not aldosterone antagonists	Thank you for your comment. The algorithm has been moved to an earlier section of the guideline. We consider the order of the pharmacological section to be logical and needs to slot into the existing recommendations from the 2010 guideline, but we have reviewed the short version and revised the order of the pharmacological in this document. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug.
UK Clinical Pharmacy Association	Full	114	11-19	Consider adding a specific statement about the need for abstinence in alcohol induced cardiomyopathy	Thank you for your comment. This is beyond the scope identified for review in this guideline but has been reviewed in NICE guidance on the physical complications of alcohol-use disorders (CG100).
UK Clinical Pharmacy Association	Full	114	21-28	The statements on salt and fluid are not clear as there is no definition of what 'dilutional' hyponatraemia is and what are considered high levels of water and salt intake. Should fluid and/or salt restriction also be considered in grossly fluid overloaded patients with normal sodium levels?	Thank you for your comment. The committee consider the wording of the recommendation allows for a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided. Dilutional hyponatraemia is a well-established concept in critical care medicine and endocrinology
UK Clinical Pharmacy Association	full	170	2	IV iron – No recommendation. We agree there is no evidence for mortality and hospital admission. However, there is some trial date on quality of life and hence its inclusion into ESC Heart failure guidelines. It could be included as an option for those patients on maximum tolerated treatment who meet criteria for iron deficiency for symptomatic benefit.	Thank you for your comment. The protocol on iron supplementation was agreed by the committee and quality of life was included as critical outcome. All the studies identified that met the inclusion criteria were included in the evidence review. The protocol provides further detail about the inclusion and exclusion criteria. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version. Following the methods set out in the NICE guidelines manual the committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation.
UK Clinical Pharmacy Association	Full	197	10-12	You mention to avoid verapamil, diltiazem, and short acting dihydropyridines but do not include other classes of medicines that are contra-indicated – e.g.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				NSAIDS, glitazones, anti-arrhythmics etc. Should a section be added that is more inclusive	therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
UK Clinical Pharmacy Association	Full	197	6-9	The advice on diuretic doses for HFpEF is very prescriptive. We would recommend that this is reworded to say that doses should be tailored to the fluid balance needs of the patient. Some patients will need much higher doses than 80mg. The message should be to use the minimum required dose rather than stating a specific dose range. This could be added as a starting dose if felt necessary. Titration of diuretic doses is relevant to all cause heart failure	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
UK Clinical Pharmacy Association	Full	198 198	7-9 28-30	Do not routinely offer a beta-blocker to threat HFrEF to people who have AF. The evidence for this recommendation was taken from sub-analysis of original studies to set out to determine this. This goes against all previous RCT evidence for BBs that did show a mortality improvement. Also since increasing the prescribing of these data from the National Heart Failure Audit has seen an improvement in mortality rates. Does this include all types of AF – for example what about the patient with paroxysmal AF who is in sinus rhythm for 95%+ of time? Does this apply to all beta-blockers?	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				We are concerned that this would be detrimental to patient care. What does 'manage the heart rate' mean <120bpm? < 100bpm? <80bpm?..... Heart rate should be checked after each dose increment of beta-blockers	
UK Clinical Pharmacy Association	Full	199	20-23	Should the use of eplerenone (as supported by the EPHUSUS trial EJHF 2009 11 1099-1105) be included or cross referenced to the relevant NICE guideline. This needs to be started early before full titration of ACE and BB to reflect the trial evidence of beneficial effects on cardiac remodelling	Thank you for your comment. The EPHESUS trial was excluded from this review as the population in the trial was those with heart failure post-acute myocardial infarction, which are no longer covered in the scope of the chronic heart failure guideline.
UK Clinical Pharmacy Association	Full	200	20-22	Sacubitril valsartan should have the same information from the NICE TA included in the document (as you have done for ivabradine.) It would be sensible to add practical how to initiate and monitor like you have for ACEI/ ARB etc	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have now been included in full.
UK Clinical Pharmacy Association	Full	201	7-18	The section on dosing and eGFR is confusing. There are 2 ranges of eGFR that give the same advice and a 3rd covering the same ranges to consider lower doses and slower titration. Considering eGFR is an estimate based on a number of factors is this the most appropriate way to direct treatment. Renal physicians would use ACEI/ARBs for	Thank you for your comment. The committee have revisited the evidence and wording of the recommendations and have updated the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				their renal protective properties and monitor the effects on renal function. This seems more sensible. If Heart failure teams liaised with renal consultants for all patients with an eGFR < 30 they would be inundated with heart failure patients. We agree that patients with reduced kidney function should have more careful titration and monitoring but that it should be evaluated against this monitoring and treatment effect. This seems to give a 'get out of jail' card for not titrating to the maximum tolerated doses with careful monitoring We are concerned that this will be detrimental to patient care with patients not receiving appropriate treatment.	recommendations to make them clearer. The updated recommendations are: For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m^2 or above: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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UK Clinical Pharmacy Association	Full	217	Figure 5	The therapeutic algorithm could be clearer as this will be the 'take home' message for many clinicians. For 1st line therapies – consider adding 'titrated to target or maximum tolerated doses' Beta-blockers and AF as per comment 6 CKD recommendations as per comment 9 2nd line MRA – state NYHA class II-IV rather than 'mildly symptomatic' 3rd line – such as sacubitril/valsartan , CRT-P.CRT-D should be recommendations and appear higher in the algorithm than digoxin –hydralazine / digoxin / ivabradine	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
UK Clinical Pharmacy Association	Full	413	30-36	Part of the role of the community team is to optimise treatment as part of the heart failure service. Is this suggestion that this should all be done in a secondary care setting? Community teams currently optimise treatment and manage newly diagnosed patients. This should continue. The service should be delivered where it is most accessible and appropriate for the patient's needs.	Thank you for your comment. No, the HF MDT would manage the person's care in collaboration with the primary care team. Configuration of services will vary but once discharged into the community the primary care team would manage the patient and ensure there are effective communication links between the different care settings and clinical services involved in a person's care to facilitate re-access to specialist HF services as required.
University Hospital Southampton NHS Trust	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment The full guideline is lengthy because of the large scope and number of evidence reviews conducted; however there is a short version containing just the recommendations.
University Hospital Southampton NHS Trust	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment. The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Full	14-25	General	On the full guideline there is a summary of all key recommendations. These will need to be changed based upon the incorporation of stakeholder comments.	Thank you for your comment. The summary has been updated to reflect any changes made to recommendations.
University Hospital Southampton NHS Trust	Full	15	13	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospital Southampton NHS Trust	Full	23	36-42	We are concerned that 3 out of 6 research recommendations are about NT-proBNP – does this suggest the importance of this subject matter, or the research interests of the panel? Surely there are greater heart failure research questions requiring to be answered. Can these 3 recommendations on NT-proBNP be amalgamated into one (with stems)?	Thank you for your comment. The committee flagged a number of areas requiring further research throughout guideline development process. However, upon further discussion realised that many of these areas already had trials currently underway or that were planned to start in the near future. Therefore these areas were not prioritised as research recommendations.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Full	23	General	With the important findings of the DANISH study, which questioned the importance of defibrillator therapy in patients with heart failure of a non-ischaemic aetiology, we would like to suggest an additional research recommendation of: "The comparison of CRT-pacemakers with CRT-defibrillators in a prospective study in heart failure patients of any aetiology", assessing the efficacy (non-inferiority of CRT-pacemakers) and cost-effectiveness in a UK population. This is a particularly important question given the increasing numbers of these high value devices being implanted across the country.	Thank you for your comment. Research recommendations can only be made for topics in which the guideline has searched for the evidence and has established a gap in available evidence. The review question addressed in this guideline was specifically on the criteria to determine when to discuss deactivation of a defibrillator, and we are therefore not able to make a research recommendation as you suggest.
University Hospital Southampton NHS Trust	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospital	Full	103	3	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Southampton NHS Trust			(Algorithm)	"specialist clinical assessment and doppler echocardiography"	referral but could also be done in primary care. The algorithm has been updated to reflect this.
University Hospital Southampton NHS Trust	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from clinical trials. Such an approach would be consistent with all other recent national[1] and international[2,3] heart failure guidelines. 10. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 11. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 12. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
University Hospital Southampton NHS Trust	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with prognostic importance follow thereafter. This is very strange prioritisation.	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Full	217	2	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** **Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include: ○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm displays this flow more appropriately.	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.
University Hospital Southampton NHS Trust	Full	228	27	(Recommendation 7.1.6) We would recommend removal of 'devices' from the statement, 'unless their condition is unstable or they have a condition or device that precludes such a programme.' This may reduce the number of patients with implantable devices being offered rehabilitation unnecessarily.	Thank you for your comment. The recommendation has been amended to remove any reference to devices.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Full	377	10	The advice on writing a plan is clear and an important addition to the guideline.	Thank you for your comment.
University Hospital Southampton NHS Trust	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised to start with treatment for HF with reduced ejection fraction as this is a more logical order.
University Hospital Southampton NHS Trust	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
University Hospital Southampton NHS Trust	Short	5	27-29	There are also instances where the specialist heart failure MDT may need to continue to manage the patients, even after they have been stabilised and management has been optimised. This is in particular cases such as cardiac transplantation and LVADS. This section could be changed to include: There may be instances where the specialist heart failure team need to continue to manage heart failure patients such as post cardiac transplant and after implantation of Ventricular Assist Devices	Thank you for your comment. A recommendation has been made stating that the specialist HF MDT should continue to manage patients after an interventional procedure. Collaboration between primary care teams and the specialist HF MDT should ensure transfer of care is made at the appropriate time.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Short	7	1-29	We agree that NTproBNP is the ideal blood test to assist in the diagnosis of heart failure and we should encourage localities to make it readily available to GPs. However, many localities already have access to BNP (included in previous guidelines). Access to and the use of any natriuretic peptide test to assist in making the timely diagnosis of heart failure is preferable to no availability. As such it would be wrong for this guideline not to mention BNP and the relevant cut-offs.	Thank you for your comment. The committee considered that a number of factors would favour the use of NT-proBNP as outlined in the LETR. The committee was unable to locate data for BNP equivalent concentrations given biological variances in the recent evidence base as this was not measured simultaneously in the studies used to define this recommendation.
University Hospital Southampton NHS Trust	Short	7	7	We agree with NICE that the cut-offs for BNP and NT Pro-BNP should remain as described.	Thank you for your comment.
University Hospital Southampton NHS Trust	Short	9	16-26	We find the advice on giving information to people with heart failure extremely helpful and considered.	Thank you for your comment.
University Hospital Southampton NHS Trust	Short	10	1-11	Advice on first consultation is clear and useful.	Thank you for your comment.
University Hospital Southampton NHS Trust	Short	10	17	We like this wording (diuretics). Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital Southampton NHS Trust	Short	10	26-29	Calcium channel blockers. (Also full Page 197 Lines 10-12 'Calcium-channel blockers. Avoid verapamil, diltiazem and short-acting dihydropyridine agents in people who have heart failure with reduced ejection fraction. [2003, amended 2018]'). Why have you singled out one class of contraindicated medications only? What about NSAIDs, glitazones, anti-arrhythmics, moxonidine etc? The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This should be a section on contra-indicated medication and not simply calcium-channel blockers.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital Southampton NHS Trust	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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University Hospital Southampton NHS Trust	Short	11	1-8	Amiodarone. This would be better placed after treating heart failure with reduced ejection fraction section (section 1.5). The wording is appropriate.	Thank you for your comment. This has been moved to after treating heart failure with reduced ejection fraction.
University Hospital Southampton NHS Trust	Short	11	9-16	Anticoagulants. The wording is fine but as per comment directly above, this would sit better in a separate section after disease modifying drugs with prognostic benefit.	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF with reduced ejection fraction followed by the management for all types of heart failure.
University Hospital Southampton NHS Trust	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict? We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				judgement should be used to consider applying this on an individual patient basis'.	
University Hospital Southampton NHS Trust	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital Southampton NHS Trust	Short	13	13-16	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines. The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example,	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias. The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-blockers around the country. Withdrawal of beta-blockade is unsafe for heart failure patients[8,9]. Whilst these studies are small they are biologically plausible. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely. These comments also applies to Main Document P198 Lines 7-9 17. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 18. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 19. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 20. Kotecha D, et al. Efficacy of beta blockers in patients with heart failure plus atrial fibrillation: an individual-patient data meta-analysis. Lancet. 2014; 384(9961):2235-43 21. Swedberg K, *et al*. Prognostic relevance of atrial fibrillation in patients with chronic heart failure on long-term treatment with beta-blockers: results from COMET. *Eur Heart J* 2005;26:1303–1308 22. Joglar, J.A. et al. Effect of carvedilol on survival and hemodynamics in patients with atrial fibrillation and left ventricular dysfunction: Retrospective analysis of the US Carvedilol Heart Failure Trials Program. *Am Heart J;* 142 (3): 498-501 23. Cadrin-Tourigny J, *et al*. Decreased Mortality With Beta-Blockers in Patients With Heart Failure and Coexisting Atrial Fibrillation. *JACC: Heart Failure* 2017, 579; DOI: 10.1016/j.jchf.2016.10.015 24. Waagstein F et al. Long-term betablockade in dilated cardiomyopathy; effects of short-term	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and long-term metoprolol followed by withdrawal and re-administration of metoprolol. Circulation 1989;80:551-63 Morimoto et al. Can β-blocker therapy be withdrawn from patients with dilated cardiomyopathy? Am Heart J 1999;137:456-9	
University Hospital Southampton NHS Trust	Short	13	2	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains the importance of disease modifying medications on mortality and morbidity in HF-REF. Such a message is needed to reinforce the importance of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. Discussion on the importance of treatments is included in the full guideline.
University Hospital Southampton NHS Trust	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospital	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped	Thank you for your suggestion. The committee do not consider it necessary to apply this level of

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Southampton NHS Trust				due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
University Hospital Southampton NHS Trust	Short	14	17	We feel that the example of 'dry cough' should be added, as essentially the side effect profile of ACEI and ARB are similar bar dry cough. This comment also applies to Main Document P199 Lines 5	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital Southampton NHS Trust	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospital Southampton NHS Trust	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 8	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
University Hospital Southampton NHS Trust	Short	14	3-12	We think these recommendations are good and we fully agree with them	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital Southampton NHS Trust	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
University Hospital Southampton NHS Trust	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospital Southampton NHS Trust	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 26	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
University Hospital Southampton NHS Trust	Short	15	2-4	We feel that this recommendation does not fit well at this stage (i.e. the prioritisation and it's stage in clinical reasoning) and that this recommendation should be moved to a later place in the document and amalgamated with the other statement on hydralazine-ISDN (i.e. Page 16 Line 20-24). Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines. This comment also applies to Main Document P199 Lines 15-18 3. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website **https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.** The ordering of the pharmacological section has been reviewed and revised to start with treatment for HF with reduced ejection fraction followed by

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2016 Available at http://www.sign.ac.uk/assets/sign147.pdf Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m	the management of all types of heart failure as this is a more logical order.
University Hospital Southampton NHS Trust	Short	16	16-19	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)': In an area of such clinical importance (i.e. mortality benefit) and change from previous NICE heart failure guidelines, why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388[1] should be replicated verbatim in this guidance to make the document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations have been included in full on publication of the guideline. As we are incorporating the recommendations made within the TA and not reviewing the evidence as part of the update of this guideline we are unable to advise on the monitoring of this medication.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, the Board of the BSH would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed. This comment also applies to Main Document P200 Lines 20-22 National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
University Hospital Southampton NHS Trust	Short	16	20-24	'Considerations' for both indications for hydralazine-ISDN should be displayed at this stage: - Hydralazine and isosorbide dinitrate may be considered in symptomatic patients with HFREF who can tolerate neither an ACEI nor an ARB (or they are contra-indicated) to reduce the risk of death. - Hydralazine and isosorbide dinitrate should be considered in black patients with LVEF≤35% or with an LVEF <45% combined with a dilated LV in NYHA Class	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				III–IV despite treatment with an ACEI, a beta-blocker and an MRA to reduce the risk of HF hospitalization and death This comment also applies to Main Document P200 Lines 24-27	
University Hospital Southampton NHS Trust	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
University Hospital Southampton NHS Trust	Short	17	1-3	Digoxin is recommended for worsening or severe heart failure with reduced ejection fraction despite first and second line treatment for heart failure: We feel that this should be re-worded to 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in…..' 'Severe heart failure' is also ambiguous (i.e. Severe LVEF? Severe symptoms?) and should be changed to 'patients with symptomatic heart failure with reduced ejection fraction' Digoxin is also only indicated in such patients with sinus rhythm. The final wording should be 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in patients with symptomatic heart failure due to reduced ejection fraction in sinus rhythm'	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines and the evidence base[3]. This comment also applies to Main Document P200 Lines 31-33 5. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 6. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1997;336:525–533	
University Hospital Southampton NHS Trust	Short	17	13-22	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction (LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled, clinical trials, of benefits to patients in both life expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely. References 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m	agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				3. Yancy C, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509	reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.
University Hospital Southampton NHS Trust	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
University Hospital Southampton NHS Trust	Short	18	1-3	(Section 6.1.3) The Board of the British Society for Heart Failure agrees with this recommendation	Thank you for your comment.
University Hospital Southampton NHS Trust	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion is to give the correct amount of diuretics. In advanced	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing risk of becoming dehydrated, which can lead to hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the necessary information (ie measuring urea as well as creatinine and eGFR).	kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospital Southampton NHS Trust	Short	18	4-7	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of renal physicians in patients showing "deterioration" in	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of deteriorating renal function, patients have better outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patients. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in	The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the doses of these medications. Advice on this is given in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014 Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
University Hospital Southampton NHS Trust	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read: 'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
University Hospital Southampton NHS Trust	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospital	Short	19	26	Section 1.8.3. Bullet point 2. It is unclear what is meant by the term 'partially deactivate'. The tachycardia treatment functions of a defibrillator are	Thank you for your comment. The committee agree the term is unclear and have revised this to remove fully and partially and have removed

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Southampton NHS Trust				either on or off. A reader might think the authors are advocating turning off ICD shocks but leaving on anti-tachycardia pacing – this is generally inadvisable because anti-tachycardia pacing may be pro-arrhythmic. If the authors are referring to deactivation of tachycardia treatment function of CRT-D devices, then this should be more clearly worded.	reference to potential harms of unnecessary shocks.
University Hospital Southampton NHS Trust	Short	19	29	Section 1.8.3. Bullet point 3. Unnecessary shocks is not a recognised term. One assumes that the authors are referring to appropriate shocks that occur in the minutes, hours or days before an expected death in a patient with heart failure. These might be better described as 'futile' shocks but this may only be apparent in retrospect.	Thank you for your comment. The committee agree this term is unhelpful and have removed this.
University Hospital Southampton NHS Trust	Short	20	26	Section 1.10.1. This statement may be mis-interpreted. It only applies to patients with advanced heart failure who do not have hypoxaemia. As discussed in the full version, there is clear guidance from the British Thoracic Society that home oxygen should be offered to patients with advanced heart failure who have symptoms and a low resting pO2.	Thank you for your comment. We think the wording of the recommendation is clear. Whilst the Committee acknowledged the guidance made by the British Thoracic society, they made the recommendation based on the evidence reviewed for the guideline which did not demonstrate a benefit for the key pre-specified outcomes. However the committee did recognise there may be other comorbid conditions where people may benefit from oxygen therapy and this has been stated in the recommendation.
University Hospital Southampton NHS Trust	Short	20	5	Section 1.8.4. There are two additional time points where the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure should be reviewed	Thank you for your comment. The focus of the review undertaken was specifically on discussing deactivation of ICDs with patients. Decisions

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1. After any appropriate or inappropriate ICD therapy 2. Before any planned replacement of the ICD pulse generator	around the management of ICDs is outside the scope of this guideline.
University Hospital Southampton NHS Trust	Short	21	1	Section 1.10.2. It would be useful for the reader to include positive guidance about how to decide which patients should be offered referral to palliative care services.	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
University Hospital Southampton NHS Trust	Short	21	10	Section 1.10.5. The NICE guideline does not specify that the patient must be in the last 2-3 days of life. We would suggest that the wording 'last 2-3 days of life' is replaced with 'last days of life' as per the NICE guideline	Thank you for your suggestion, however the guideline states it 'covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life'.
University Hospital Southampton NHS Trust	Short	21	3	Section 1.10.3. This section should be expanded to include clinical triggers for consideration of a palliative care referral, such as , 1. More than 3 unplanned hospital admissions in the last 12 months 2. Important therapies are being withdrawn in the face of worsening heart failure and renal function	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
University Hospital	Short	25	14-15	The statement "Intravenous and subcutaneous diuretics need to be administered by nursing or healthcare staff, whereas oral formulations do not" is	Thank you for your comment and this information. We have updated this statement to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Southampton NHS Trust				not true in that a self-adhesive subcutaneous pump has been developed to be self-administered by patients.	
University Hospital Southampton NHS Trust	Short	27	3	We are concerned about the research question "Risk tools for predicting **non-sudden** death in heart failure". BNP/NT-proBNP are excellent markers of pump failure death. Predicting sudden death is far more of a challenge, and relevant when considering who to consider for expensive device-based therapies. Only one study found BNP to be predictive of sudden death (Berger *et al.* Circulation 2002;105:2392-7), a finding that has not been replicated. We would suggest that the question should then be "Risk tools for predicting **sudden and** non-sudden death in heart failure'.	Thank you for your comment. The question addressed by the guideline was to determine which are the most accurate prognostic risk tools at predicting patient mortality in the short term, to support decisions about involvement of palliative care services and the use of palliative care processes. The guideline did not consider tools to predict sudden death and therefore cannot widen the question.
University Hospitals of Leicester	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment The full guideline is lengthy because of the large scope and number of evidence reviews conducted, however there is a short version containing just the recommendations
University Hospitals of Leicester	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment. The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug
University Hospitals of Leicester	Full	14-25	general	On the full guideline there is a summary of all key recommendations. These will need to be changed based upon the incorporation of stakeholder comments.	Thank you for your comment. The summary has been updated to reflect any changes made to recommendations.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Full	15	13	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospitals of Leicester	Full	23	36-42	We are concerned that 3 out of 6 research recommendations are about NT-proBNP – does this suggest the importance of this subject matter, or the research interests of the panel? Surely there are greater heart failure research questions requiring to be answered. Can these 3 recommendations on NT-proBNP be amalgamated into one (with stems)?	Thank you for your comment. The committee flagged a number of areas requiring further research throughout guideline development process. However, upon further discussion realised that many of these areas already had trials currently underway or that were planned to start in the near future. Therefore these areas were not prioritised as research recommendations.
University Hospitals of Leicester	Full	23	general	With the important findings of the DANISH study, which questioned the importance of defibrillator therapy in patients with heart failure of a non-ischaemic aetiology, we would like to suggest an additional research recommendation of: "The comparison of CRT-	Thank you for your comment. Research recommendations can only be made for topics in which the guideline has searched for the evidence and has established a gap in available evidence. The review question addressed in this

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				pacemakers with CRT-defibrillators in a prospective study in heart failure patients of any aetiology", assessing the efficacy (non-inferiority of CRT-pacemakers) and cost-effectiveness in a UK population. This is a particularly important question given the increasing numbers of these high value devices being implanted across the country.	guideline was specifically on the criteria to determine when to discuss deactivation of a defibrillator, and we are therefore not able to make a research recommendation as you suggest.
University Hospitals of Leicester	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospitals of Leicester	Full	103	3 (Algorithm)	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than "specialist clinical assessment and doppler echocardiography"	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at referral but could also be done in primary care. The algorithm has been updated to reflect this.
University Hospitals of Leicester	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines,	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from clinical trials. Such an approach would be consistent with all other recent national[1] and international[2,3] heart failure guidelines. 13. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 14. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and	the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				chronic heart failure. *Eur. Heart J.* 2016;37(27):2129-2200m 15. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
University Hospitals of Leicester	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with prognostic importance follow thereafter. This is very strange prioritisation.	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.
University Hospitals of Leicester	Full	217	2	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** **Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include:	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm displays this flow more appropriately. The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of	This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
University Hospitals of Leicester	Full	228	27	(Recommendation 7.1.6) We would recommend removal of 'devices' from the statement, 'unless their condition is unstable or they have a condition or device that precludes such a programme.' This may reduce the number of patients with implantable devices being offered rehabilitation unnecessarily.	Thank you for your comment. The recommendation has been amended to remove any reference to devices.
University Hospitals of Leicester	Full	377	10	The advice on writing a plan is clear and an important addition to the guideline.	Thank you for your comment.
University Hospitals of Leicester	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					to start with treatment for HF with reduced ejection fraction as this is a more logical order.
University Hospitals of Leicester	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
University Hospitals of Leicester	Short	5	27-29	There are also instances where the specialist heart failure MDT may need to continue to manage the patients, even after they have been stabilised and management has been optimised. This is in particular cases such as cardiac transplantation and LVADS. This section could be changed to include: There may be instances where the specialist heart failure team need to continue to manage heart failure patients such as post cardiac transplant and after implantation of Ventricular Assist Devices	Thank you for your comment. A recommendation has been made stating that the specialist HF MDT should continue to manage patients after an interventional procedure. Collaboration between primary care teams and the specialist HF MDT should ensure transfer of care is made at the appropriate time.
University Hospitals of Leicester	Short	7	1-29	We agree that NTproBNP is the ideal blood test to assist in the diagnosis of heart failure and we should encourage localities to make it readily available to GPs. However, many localities already have access to BNP (included in previous guidelines). Access to and the use of any natriuretic peptide test to assist in making the timely diagnosis of heart failure is preferable to no availability. As such it would be wrong for this guideline not to mention BNP and the relevant cut-offs.	Thank you for your comment. The committee considered that a number of factors would favour the use of NT-proBNP as outlined in the LETR. The committee was unable to locate data for BNP equivalent concentrations given biological variances in the recent evidence base as this was not measured simultaneously in the studies used to define this recommendation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	7	7	We agree with NICE that the cut-offs for BNP and NT Pro-BNP should remain as described.	Thank you for your comment.
University Hospitals of Leicester	Short	9	16-26	We find the advice on giving information to people with heart failure extremely helpful and considered.	Thank you for your comment.
University Hospitals of Leicester	Short	10	1-11	Advice on first consultation is clear and useful.	Thank you for your comment.
University Hospitals of Leicester	Short	10	17	We like this wording (diuretics). Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospitals of Leicester	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	10	26-29	Calcium channel blockers. (Also full Page 197 Lines 10-12 'Calcium-channel blockers. Avoid verapamil, diltiazem and short-acting dihydropyridine agents in people who have heart failure with reduced ejection fraction. [2003, amended 2018]'). Why have you singled out one class of contraindicated medications only? What about NSAIDs, glitazones, anti-arrhythmics, moxonidine etc? The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This should be a section on contra-indicated medication and not simply calcium-channel blockers.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospitals of Leicester	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.
University Hospitals of Leicester	Short	11	1-8	Amiodarone. This would be better placed after treating heart failure with reduced ejection fraction section (section 1.5). The wording is appropriate.	Thank you for your comment. This has been moved to after treating heart failure with reduced ejection fraction.
University Hospitals of Leicester	Short	11	9-16	Anticoagulants. The wording is fine but as per comment directly above, this would sit better in a separate section after disease modifying drugs with prognostic benefit.	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF with reduced ejection fraction followed by the management for all types of heart failure.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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University Hospitals of Leicester	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict? We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical judgement should be used to consider applying this on an individual patient basis'.	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.
University Hospitals of Leicester	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	13	13-16	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines. The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example, does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias. The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-blockers around the country. Withdrawal of beta-blockade is unsafe for heart failure patients[8,9]. Whilst these studies are small they are biologically plausible. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
				The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely. These comments also applies to Main Document P198 Lines 7-9 25. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 26. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 27. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 28. Kotecha D, et al. Efficacy of beta blockers in patients with heart failure plus atrial fibrillation:	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				an individual-patient data meta-analysis. Lancet. 2014; 384(9961):2235-43 29. Swedberg K, *et al*. Prognostic relevance of atrial fibrillation in patients with chronic heart failure on long-term treatment with beta-blockers: results from COMET. *Eur Heart J* 2005;26:1303–1308 30. Joglar, J.A. et al. Effect of carvedilol on survival and hemodynamics in patients with atrial fibrillation and left ventricular dysfunction: Retrospective analysis of the US Carvedilol Heart Failure Trials Program. *Am Heart J;* 142 (3): 498-501 31. Cadrin-Tourigny J, *et al*. Decreased Mortality With Beta-Blockers in Patients With Heart Failure and Coexisting Atrial Fibrillation. *JACC: Heart Failure* 2017, 579; DOI: 10.1016/j.jchf.2016.10.015 32. Waagstein F et al. Long-term betablockade in dilated cardiomyopathy; effects of short-term and long-term metoprolol followed by withdrawal and re-administration of metoprolol. Circulation 1989;80:551-63 Morimoto et al. Can β-blocker therapy be withdrawn from patients with dilated cardiomyopathy? Am Heart J 1999;137:456-9	
University Hospitals of Leicester	Short	13	2	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains the importance of disease	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				modifying medications on mortality and morbidity in HF-REF. Such a message is needed to reinforce the importance of treatment.	additional text to support recommendations. Discussion on the importance of treatments is included in the full guideline.
University Hospitals of Leicester	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospitals of Leicester	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
University Hospitals of Leicester	Short	14	17	We feel that the example of 'dry cough' should be added, as essentially the side effect profile of ACEI and	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				ARB are similar bar dry cough. This comment also applies to Main Document P199 Lines 5	therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospitals of Leicester	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
University Hospitals of Leicester	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 8	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	14	3-12	We think these recommendations are good and we fully agree with them	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospitals of Leicester	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
University Hospitals of Leicester	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 26	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
University Hospitals of Leicester	Short	15	2-4	We feel that this recommendation does not fit well at this stage (i.e. the prioritisation and it's stage in clinical reasoning) and that this recommendation should be moved to a later place in the document and amalgamated with the other statement on hydralazine-ISDN (i.e. Page 16 Line 20-24). Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines. This comment also applies to Main Document P199 Lines 15-18 4. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope. The ordering of the pharmacological section has been reviewed and revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.
University Hospitals of Leicester	Short	16	16-19	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD**	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)': In an area of such clinical importance (i.e. mortality benefit) and change from previous NICE heart failure guidelines, why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388[1] should be replicated verbatim in this guidance to make the document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, the Board of the BSH would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a	the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations has been included in full on publication of the guideline. As we are incorporating the recommendations made within the TA and not reviewing the evidence as part of the update of this guideline we are unable to advise on the monitoring of this medication.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed. This comment also applies to Main Document P200 Lines 20-22 National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
University Hospitals of Leicester	Short	16	20-24	'Considerations' for both indications for hydralazine-ISDN should be displayed at this stage: - Hydralazine and isosorbide dinitrate may be considered in symptomatic patients with HFREF who can tolerate neither an ACEI nor an ARB (or they are contra-indicated) to reduce the risk of death. - Hydralazine and isosorbide dinitrate should be considered in black patients with LVEF≤35% or with an LVEF <45% combined with a dilated LV in NYHA Class III–IV despite treatment with an ACEI, a beta-blocker and an MRA to reduce the risk of HF hospitalization and death This comment also applies to Main Document P200 Lines 24-27	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
University Hospitals of Leicester	Short	17	1-3	Digoxin is recommended for worsening or severe heart failure with reduced ejection fraction despite first and second line treatment for heart failure: We feel that this should be re-worded to 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in…..' 'Severe heart failure' is also ambiguous (i.e. Severe LVEF? Severe symptoms?) and should be changed to 'patients with symptomatic heart failure with reduced ejection fraction' Digoxin is also only indicated in such patients with sinus rhythm. The final wording should be 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in patients with symptomatic heart failure due to reduced ejection fraction in sinus rhythm' Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines and the evidence base[3]. This comment also applies to Main Document P200 Lines 31-33	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				7. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 8. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1997;336:525–533	
University Hospitals of Leicester	Short	17	13-22	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction (LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled, clinical trials, of benefits to patients in both life	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely. References 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m 3. Yancy C, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509	generally be applied, subject to the consideration of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
University Hospitals of Leicester	Short	18	1-3	(Section 6.1.3) The Board of the British Society for Heart Failure agrees with this recommendation	Thank you for your comment.
University Hospitals of Leicester	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion is to give the correct amount of diuretics. In advanced heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				risk of becoming dehydrated, which can lead to hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the necessary information (ie measuring urea as well as creatinine and eGFR).	
University Hospitals of Leicester	Short	18	4-7	**THIS COMMENT IS IDENTIFIED AS A PRIORITY BY THE BSH BOARD** (Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of renal physicians in patients showing "deterioration" in renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4. The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of deteriorating renal function, patients have better outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patients. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the doses of these medications. Advice on this is given in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014 Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure. https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
University Hospitals of Leicester	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read: 'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
University Hospitals of Leicester	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
University Hospitals of Leicester	Short	19	26	Section 1.8.3. Bullet point 2. It is unclear what is meant by the term 'partially deactivate'. The tachycardia treatment functions of a defibrillator are either on or off. A reader might think the authors are advocating turning off ICD shocks but leaving on anti-tachycardia pacing – this is generally inadvisable because anti-tachycardia pacing may be pro-arrhythmic. If the authors are referring to deactivation of tachycardia treatment function of CRT-D devices, then this should be more clearly worded.	Thank you for your comment. The committee agree the term is unclear and have revised this to remove fully and partially and have removed reference to potential harms of unnecessary shocks.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester	Short	19	29	Section 1.8.3. Bullet point 3. Unnecessary shocks is not a recognised term. One assumes that the authors are referring to appropriate shocks that occur in the minutes, hours or days before an expected death in a patient with heart failure. These might be better described as 'futile' shocks but this may only be apparent in retrospect.	Thank you for your comment. The committee agree this term is unhelpful and have removed this.
University Hospitals of Leicester	Short	20	26	Section 1.10.1. This statement may be mis-interpreted. It only applies to patients with advanced heart failure who do not have hypoxaemia. As discussed in the full version, there is clear guidance from the British Thoracic Society that home oxygen should be offered to patients with advanced heart failure who have symptoms and a low resting pO2.	Thank you for your comment. We think the wording of the recommendation is clear. Whilst the Committee acknowledged the guidance made by the British Thoracic society, they made the recommendation based on the evidence reviewed for the guideline which did not demonstrate a benefit for the key pre-specified outcomes. However the committee did recognise there may be other comorbid conditions where people may benefit from oxygen therapy and this has been stated in the recommendation.
University Hospitals of Leicester	Short	20	5	Section 1.8.4. There are two additional time points where the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure should be reviewed 1. After any appropriate or inappropriate ICD therapy 2. Before any planned replacement of the ICD pulse generator	Thank you for your comment. The focus of the review undertaken was specifically on discussing deactivation of ICDs with patients. Decisions around the management of ICDs is outside the scope of this guideline.
University Hospitals of Leicester	Short	21	1	Section 1.10.2. It would be useful for the reader to include positive guidance about how to decide which patients should be offered referral to palliative care services.	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
University Hospitals of Leicester	Short	21	10	Section 1.10.5. The NICE guideline does not specify that the patient must be in the last 2-3 days of life. We would suggest that the wording 'last 2-3 days of life' is replaced with 'last days of life' as per the NICE guideline	Thank you for your suggestion, however the guideline states it 'covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life'.
University Hospitals of Leicester	Short	21	3	Section 1.10.3. This section should be expanded to include clinical triggers for consideration of a palliative care referral, such as , 1. More than 3 unplanned hospital admissions in the last 12 months 2. Important therapies are being withdrawn in the face of worsening heart failure and renal function	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
University Hospitals of Leicester	Short	25	14-15	The statement "Intravenous and subcutaneous diuretics need to be administered by nursing or healthcare staff, whereas oral formulations do not" is not true in that a self-adhesive subcutaneous pump has been developed to be self-administered by patients.	Thank you for your comment and this information. We have updated this statement to reflect this.
University Hospitals of Leicester	Short	27	3	We are concerned about the research question "Risk tools for predicting **non-sudden** death in heart failure". BNP/NT-proBNP are excellent markers of pump failure death. Predicting sudden death is far more of a	Thank you for your comment. The question addressed by the guideline was to determine which are the most accurate prognostic risk tools at predicting patient mortality in the short term, to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				challenge, and relevant when considering who to consider for expensive device-based therapies. Only one study found BNP to be predictive of sudden death (Berger *et al.* Circulation 2002;105:2392-7), a finding that has not been replicated. We would suggest that the question should then be "Risk tools for predicting **sudden and** non-sudden death in heart failure'.	support decisions about involvement of palliative care services and the use of palliative care processes. The guideline did not consider tools to predict sudden death and therefore cannot widen the question.
Vifor Pharma UK Limited	Full	General	General	Vifor Pharma UK Limited welcomes the update to the "Chronic Heart Failure: Management of heart failure in adults in primary and secondary care in adults" Guideline and believe that this offers an excellent opportunity to embed best practice into routine practice.	Thank you for your comment.
Vifor Pharma UK Limited	Full	General	General	We are concerned that the conclusions leading to 'No recommendation' for the treatment of iron deficiency in patients with heart failure are out-of-keeping with current clinical opinion and practice, based on an incomplete assessment of the clinical trial evidence. Treatment of this common comorbidity is supported by clinical trial evidence, other clinical guidelines and by the larger clinical community who are starting to do this in routine practice. We would request the panel to reconsider their conclusions, based on the following key points: 1. There is inconsistency in waiting for more evidence on mortality before making a recommendation when high-quality evidence exists for benefits of intravenous	Thank you for your comment. The protocol on iron supplementation was agreed by the committee and all the studies that met the inclusion criteria were included in the evidence review. The protocol provides further detail about the inclusion and exclusion criteria. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version. Following the methods set out in the NICE guidelines manual the committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				iron treatment on quality of life, judged to be a critical decision-making factor by the panel, thus supporting a recommendation in these areas. 2. Other independent guideline committees assessing the same evidence have concluded differently on the clinical effectiveness of intravenous iron treatment in this patient group. 3. Meta-analyses support the conclusion of these other guidelines, showing that intravenous iron can improve important patient outcomes, including symptoms, exercise tolerance, quality of life and risk of hospitalization. We will address these points further in response to specific comments from the draft guidance in our detailed response below. However, in summary, we consider that 'No recommendation' misjudges the clinical trial evidence and wider clinical opinion. Based on: • The original review question • Existing clinical data • Existing clinical guidelines • Emerging clinical practice	the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee have taken into account your comments but are not convinced that the high (and low quality) evidence on quality of life alone was enough to support a recommendation when taking into account the evidence on the other outcomes. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and in recognition of the evidence to support the use of intravenous iron to improve quality of life, symptoms and exercise capacity in people with iron deficiency and chronic heart failure, Vifor Pharma propose that the current recommendation in the draft guideline be amended to: *"Consider intravenous iron in patients with symptomatic chronic heart failure with reduced ejection fraction, NYHA class II or NYHA class III, and iron deficiency (serum ferritin <100 µg/L, or ferritin <300 µg/L if transferrin saturation <20%), in order to alleviate symptoms and improve exercise capacity and quality of life."*	
Vifor Pharma UK Limited	Full	General	General	We agree with the need for additional evidence on outcomes, particularly mortality, for patients with heart failure when iron deficiency is addressed with different forms of iron replacement. We are pleased that there are large, ongoing trials addressing this question and look forward to future results. However, we believe that there is sufficient evidence already in existence to make some recommendation on the treatment of iron deficiency in patients with heart failure, particularly given the number of such patients who will be discovered through testing in specialist care, as the Committee recognises. A number of independent bodies have assessed that there is	Thank you for your comment. The committee agree there is need for additional evidence and have outlined this in the linking evidence to recommendations section. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation. Following the methods set out in the NICE guidelines manual the committee made their decision based on the best evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				evidence of improvements in patients function, symptoms and quality of life when iron deficiency is treated with intravenous iron in patients who are symptomatic with HFrEF and the trial data do not show adverse effects of doing so. Whilst there is no prospective mortality data, clinicians need and want to balance years of life remaining with the patient's quality of life during their remaining years.	committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee have taken into account your comments but are not convinced that the high (and low quality) evidence on quality of life alone was enough to support a recommendation when taking into account the evidence on the other outcomes. NICE guidance does not override the responsibility of the clinician to make decisions appropriate to the individual patient. The committee noted that it is important that any treatment decision is made with the person.
Vifor Pharma UK Limited	Full	General	General	We consider that the assessment of the clinical evidence is not robust, in particular the failure to consider improvements in NYHA class from the two largest randomised controlled trials of intravenous iron included in the evidence review. This leads to the inaccurate conclusion of no clinical effect of intravenous iron and fails to recognise the clinical benefit treatment has on this outcome, as recognised in a published meta-analysis of the same evidence. The Committee conclude that there is a) evidence of clinically important benefits on critical and important decision-making factors and b) cost-effectiveness of intravenous iron with a dosing regimen based on CONFIRM-HF over a 12 month period. This	Thank you for your comment This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version. Following the methods set out in the NICE guidelines manual the committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee have taken into account your comments but are not

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				conclusion would be even stronger if the effect on NYHA class was properly considered and, overall, makes the conclusion that clinical and cost-effectiveness of intravenous iron has not been demonstrated such that a recommendation cannot be made illogical. The suggestion to wait for further evidence before making recommendations is in conflict with the conclusions of other groups who have judged the same evidence differently: Scottish Intercollegiate Guidelines Network (SIGN) 2016, the European Society of Cardiology (ESC) 2016 and the American Heart Association American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) 2017 each recommend consideration of intravenous iron in symptomatic patients with HFrEF and iron deficiency to improve function and quality of life. We believe there is sufficient existing evidence to make a recommendation now, in line with existing major evidence based guidelines. Based on: • The original review question • Existing clinical data • Existing clinical guidelines • Emerging clinical practice	convinced that the very low quality evidence on NYHA class is robust enough to support a recommendation when taking into account the evidence on the other outcomes. The committee disagree there is enough evidence to make a recommendation and have acknowledged the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation. When setting the protocol (see Appendix A) the GC agreed that where quality of life is not reported but data showing change in NYHA class is reported, the data on change in NYHA class will be extracted to support the GC in making decisions about overall improvement in the severity of HF symptoms as a partial measure within the overall quality of life of physical effects of heart failure. According to the protocol this data has been downgraded for indirectness. Both the CONFIRM – HF and FAIR-HF trial had quality of life outcomes that could be extracted and this effect has been acknowledged. The GC noted quality of life was a secondary endpoint in the trials. The results for NYHA while positive for iron supplementation (less so for IV iron compared to oral) were based on one study of low numbers (n=16) for only 3months duration. The confidence

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Vifor Pharma propose that the current recommendation for the management of iron deficiency in people with chronic heart failure in the draft guideline be amended to: *"Consider intravenous iron in patients with symptomatic chronic heart failure with reduced ejection fraction, NYHA class II or III, and iron deficiency (serum ferritin <100 µg/L, or ferritin <300 µg/L if transferrin saturation <20%), in order to alleviate symptoms and improve exercise capacity and quality of life."*	intervals surrounding the effect estimate were wide which reduced the committee's ability to be confident in the results. The committee disagree there is enough convincing evidence to make a recommendation and have acknowledged the long term trials that are underway and hope this will aid evidence based decision making on intravenous iron supplementation.
Vifor Pharma UK Limited	Full	156	Table 50	We are concerned that the way this evidence is presented is inconsistent and potentially misleading. The outcomes listed are not clearly identified in relation to the primary and secondary endpoints of the study. None of the trials were designed to investigate mortality and were not powered to do so. The studies presented in this summary included outcomes pre-defined as "critical" and "important" within this guideline and benefit was observed. This is not apparent in the current draft of the document. This is inconsistent with how the summaries of studies have been written elsewhere within the same document. We suggest making this table consistent with the other tables within the guideline and that the outcome column lists the outcomes specifically under	Thank you for your comment. The evidence is presented in the same format as the other reviews and we disagree that this is misleading in this chapter. The critical outcomes are identified in the protocol and are listed first in the table in the outcomes column. The protocol on iron supplementation and the outcomes were agreed by the committee and all the identified studies that met the inclusion criteria were included in the evidence review. The protocol provides further detail about the inclusion and exclusion criteria. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2014 version.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				investigation in each trial. The proposed changes would display the data in a consistent and fair balanced way and would make more clear to the audience that a lack of evidence in some areas is not evidence of a lack of benefit. We are also concerned that symptom improvement is not considered as a critical or important outcome in relation to the review question. As such, benefits of intravenous iron experienced by patients in the clinical trials are not fully incorporated in the assessment of the evidence. We request that the evidence for symptom improvement as measured by the Patient Global Assessment and NYHA class, is re-considered when assessing the clinical benefit of iron replacement and included as important to the review question. We suggest re-presenting the 'Outcomes' column in table 50 in the following way: **Trial** **Outcome** FAIR-HF **Primary endpoints:** Critical to review question: Important to review question: Patient Global Assessment (PGA) NYHA class	Following the methods set out in the NICE guidelines manual the committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Other: **Secondary endpoints:** Critical to review question: EQ5D-VAS KCCQ Hospitalization (all cause, HF, CV cause) Death (all cause, HF, any CV cause) Important to review question: 6 minute walk test (6MWT) Adverse events to study drug Other: CONFIRM-HF **Primary endpoint:** Critical to review question: Important to review question: 6MWT Other: **Secondary endpoints:** Critical to review question: EQ5D-VAS KCCQ	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Hospitalization (all cause, HF, CV cause) Death (all cause, HF, any CV cause) Adverse events to study drug Important to review question: PGA NYHA class Other: Fatigue score IRON-HF **Primary endpoint:** Critical to review question: Important to review question: VO_2 max Other: **Secondary endpoints:** Critical to review question: Important to review question: NYHA class Change in Hb Other: Change in ferritin, TSAT	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				IRONOUT **Primary endpoint:** Critical to review question: Important to review question: Exercise capacity Other: **Secondary endpoints:** Critical to review question: KCCQ Hospitalization Death Important to review question: Adverse events to study drug Other: NT-proBNP Iron studies Toblli 2007/2015 **Primary endpoint:** Critical to review question: Important to review question: Other: Laboratory parameters	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Secondary endpoints: Critical to review question: Quality of life (NYHA class, MLHFQ; 2007 only) Hospitalization (HF) Important to review question: 6MWT (2007 only) Other: Echocardiographic parameters We request that the Committee consider what recommendations can be made based on the "critical" and "important" evidence generated by these trials.	
Vifor Pharma UK Limited	Full	159	Table 51	Table 51 does not consider the totality of the evidence: Improvement in patient symptoms: The evidence table includes one study of 16 participants, where NYHA class is taken as a surrogate maker of Quality of Life. However, NYHA class improvement was a primary endpoint of FAIR-HF (459 enrolled) and a secondary endpoint of CONFIRM-HF (304 enrolled). The FAIR-HF study evaluated the change in NYHA class as part of its co-primary endpoint over a 24 week period. The CONFIRM-HF	Thank you for your comment. **Improvement in patient symptoms and response to question 1.** The protocol sets out that where quality of life is not reported but data showing change in NYHA class is reported, the data on change in NYHA class will be extracted. Quality of life data is reported. Hospitalisation due to heart failure

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				study evaluated the change in NYHA class as a secondary endpoint and evaluated patients over a 52 week period. In each of these trials, there was a significant improvement in NYHA class from baseline to the predefined assessment period versus the control group. Improvement in symptoms, as measured by NYHA class and the Patient Global Assessment should be regarded as an important outcome measure for patients with heart failure. These trials and their results are not in the current version of Table 51 and should be added for completeness so that the totality of evidence can be considered. Hospitalisation due to heart failure: The evidence table includes one study of 40 participants, but this was also explored in FAIR-HF (459 enrolled) and CONFIRM-HF (304 enrolled) as secondary endpoints. In FAIR-HF there was a trend toward a lower rate of first hospitalization for any cardiovascular reason among patients in the treatment group vs the control group (hazard ratio, 0.53; 95% CI, 0.25 to 1.09; p = 0.08). In CONFIRM-HF the treatment group experienced a significant reduction in the risk of hospitalization due to worsening heart failure with a time-to-event analysis returning a hazard ratio of 0.39 (95% CI 0.19–0.82, p= 0.009) versus the control group.	The data for hospitalisation for these studies are reported under all-cause hospitalisation according to the criteria in the protocol agreed by the committee. The committee disagree that the evidence is not representative of the full data and the protocol clearly sets out the criteria for the review. Both the reviews referenced in your comment were identified and the references checked against the review protocol.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				These individual trial findings are supported by independent meta-analyses. A meta-analysis published in 2016, including the four trials of intravenous iron vs placebo assessed by the NICE committee, found a significant improvement in NYHA class with intravenous iron,[1] as well as benefits on exercise capacity and quality of life. A different meta-analysis published in the same year, including the three largest randomised controlled trials of intravenous iron vs placebo assessed by the NICE panel, found that compared with placebo or no treatment, iron therapy was associated with a significantly reduced rate of hospitalization for heart failure (odds ratio, 0.28; 95% CI,0.16-0.49).[2] We are concerned that the evidence presented in the table is not representative of the full data available for these outcome measures; therefore the 'Quality of evidence grade' is unreasonably negative and misleading. Question 1: the data from FAIR-HF and CONFIRM-HF both indicate patients can benefit from an improvement in NYHA class and a reduced risk of hospitalisation due to worsening heart failure. This impact needs to be considered.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We request that the NICE panel re-assesses the evidence, taking into account all the available data relating to outcomes of interest and bases recommendations on all the evidence available. 1. Jankowska EA, Tkaczyszyn M, Suchocki T et al. Effects of intravenous iron therapy in iron-deficient patients with systolic heart failure: a meta-analysis of randomized controlled trials. Eur J Heart Fail. 2016;18(7):768-95 2. Qian C, Wei B, Ding J et al. The efficacy and safety of iron supplementation in patients with heart failure and iron deficiency: a systematic review and meta-analysis. Can J Cardiol. 2016;32(2):151-9	
Vifor Pharma UK Limited	Full	169	13	We find the conclusion of no clinical effect of intravenous iron on exercise tolerance inaccurate. The evidence level is adjudged as moderate due to imprecision; however that evidence did show a benefit of intravenous iron in all trials considered, and on aggregation of the clinical trial data, as shown in the supplementary appendix. This is also contradicted later in the guidance document on page 171 'Trade-off between clinical benefits and harms' where it is written that 'IV iron for people with HFrEF and iron deficiency appeared to	Thank you for your comment. The mean exercise tolerance in the intervention groups was 39.5 higher with a confidence interval of 25.11 to 53.88 higher. This is considered imprecise according to the principles outlined in the methods chapter. The committee do not agree that this demonstrates a convincing clinical benefit to base a recommendation on. Thank you for drawing our attention to our error on page 171; this has been corrected to no clinical benefit.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				have a clinically important benefit on quality of life, **exercise tolerance** and Hb levels ….' The guideline should be consistent throughout on the benefits of intravenous iron demonstrated from the included trials and this should be clarified earlier during the clinical evidence summary.	The criteria applied for imprecision were based on the 95% CIs for the pooled estimate of effect, and the minimal important differences (MID) for the outcome. The MIDs are the threshold for appreciable benefits and harms, separated by a zone either side of the line of no effect where there is assumed to be no clinically important effect. If either end of the 95% CI of the overall estimate of effect crossed 1 of the MID lines, imprecision was regarded as serious and a 'serious' score of −1 was given. This was because the overall result, as represented by the span of the confidence interval, was consistent with 2 interpretations as defined by the MID (for example, both no clinically important effect and clinical benefit were possible interpretations). For continuous outcome variables the MID was taken as half the median baseline standard deviation of that variable, across all studies in the meta-analysis. Hence the MID denoting the minimum clinically significant benefit was positive for a 'positive' outcome (for example, a quality of life measure where a higher score denotes better health), and negative for a 'negative' outcome (for example, a visual analogue scale [VAS] pain score). Clinically significant harms will be the converse of these. If baseline values are unavailable, then half the median comparator

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					group standard deviation of that variable will be taken as the MID.
Vifor Pharma UK Limited	Full	169	18	We are concerned that there is a statement of a clinical harm of intravenous iron for the outcome of ischaemic stroke and consider this to be unfounded. The committee acknowledge that this is based on very low quality evidence, from an outcome occurring in two patients in a trial population of 459 patients and a patient group with significant risk factors for stroke, (and not a statistically significant result). We believe it is incorrect to suggest this as a potential harm of intravenous iron on this basis. Further, there was no such indication in two other long-term trials of ferric carboxymaltose (FCM) in at-risk patient groups (CONFIRM-HF (304 patients), FIND-CKD (626 patients)) and has not emerged as a concern in over 10 years of post-marketing surveillance with FCM. The impact of such an inaccurate statement could have significant negative potential for the treatment of patients in existing services as it raises unfounded doubt which may lead to treatment (and benefit on quality of life) being withheld.	Thank you for your comment. As you note the committee acknowledge that the risk of ischaemic stroke is based on very low quality evidence and that this was from only 2 occurrences in 1 study. However ischaemic stroke is a serious adverse event and the committee considered it was very important to take this in to account and record this in the trade-off between clinical benefits and harms section of the linking evidence to recommendations. NICE guidance does not override the responsibility of the clinician to make decisions appropriate to the individual patient. The committee noted that it is important that any treatment decision is made with the person.
Vifor Pharma UK Limited	Full	169	19	We do not agree that an assessment of evidence shows no clinical effect of intravenous iron on improvement in NYHA class. Only one study was included in the assessment of this outcome measure, a very small study with a high risk of a type II error; yet	Thank you for your comment. The committee disagree that the evidence is not representative of the full data of clinical effect and the protocol clearly sets out the criteria for the review.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				improvement in NYHA class was a primary endpoint of FAIR-HF with 459 patients enrolled, and a secondary endpoint of CONFIRM-HF with 304 patients enrolled, both of which concluded that treatment with ferric carboxymaltose (FCM) resulted in a significantly improved odds of being in a better NYHA class vs placebo. A meta-analysis published in 2016, including the four trials of intravenous iron vs placebo included by the NICE committee, found a significant improvement in NYHA class with intravenous iron.[1] The endpoint of NYHA class improvement for symptomatic HFrEF patients treated with FCM has been demonstrated. Improvements in heart failure symptoms in patients with HFrEF should be considered as part of this guideline update, in keeping European and American guidelines. 1. Jankowska EA, Tkaczyszyn M, Suchocki T et al. Effects of intravenous iron therapy in iron-deficient patients with systolic heart failure: a meta-analysis of randomized controlled trials. Eur J Heart Fail. 2016;18(7):768-95	When setting the protocol (see Appendix A) the GC agreed that where quality of life is not reported but data showing change in NYHA class is reported, the data on change in NYHA class will be extracted to support the GC in making decisions about overall improvement in the severity of HF symptoms. According to the protocol this data has been downgraded for indirectness. Both the CONFIRM – HF and FAIR-HF trial had quality of life outcomes that could be extracted and this effect has been acknowledged. The GC noted quality of life was a secondary endpoint in the trials. The review by Jankowska was identified and the references checked against the review protocol and all relevant studies included.
Vifor Pharma UK Limited	Full	170	17	*'The incidence of anaphylaxis/hypersensitivity was not reported in any of the included trials'*	Thank you for your comment. The CONFIRM-HF reports the text,' No severe allergic reactions related to the study treatment were reported'. No

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The trials do not report the incidence of hypersensitivity (which would include all reactions from mild to severe), but both FAIR-HF and CONFIRM-HF trials report that there were no cases of serious allergic reactions (i.e. anaphylaxis).	data is reported or could be extracted; there is no useable information to include this in the outcomes.
Vifor Pharma UK Limited	Full	170	2-	We would like to re-assert that the evidence and commentary from the literature search has not been accurately reflected in the previous pages (156-169), and differs from the assessment of the same evidence by other bodies (see points 10, 14 and 17 below). As a result, 'No recommendation' would be insecure due to the inaccuracy of conclusions drawn. Further, it should not be assumed that currently available intravenous iron preparations are interchangeable: they are different iron-carbohydrate complexes which can be considered as prodrugs and display correspondingly different physicochemical characteristics that can effect clinically relevant properties. Hence, choice of intravenous iron complex should be considered on the clinical data specifically associated with it and any prescribing decision should be made based on clinical evidence.	Thank you for your comment. The GC considered there was likely to be a class effect for intravenous iron supplements as probable differences in the bioavailability of different intravenous iron preparations were likely to be small and thus would not preclude meta-analysis of the data from iron studies. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.
Vifor Pharma UK Limited	Full	171	36	*'Despite these findings the committee was uncertain that the benefits of IV iron had been completely demonstrated.'*	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Despite citing evidence of clinically important benefits on quality of life and unplanned hospitalisation (stated as critical outcomes for decision making on page 155, table 49, line 13) and exercise tolerance and Hb change in anaemic patients (stated as an important outcomes for decision making) it would appear contradictory that the committee would then purport that the benefits of intravenous iron had not been demonstrated. In addition, the failure to include improvement in patient symptoms and the assessed lack of clinical benefit on NYHA class improvement, we consider has been misjudged by the committee (see point 7 above). This conclusion sharply contrasts with the opinion of national and international groups, including Scottish Intercollegiate Guidelines Network (SIGN) 2016, the European Society of Cardiology (ESC) 2016 and the American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) 2017, all of whom have assessed the same evidence and recommend the consideration of intravenous iron in symptomatic patients with HFrEF and iron deficiency to improve function and quality of life. The conclusion of the committee puts the UK at odds with the rest of Europe and North America in this area. As stated in the rationale for the update to the NICE guidance '*Since 2010, European and North American guidelines, based on new high-quality evidence from randomised controlled trials in*	the evidence was lacking the committee used their clinical experience and consensus. The GC was aware that epidemiological data showed a strong relationship between the extent of iron deficiency and heart failure outcomes. Trials of intravenous iron therapy were associated with improvements in quality of life, exercise capacity and class of heart failure but most of the trials were short-term and only of small to moderate size. All trials were designed with surrogate outcomes as the primary endpoint and evidence on outcomes extracted in the evidence review were assessed as of low quality. The GC was mindful of guidance that definitive evidence of benefit was required to justify the cost consequences of an intervention for a common finding in patients with heart failure. The GC was concerned that while significant effects were reported on surrogate outcomes these did not translate clearly to substantial benefits on hospitalisation despite improvements in exercise capacity or NYHA class being associated with improvements in hospital outcome measures with other interventions for heart failure. Iron therapy would likely need to be administered on a long-term basis and this had significant implications for resources in the NHS. The linking evidence to recommendations section outlines the committee's rationale for their

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnosis, treatment and monitoring have been published. A partial update of the existing NICE guideline is necessary to ensure that the recommendations take into account the new evidence available' (page 28 full version lines 4-6). Also, in the time since the publication of the ESC guidance in 2016, a considerable number of hospital trusts have implemented the existing guidance in relation to iron deficiency. This puts the draft NICE guidance at odds with current clinical practice in these area, increasing the risk of confusion and potential adverse patient outcomes. Question 3. The current recommendations and statements within the full version would present unnecessary challenges to currently accepted and implemented clinical practice concerning the treatment of iron deficiency in heart failure which has been adopted following the publication of FAIR-HF (2009), CONFIRM-HF (2014) and the ESC guidelines 2016.	decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge that other publications have reached different conclusions however in order to recommend this treatment for the NHS it is necessary to await results from the long term trials that are underway, and hope this will aid evidence based decision making on iron supplementation.
Vifor Pharma UK Limited	Full	171	50	*'There was also concern that because iron deficiency can be a symptom of other disorders, particularly gastrointestinal tract cancer, there was a risk of missing other causes if the iron was replaced without further investigation.'* Iron deficiency can be a marker of underlying gastrointestinal disease and appropriate consideration needs to be given to investigation; however, this should not preclude making recommendations about the treatment of iron deficiency. No other guidelines that	Thank you for your comment. The subject of the investigation of iron deficiency anaemia is outside of the scope of this guideline but the committee considered that other causes of iron deficiency would need to be excluded prior to any consideration of iron therapy.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				have addressed this area have shied away from the benefits of iron replacement due to uncertainty over underlying causes. It should thus be considered reasonable to re-emphasise good practice by making recommendations for treatment in those patients who are found to have iron deficiency, while investigating the cause of the clinical problem, given the evidence supporting the benefits of ferric carboxymaltose and the lack of benefit of oral iron in this patient group. Question 1. This statement contributes to a 'no recommendation'. It will have a significant negative impact on symptomatic heart failure with reduced ejection fraction (HFrEF) patients, NYHA class II-III by denying them the demonstrated improvements in function and quality of life from FAIR-HF and CONFIRM-HF whilst waiting for other potential causes of iron deficiency to be investigated	
Vifor Pharma UK Limited	Full	172	8	*'No evidence was found indicating whether repeat administration will always be necessary …'* We note a renal physician not regularly engaged in the care of heart failure patients was invited to consult on this point. The comparison of chronic kidney disease (CKD) patients with heart failure patients is not valid for this consideration. Patients with CKD, particularly those on dialysis and erythropoietin-stimulating agents (ESAs), have different risk factors for iron deficiency and require a different approach to iron replacement	Thank you for your comment and clarification of the likely frequency of iron infusion in patients with heart failure. The co-optee who attended the meeting as an advisor to the committee is a consultant Nephrologist and Acute Physician who regularly oversees IV infusion on an outpatient basis for patients with anaemia and/or renal disease and has extensive experience of caring for people with HF. A declaration was made and recorded that the expert was a local investigator on the Ironman

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				therapy; they do not constitute an appropriate comparator group. CONFIRM-HF identified that 75% of the trial population required no more than two infusions over the 52 weeks to maintain iron repletion. It is acknowledged that experts within the field of iron deficiency are limited. However we do not feel that the experts called upon to guide this decision have been entirely clinically appropriate and able to provide a balanced perspective. The experts used for pivotal decisions have been nephrologists. This is a heart failure guideline and so if a nephrologist is selected for their clinical experience of using intravenous iron then it should be one who can also draw from their experience of caring for patients with heart failure. Additionally, it is known that a potential conflict exists as members of the review committee have conflicts of interest with a single iron product. We would request that in order to ensure an unbiased expert opinion a cardiologist who has experience with both of the currently available high dose iv iron formulations or a cardiologist who declares no conflict should be consulted. Question 3. It is valuable to gain expert testimony from healthcare professionals currently engaged in treating	trial, and as this trial was not being considered by the committee it was not deemed a conflict of interest. Similarly a committee member declared that he was a member of the Ironman trial steering committee. As the Ironman trial is ongoing and was not considered by the committee it was not deemed to be a conflict of interest. The committee were clear that they required further RCT data to answer this review question and to make an evidence based recommendation. The co-optee expert regularly cares for people with heart failure and the committee did not consider it necessary to seek any further experts experience in this area.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the patient population being considered. We welcome the group seeking further expert testimony on the use of intravenous iron products in the heart failure population from those currently doing so.	
Vifor Pharma UK Limited	Full	173	33	'…. *a positive recommendation for IV iron supplementation would have a large cost impact for the NHS.'* We agree that if the NHS was to implement screening, diagnosis and treatment of all patients in the scope of the guideline i.e. adults with symptoms or a diagnosis of heart failure with reduced ejection fraction (HFrEF) or heart failure with preserved ejection fraction (HFpEF), the cost would be substantial. In practice the population where evidence supports treatment is those with HFrEF, NYHA class II-III, symptomatic and presenting at secondary care. We have performed an economic analysis based on the European Society of Cardiology (ESC) recommendations, utilising the CONFIRM-HF data on reducing hospitalisations due to worsening heart failure, along with data from National Institute for Cardiovascular Outcomes Research (NICOR) and Payment By Results. This shows a saving to providers in year 1, and a significant saving to both providers and commissioners from year 2 onwards. This model is available on request.	Thank you for your comment. Although the committee considered that IV iron may be cost effective at 12 month time horizon, due to the uncertainty of the clinical effectiveness of IV iron after 12 months and whether to continue or stop supplementation, the committee could not be certain of this. They were also concerned that 12 months was not a sufficient follow-up period to capture all costs and effects of IV iron supplementation. The committee were aware that some centres are already providing an IV iron services. However, the committee did not consider that there was strong enough clinical evidence to make a positive recommendation based on the clinical evidence. The committee were also concerned that the population included in the clinical trials may not be reflective of the population treated for heart failure in practice, and that tolerability of IV iron may be worse in 'typical' patients with HF who are on average older and have more comorbidities.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
				Question 1. The Committee should consider the negative impact that could result from trying to apply the evidence to all HF patients (where it is not applicable) and thereby failing to make any recommendation, thus potentially denying symptomatic HFrEF NYHA class II-III patients (reflective of the clinical trial population) ferric carboxymaltose (FCM) where the evidence does exist for clinical benefit. As mentioned in the draft guidelines, FCM is considered cost effective based on the FAIR-HF trial with an incremental cost-effectiveness ratio of £3,977 per QALY gained. The probability that IV iron is cost effective at the £20,000 per QALY threshold was around 99%. Rohde LE et al; Nat Rev Cardiol. 2013 Jun;10(6):338-54 also stated that compared to other chronic heart failure treatments, FCM has a very favourable cost effectiveness ratio. Question 3. Many hospital trusts already have existing intravenous iron services, to which diagnosed symptomatic HFrEF patients could be referred , thereby reducing the impact expressed by the current draft guidance. The committee have concluded that intravenous iron treatment is cost-effective but still likely to be	The committee were aware of a clinical trial currently underway that is due to assess longer time points, which they hope will provide definitive evidence of long term clinical effectiveness. Until this trial has been completed the committee did not consider there was sufficient evidence to make a positive or negative recommendation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				unaffordable to the NHS due to the size of the potential patient population. Limiting the cohort of patients for whom FCM should be recommended to that mirroring the patient population in the largest clinical trials, FAIR-HF and CONFIRM-HF, would result in a significantly smaller group of patients being in scope for treatment. This would significantly reduce any additional costs incurred.	
Vifor Pharma UK Limited	Full	173	37	*'The Committee stated that the IRONMAN trial currently underway should help to strengthen both the clinical and economic evidence to aid recommendations for IV iron supplementation in the future.'* Reference to the IRONMAN trial in isolation is not justified. It requires qualifying information such as endpoints, estimated completion date and the clarification that it uses a different intravenous iron, with no previous randomised controlled trial evidence in heart failure, to ferric carboxymaltose, which currently carries the weight of evidence in heart failure. Intravenous irons cannot be considered as interchangeable, as each is a distinct complex of iron and carbohydrate, with different physicochemical properties that can impact clinically relevant features; as such the data produced for one does not imply that another will replicate the same effects, a distinction	Thank you for your comment and the additional information about the interchangeability of different iron preparations. Further research is on-going in this area due to uncertainty in initial trials around critical outcomes in our review protocol, namely mortality and hospitalisation, and that these trials acknowledge that longer term outcomes are required to truly demonstrate the effectiveness of IV iron. As the AFFIRM-AHF trial is in an acute heart failure population, it is outside the scope for this guideline; however we will also mention the two other trials in the LETR to support the committees view that further research is required in this area before a recommendation can be confidently made. Draft protocols for all questions addressed by the guideline are discussed and revised by the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				which should be noted. These differences are appreciated by regulatory authorities who include intravenous iron preparations in the class of non-biologic complex drugs (NBCDs), with particular regulatory requirements. This leaves NICE in an insecure position regarding balanced assessment of evidence. Indeed, reference should also be made to all other ongoing trials of iron in heart failure as these will bring equally important information to inform future decision-making within a similar time frame: AFFIRM-AHF (NCT02937454), FAIR-HF2 (NCT03036462), HEART-FID (NCT03037931). We are concerned that an original recommendation on the protocol for the use of intravenous iron was amended during the Guideline Development process. This occurred during the only meeting at which a co-opted Guideline Committee member was present, and coincidentally an investigator in the IRONMAN clinical trial. A second Guideline Member lay representative is noted to be a Chair of the Steering Committee for the IRONMAN clinical trial, representing a significant conflict of interest. The committee have themselves acknowledged evidence of a clinically important benefit of intravenous	committee prior to undertaking the systematic review. This is standard NICE methodology and process. A co-optee member attended as a nephrology expert to answer any questions the committee had when considering the evidence on BNP in people with CKD. A declaration was made and recorded that the expert was a local investigator on the Ironman trial, and as this trial was not being considered by the committee it was not deemed a conflict of interest. The lay committee member declared that he was a member of the Ironman trial steering committee not the Chair. As the Ironman trial is ongoing and was not considered by the committee it was not deemed to be a conflict of interest

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				iron on a) factors considered critical, including quality of life and unplanned hospitalisation and b) factors considered important, including exercise tolerance and change in haemoglobin in anaemic patients. Further, the committee also assess that intravenous iron therapy as per the CONFIRM-HF dosing regimen over a 12 month period is likely to be cost-effective (see points 10 and 13 above). The decision to wait for further evidence before making recommendations is in conflict with the conclusions of other groups who have judged the same evidence differently: Scottish Intercollegiate Guidelines Network (SIGN) 2016, the European Society of Cardiology (ESC) 2016 and the American Heart Association American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) 2017 each recommend consideration of intravenous iron in symptomatic patients with HFrEF and iron deficiency to improve function and quality of life. We believe there is sufficient existing evidence to make a recommendation now, in line with existing major evidence based guidelines. Indeed, we have experience that clinical trials investigating iron treatment in patients with chronic heart failure now have difficulty gaining ethical approval to include a	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				placebo group based on the strength of the evidence for treatment with intravenous iron. If the committee were to re-evaluate the current evidence available with consideration to the points highlighted in this feedback, they should be in a position to make recommendations based on quality of life, exercise capacity and risk of unplanned hospitalisations in HFrEF patients now. When future mortality data become available, the committee will be in a positon to use these new data to inform future recommendations.	
Vifor Pharma UK Limited	Full	173	43	*'Therefore, any recommendations will have implications for a large number of people covered by this guideline'* We are in full agreement with this statement – recommendations, or lack of them, will indeed have implications for a large number of patients. We would ask you to consider that, with respect to a recognised co-morbidity of heart failure that results in a worse prognosis and where there is accepted evidence that treatment improves outcomes, not making a recommendation about treatment affects a large number of patients in an adverse way. The committee have themselves acknowledged clinically important benefits of intravenous iron on quality of life, unplanned	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation. The committee discussed the population currently given IV iron, similarly to the population included in the clinical trials, may not be reflective of the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				hospitalisation and exercise tolerance, which could potentially be withheld from patients with the lack of a recommendation from NICE in this area. This should be considered in the light of the knowledge that 50% of HFrEF patients die within five years and so any improvements we can offer in quality of life and functional capacity in their remaining years should not be underestimated. In particular, we are concerned that this will disproportionately affect older patients. Older people represent the majority of patients with heart failure; these patients may be additionally compromised by iron deficiency, due to the effect of iron depletion on other co-morbidities these patients experience, including sarcopenia (with its associated risks of frailty, gait disturbance and falls)[1-3] chronic kidney disease[4] and chronic obstructive pulmonary disease.[5,6] Question1. If the committee relates its recommendations to those patients reflected in the clinical trials, the impact will be greatly reduced to only include a patient cohort where a demonstrated benefit has been proven, instead of the entire heart failure population within scope of this guideline. This would also then align with the most recent international guidelines in this area that have been published.	population treated for HF in practice, and that tolerability may be worse in 'typical' patients with HF who are on average older and have more comorbidities.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
				No recommendation at this time could have a significant negative impact on the population of symptomatic HFrEF patients in NYHA class II or III by denying them the clinical benefits of intravenous iron that the committee have acknowledged. 1. Chaves PH. Semba RD, Leng SX et al. Impact of anemia and cardiovascular disease on frailty status of community-dwelling older women: the Women's Health and Aging Studies I and II. J Gerontol A Biol Sci Med Sci 2005;60:729-35 2. Penninx BW, Pahor M, Cesari M et al. Anemia is associated with disability and decreased physical performance and muscle strength in the elderly. J Am Geriatr Soc 2004;52:719-24 3. Penninx BW, Pluijm SM, Lips P et al. Late-life anemia is associated with increased risk of recurrent falls. J Am Geriatr Soc 2005;53:2106-11 4. NICE 2015 Chronic kidney disease: managing anaemia (NG8). 5. Sliverberg DS, Mor R, Weu MT et al. Anemia and iron deficiency in COPD patients: prevalence and the effects of correction of the anemia with erythropoiesis stimulating agents and intravenous iron. BMC Pulmonary Medicine 2014;14:24 6. Nickol AH, Frise, MC, Cheng HY et al. A cross-sectional study of the prevalence and associations of iron deficiency in a cohort of patients with chronic	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				obstructive pulmonary disease. BMJ Open. 2015;5(7):e007911	
Vifor Pharma UK Limited	Full	174	2	*'There was consensus that iron studies were already done for everyone known to have anaemia, and that people with HF in a specialist clinic would generally also get iron studies.'* The Guideline Committee may not consider the evidence to recommend testing all heart failure patients for iron deficiency robust enough, but if it is recognised that: a) many will be tested as part of routine care, b) many of those will be found to be iron deficient, c) that there is evidence supporting clinically relevant benefits of treatment with ferric carboxymaltose and d) evidence of no benefit with oral iron, then it would seem reasonable to suggest that the committee, in effect, have enough information to be able to support and, indeed are obliged, to make a recommendation about what action a healthcare professional should take when a patient with heart failure is diagnosed with iron deficiency. Current clinical practice has evolved to include undertaking iron studies routinely (as recommend for all newly diagnosed or symptomatic heart failure patients in the ESC guidelines, 2016), therefore it would logical that this guideline should reflect the approach of modern heart failure services.	Thank you for your comment. The committee recognised that a proportion of patients may be tested for iron status. However, it was aware that variation in practice was likely across the UK and that universal testing for iron status had resource impact implications that could only be justified if substantial benefits could be demonstrated form this intervention.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
Vifor Pharma UK Limited	Full	174	29	*'The committee considered that it may be preferable for the first infusion to be given slowly and in hospital because of the risk of allergic reaction, but felt that if there was future evidence of safety, it may be possible to be given at home by the community HF or IV team.'* We are deeply concerned that this advice is in direct contradiction to the European Medicines Agency assessment of intravenous irons published in 2013, which recognised that there is a small risk of hypersensitivity reaction with each parenteral iron preparation, and that this risk is not predicted by previous response to intravenous iron. So-called 'anaphylactoid reactions' are not caused by sensitisation to the iron-carbohydrate complex and the risk is unchanged between each iron administration. Therefore, there is a potential risk attached to suggesting to the audience that it may be safe to give intravenous iron in the community if they have tolerated a first dose in hospital, as it misrepresents the nature of hypersensitivity reactions to parenteral iron. Intravenous iron can be given in the community, but where the facilities are available to manage acute, severe hypersensitivity reactions and these must be available for each administration, regardless of patient's previous tolerance.	Thank you for your comment. This paragraph has been deleted from the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
Vifor Pharma UK Limited	Full	174	37	*'There was consensus that we should be moving towards a separate pathway for iron deficiency in HF, in a manner similar to that for anaemia in CKD.'* We would recommend that if NICE feel this is appropriate, it would be more efficient and beneficial for all stakeholders if NICE consider developing a unified pathway for managing iron deficiency. The cumulation of factors such as the evidence of the deleterious effects of iron deficiency in heart failure, plus the positive effects of treatment with intravenous iron (such as benefits on quality of life, unplanned hospitalisation and exercise tolerance) together with the support of existing guidelines should be compelling enough qualification for a stand-alone pathway of care in the future. It is illogical and not in the patients' best interests for optimal treatment to refuse to make any treatment recommendations at this point. As stated earlier in the guideline and acknowledged in this statement, iron deficiency is a debilitating disorder which affects a large number of heart failure patients, therefore making no recommendations at this time disadvantages this vulnerable cohort. *'… without high quality evidence that this would be beneficial'*	Thank you for your comment. The committee acknowledged that this pathway would need to be developed if substantial evidence existed for significant benefit from iron therapy. However it did not feel that this existed at this point in time.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This is a contradiction from the trial evidence assessment where critical and important outcomes, including quality of life and Hb improvement in anaemic patients were judged to have high-quality evidence and show clinically important benefit of intravenous iron treatment (page 169, lines 10-12; see point 10 above).	
Vifor Pharma UK Limited	Full	174	9	*'… the committee could only consider a recommendation that all people with HF be tested if there was robust evidence of both clinical and cost-effectiveness of treating identified iron deficiency…. Since this was lacking the committee felt that no such recommendations could be made …'* See points 11 and 14 above – we fundamentally disagree that evidence of clinical effectiveness for ferric carboxymaltose (FCM) is lacking. The committee have themselves acknowledged the clinically important benefit of intravenous iron on a) factors considered critical, including quality of life and unplanned hospitalisation and b) factors considered important, including exercise tolerance and change in haemoglobin in anaemic patients. Further, the committee also assess that intravenous iron therapy as per the CONFIRM-HF dosing regimen over a 12 month period is likely to be cost-effective. The purported opinion of lack of clinical and cost effectiveness conflicts with that of other guidelines:	Thank you for your comment. The committee recognised that a proportion of patients may be tested for iron status. However, it was aware that variation in practice was likely across the UK and that universal testing for iron status had resource impact implications that could only be justified if substantial benefits could be demonstrated form this intervention.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Scottish Intercollegiate Guidelines Network (SIGN) 2016, the European Society of Cardiology (ESC) 2016 and the American Heart Association American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) 2017, who have assessed the same evidence and recommend the consideration of intravenous iron in symptomatic patients with HFrEF and iron deficiency to improve function and quality of life. We respectfully request that the Committee consider a recommendation for the use of FCM in a population defined to match that of the clinical trials. In this way, the number of potential patients to be tested will be rationalised and the needs of the patients with the greatest potential for demonstrated benefit will be addressed.	
Vifor Pharma UK Limited	Full	167 (&168 Table 56 & 173)	28	Question 2. The cost of ferric carboxymaltose (FCM) considered, based on the clinical trial protocol of CONFIRM-HF, is not reflective of the actual cost to the NHS – a 1000mg vial of FCM is available in the UK and means that the single doses of 1000 mg used in CONFIRM-HF will be less costly than the committee have considered (2x 500mg vials). If the panel would reflect this in the full version on page 167 line 28 and in table 56 it would be more	Thank you for your comment. The UK NHS costs reported in the guideline are those that were presented to the committee in May 2016, and are references as so. The unit costs presented are the maximum and minimum given the doses from the trials. CONFIRM-HF states that participants initial dose could be 500mg or 1000mg depending on weight and Hb value, with 500mg maintenance doses thereafter. The minimum and maximum dose reported in the trial was 500mg and 3,500mg

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				representative of current UK clinical practice with ferric carboxymaltose.	respectively. We acknowledge that the price of a 1,000mg vial has fallen and would now be cheaper than two 500mg vials, however this would only affect a scenario where the initial dose given was 1000mg rather than 500mg. The costs reported reflect the maximum cost that could be incurred at this overall dose (i.e. 7 visits of 500mg doses). It is noted in the guideline methods that' the UK NHS costs reported in the guideline are those that were presented to the committee and were correct at the time recommendations were drafted. They may have changed subsequently before the time of publication. However, we have no reason to believe they have changed substantially.' However, a footnote has been added highlighting that a 1000mg vial is now cheaper than two 500mg vials and therefore if the initial dose was 1000mg this cost is overestimated.
Worcestershire Acute hospitals NHS trust	Full	General	General	Please clarify what is the intended role of the primary care team within MDT discussions: Does this require inclusion of GPSI?	Thank you for your comment. The specialist heart failure MDT should collaborate with the primary care team to ensure information is shared across different settings. This may or may not include a GPSI depending on local configuration of services and this has been discussed within the recommendations and link to the evidence section of the full guideline.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Worcestershire Acute hospitals NHS trust	Full	General	General	We agree with an extended first consultation and 2 week follow up clinics. However, this has major resource implications that may make this impractical.	Thank you for your comment. With regard to the extended first consultation, the committee considered that this was already advocated in the patient experience guideline recommendation 1.3.4 - Hold discussions in a way that encourages the patient to express their personal needs and preferences for care, treatment, management and self-management. *Allow adequate time so that discussions do not feel rushed.* The committee wished to build upon this to highlight that a standard consultation appointment for heart failure is not usually long enough to communicate the necessary information well to a person with newly diagnosed heart failure. The committee also acknowledged that a two week follow-up clinic may not be feasible for all hospitals and therefore agreed to soften this recommendation to state that this should be done *if possible* to do so. The committee thought this appointment would allow the person time to reflect on the information and new diagnosis they had received and provide them another opportunity to discuss their condition. The committee discussed that patients usually have an appointment around this time to up-titrate medication and noted that this could provide a good opportunity to re-visit some of this information.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Worcestershire Acute hospitals NHS trust	Full	General	General	HFrEF defined as LVEF <40% a) This is the first time that NICE have followed suit with major guideline bodies and this change is welcomed! b) Offering all of these patients an MRA will be controversial (there is disagreement even within our own department). In view of limited accuracy of echocardiography and the wish to simplify protocols pragmatically this makes sense, but we expect discourse as clinical studies of MRAs all recruited patients with an LVEF<35%	Thank you for your comment. The committee reviewed the diagnostic criteria for different types of heart failure and decided that EF<40% was the best consensus definition for HFREF. The committee was aware of the recruitment criteria for the MRA trial and reviewed this in its discussion on the recommendation.
Worcestershire Acute hospitals NHS trust	Full	General	General	We disagree with not routinely offering beta-blockers routinely to patients with HFrEF and AF. This is based on a meta-analysis of sub-populations. Neither the ESC or American bodies have adopted this change. Although practically this is so unlikely to pose much of a dilemma as the vast majority will still need beta-blockers for rate control, we are worried about the message this sends. The land mark trials with beta-blockers provided the largest RRR of mortality compared to any other prognostic therapy and sympathetic nervous system activation contributes to the increased risk of sudden death.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.
Worcestershire Acute hospitals NHS trust	Full	General	General	We agree with the positioning of a Mineralocorticoid receptor antagonist (MRA)as a second line agent to be prescribed ahead of Sacubitril valsartan as this reflects the design of PARADGM HF where recruiters were encouraged to consider an MRA in all patients prior to	Thank you for your comment. The limitations of MRA therapy are discussed in the recommendations and thus if MRAs are contra-indicated then sacubutril-valsartan would be one of the next options.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recruitment and this is in line with the ESC guidance. However, there will be cases where in view of renal function and serum potassium it is preferable to use an ARNI ahead of an MRA.	
Wythenshawe hospital	Full	General	General	The guideline is for both specialists and non-specialists. 515 pages is also far too long for a guideline. The resultant document is impractical and unreadable.	Thank you for your comment The full guideline is lengthy because of the large scope and number of evidence reviews conducted, however there is a short version containing just the recommendations
Wythenshawe hospital	Full	General	General	The consistency of language in the document needs to be double checked (e.g. references to mineralocorticoid receptor antagonists in some places and aldosterone antagonists in others).	Thank you for your comment. The consistency of language has been checked prior to publication. The term Mineralocorticoid receptor antagonists has been used throughout, except when reporting studies where the author has used alternative terminology for this drug
Wythenshawe hospital	Full	14-25	general	On the full guideline there is a summary of all key recommendations. These will need to be changed based upon the incorporation of stakeholder comments.	Thank you for your comment. The summary has been updated to reflect any changes made to recommendations.
Wythenshawe hospital	Full	15	13	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Wythenshawe hospital	Full	23	36-42	We are concerned that 3 out of 6 research recommendations are about NT-proBNP – does this suggest the importance of this subject matter, or the research interests of the panel? Surely there are greater heart failure research questions requiring to be answered. Can these 3 recommendations on NT-proBNP be amalgamated into one (with stems)?	Thank you for your comment. The committee flagged a number of areas requiring further research throughout guideline development process. However, upon further discussion realised that many of these areas already had trials currently underway or that were planned to start in the near future. Therefore these areas were not prioritised as research recommendations.
Wythenshawe hospital	Full	23	General	With the important findings of the DANISH study, which questioned the importance of defibrillator therapy in patients with heart failure of a non-ischaemic aetiology, we would like to suggest an additional research recommendation of: "The comparison of CRT-pacemakers with CRT-defibrillators in a prospective study in heart failure patients of any aetiology", assessing the efficacy (non-inferiority of CRT-pacemakers) and cost-effectiveness in a UK population. This is a particularly important question given the increasing numbers of these high value devices being implanted across the country.	Thank you for your comment. Research recommendations can only be made for topics in which the guideline has searched for the evidence and has established a gap in available evidence. The review question addressed in this guideline was specifically on the criteria to determine when to discuss deactivation of a defibrillator, and we are therefore not able to make a research recommendation as you suggest.
Wythenshawe hospital	Full	99	9	Add Urea as an investigation "Urea and electrolytes" rather than "electrolytes"	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Wythenshawe hospital	Full	103	3 (Algorithm)	Add ECG in middle box "specialist clinical assessment, ECG and doppler echocardiography" rather than "specialist clinical assessment and doppler echocardiography"	Thank you for your comment. The committee did not consider that an ECG had to be undertaken at referral but could also be done in primary care. The algorithm has been updated to reflect this.
Wythenshawe hospital	Full	170	2	**No recommendation:** The decision to make no recommendation on IV iron is contrary to all other recent national[1] and international[2,3] heart failure guidelines, and at variance from evidence from multiple randomised, controlled trials that have highlighted benefit on exercise capacity and quality of life. In a clinical syndrome with such a high negative impact on quality of life[4], we do wonder whether enough weight was given to quality of life endpoints when making this judgement. We acknowledge that there are no robust data regarding the effect of IV iron on survival or heart failure hospitalisation and as such its impact on these outcomes is as yet unknown. Therefore, a strong	Thank you for your comment. The committee made their decision based on the best clinical and cost effectiveness evidence available and where the evidence was lacking the committee used their clinical experience and consensus. The linking evidence to recommendations section outlines the committee's rationale for their decision that the evidence does not support a recommendation on iron supplementation. The committee acknowledge the long term trials that are underway and hope this will aid evidence based decision making on iron supplementation.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommendation for IV iron repletion must await the results of appropriately powered trials on hospitalisation and mortality (there are four large international trials that are currently recruiting and will answer this). As such this therapy cannot be 'recommended', but we do believe that clinicians should be able to 'consider' it: IV iron might be reasonable to improve functional status and quality of life as has been seen in the evidence from clinical trials. Such an approach would be consistent with all other recent national[1] and international[2,3] heart failure guidelines. 16. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 17. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 18. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 Juenger J, *et al.* Health related quality of life in patients with congestive heart failure: comparison with other	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				chronic diseases and relation to functional variables. *Heart* 2002;87:235-241	
Wythenshawe hospital	Full	197	All lines	All recommendations for the pharmacological treatment of heart failure section. The ordering of this section does not make sense. It starts with diuretics which seems reasonable. However, it is followed with advice on calcium-channel blockers, amiodarone, anti-coagulants, inotropic agents and general advice on contraception and pregnancy. All medications with prognostic importance follow thereafter. This is very strange prioritisation.	Thank you for your comment The ordering of the pharmacological recommendations has been revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.
Wythenshawe hospital	Full	217	2	**Figure 5:** There are multiple problems with this figure, which should be the main 'take home' message for the entire guideline. This algorithm is not consistent with other recent national[1] and international[2] heart failure guidelines and some of NICE's own previous recommendations, including NICE TA Guidance 388[3]. Problems include: ○ **Beta-blockers and AF:** see relevant section in comments ○ **CKD recommendations:** see relevant section in comments ○ **2nd line MRA advice:** 'mildly symptomatic' is too ambiguous. This would be better displayed as NYHA classifications (i.e. NYHA II – IV) in keeping with the evidence base. ○ **3rd line therapies:** sacubitril/valsartan, cardiac resynchronisation therapy and ivabradine all have prognostic importance (reducing mortality	Thank you for your comment. The algorithm has been updated according to changes in recommendations and been made clearer: a. The committee revisited the review for beta-blockers in people with heart failure and atrial fibrillation and the recommendations have been removed. This has therefore also been removed from the algorithm. b. The treatment recommendations for those with heart failure and CKD have also been updated to provide further clarity and updated in the algorithm. c. We have removed 'mildly' from this recommendation as we agree this is ambiguous. As there was a mix of severity of symptoms according to NYHA

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and/or heart failure hospitalisation) and as such are all NICE 'recommended' treatments in appropriate patients but this figure designates them as therapies to 'consider'. The ordering and prioritisation of these therapies needs to be changed and moved higher up the algorithm ahead of digoxin and hydralazine-ISDN. The European Society of Cardiology (ESC) algorithm displays this flow more appropriately. The Board of the BSH sees no good reason to diverge from the Figure-presentation in the ESC guidelines[2]. ○ **Advanced therapies:** mechanical support options and cardiac transplantation should be added to this algorithm. 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure	class in patients recruited into the clinical trials the committee agreed not to specify a particular NYHA class. d. The comparative clinical and cost effectiveness of these treatments was not assessed in this guideline and therefore the committee could not determine the optimal sequence for these treatments. These treatment options have been arranged in the algorithm to reflect this, and that these should be options for consideration by a specialist depending on the person's condition. e. Mechanical support options and cardiac transplantation are highly specialised interventions and beyond the scope of this guideline and therefore have not been included in the algorithm.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
Wythenshawe hospital	Full	228	27	(Recommendation 7.1.6) We would recommend removal of 'devices' from the statement, 'unless their condition is unstable or they have a condition or device that precludes such a programme.' This may reduce the number of patients with implantable devices being offered rehabilitation unnecessarily.	Thank you for your comment. The recommendation has been amended to remove any reference to devices.
Wythenshawe hospital	Full	377	10	The advice on writing a plan is clear and an important addition to the guideline.	Thank you for your comment.
Wythenshawe hospital	Full and short	General	General	The ordering of sections in the full and short documents is inconsistent. Many healthcare professionals will focus on the short document and occasionally cross reference to the full document. This would be markedly helped by having the same ordering.	Thank you for your suggestion. The ordering of the full guideline has been reviewed by the committee and the algorithms have been moved to the full list of recommendations for ease of reference and the pharmacological chapter order has been revised to start with treatment for HF with reduced ejection fraction as this is a more logical order.
Wythenshawe hospital	Short	4	9	Please provide detail on the constituents of the primary care team. We would suggest a nominated GP and nurse for each practice.	Thank you for your comment The constituents of the primary care may often be a GP and nurse however this would need to be determined locally.
Wythenshawe hospital	Short	5	27-29	There are also instances where the specialist heart failure MDT may need to continue to manage the patients, even after they have been stabilised and management has been optimised. This is in particular cases such as cardiac transplantation and LVADS.	Thank you for your comment. A recommendation has been made stating that the specialist HF MDT should continue to manage patients after an interventional procedure. Collaboration between primary care teams and the specialist HF MDT

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This section could be changed to include: There may be instances where the specialist heart failure team need to continue to manage heart failure patients such as post cardiac transplant and after implantation of Ventricular Assist Devices	should ensure transfer of care is made at the appropriate time.
Wythenshawe hospital	Short	7	1-29	We agree that NTproBNP is the ideal blood test to assist in the diagnosis of heart failure and we should encourage localities to make it readily available to GPs. However, many localities already have access to BNP (included in previous guidelines). Access to and the use of any natriuretic peptide test to assist in making the timely diagnosis of heart failure is preferable to no availability. As such it would be wrong for this guideline not to mention BNP and the relevant cut-offs.	Thank you for your comment. The committee considered that a number of factors would favour the use of NT-proBNP as outlined in the LETR. The committee was unable to locate data for BNP equivalent concentrations given biological variances in the recent evidence base as this was not measured simultaneously in the studies used to define this recommendation.
Wythenshawe hospital	Short	7	7	We agree with NICE that the cut-offs for BNP and NT Pro-BNP should remain as described.	Thank you for your comment.
Wythenshawe hospital	Short	9	16-26	We find the advice on giving information to people with heart failure extremely helpful and considered.	Thank you for your comment.
Wythenshawe hospital	Short	10	1-11	Advice on first consultation is clear and useful.	Thank you for your comment.
Wythenshawe hospital	Short	10	17	We like this wording (diuretics). Please consider adding 'People whose heart failure do not respond to this treatment will need further specialist advice' (taken from lines 23-25 below).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	10	21-25	(Also full page 197 Lines 6-8). This is confusing. This should be removed since this is covered in lines 17-20 (see comment above).	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	10	26-29	Calcium channel blockers. (Also full Page 197 Lines 10-12 'Calcium-channel blockers. Avoid verapamil, diltiazem and short-acting dihydropyridine agents in people who have heart failure with reduced ejection fraction. [2003, amended 2018]'). Why have you singled out one class of contraindicated medications only? What about NSAIDs, glitazones, anti-arrhythmics, moxonidine etc? The ordering of these sections is odd. Would it not be better to have a section on how to treat HFREF (with a preamble as suggested in a later comment) and then have a section: 'Drugs to avoid in heart failure' ? This should be a section on contra-indicated medication and not simply calcium-channel blockers.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Wythenshawe hospital	Short	11	17-21	Inotropes. This should be removed from this document on chronic heart failure. It is covered in the NICE Acute Heart Failure Guideline and has little relevance here. It merely adds to confusion.	Thank you for highlighting this. The recommendation on inotropes has been removed.
Wythenshawe hospital	Short	11	1-8	Amiodarone. This would be better placed after treating heart failure with reduced ejection fraction section (section 1.5). The wording is appropriate.	Thank you for your comment. This has been moved to after treating heart failure with reduced ejection fraction.
Wythenshawe hospital	Short	11	9-16	Anticoagulants. The wording is fine but as per comment directly above, this would sit better in a separate section after disease modifying drugs with prognostic benefit.	Thank you for your suggestion. This was considered and the ordering of the pharmacological recommendations have been revised and now start with the treatment of HF with reduced ejection fraction followed by the management for all types of heart failure.
Wythenshawe hospital	Short	12	9-18	Salt and fluid restriction (also full page 114 lines 21-28). 'Do not routinely advise people with heart failure to restrict their sodium or fluid consumption. Ask about salt and fluid consumption and, if needed, advise as follows: restricting fluids for people with dilutional hyponatremia, reducing intake for people with high levels of salt and/or fluid consumption. Continue to review the need to restrict salt or fluid. [2018] Advise people with heart failure to avoid salt substitutes that contain potassium. [2018]' This is ambiguous. What is 'dilutional hyponatremia'? What are 'high levels of salt and/or fluid consumption'? Should a grossly fluid overloaded patient without dilutional hyponatremia and with normal levels of salt and/or fluid consumption not fluid restrict?	Thank you for your comment. The lack of evidence did not allow the committee to provide guidance on recommended thresholds for salt or fluid consumption; Instead the committee have advocated a tailored approach depending on individual circumstances. There is limited evidence in this area, but the committee acknowledged the negative impact restricting salt or fluid can have on patient's quality of life and decided that patients should not be routinely advised to restrict their salt and fluid consumption unless there are specific clinical circumstances where restriction is appropriate and examples of this have been provided.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We would recommend re-wording along the lines of: 'There is no robust evidence to inform the routine advice that people with heart failure should restrict their sodium or fluid consumption. However, clinical judgement should be used to consider applying this on an individual patient basis'.	
Wythenshawe hospital	Short	13	10-12	Recommendation 1.5.2 is ambiguous. What does 'haemodynamically significant valve disease' mean? There is no evidence for such a broad statement. This comment also applies to Main Document P198 Lines 5-6.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	13	13-16	Recommendation 1.5.3 'Do not routinely offer a beta-blocker to treat heart failure with reduced ejection fraction to people who also have atrial fibrillation. Be aware that beta-blockers may be offered to these people to manage heart rate or cardiac ischaemia': We believe this recommendation should be removed entirely from the guidance. There is **no** *a priori* evidence to support this recommendation but only a secondary, subgroup, analysis which introduces additional and unacceptable levels of bias and uncertainty. The recommendation is contrary to the *a priori* trial protocols of all the seminal heart failure beta-blocker outcome studies and all other recent national[1] and international[2,3] heart failure guidelines.	Thank you for your comment. The committee have reconsidered the evidence and the recommendation and agree that the recommendation may be misinterpreted and have the unintended consequence of beta-blockers not being prescribed for this population when they might be indicated. The committee also thought that the evidence might also be consistent with a potential difference between populations with heart failure with and without AF. The recommendation has been removed and the need for a prospective research study to be undertaken is discussed in the LETR.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The recommendation is overly simplistic and as such may ultimately be harmful in many cases. For example, does this statement apply to all types of atrial fibrillation (i.e. paroxysmal, persistent and permanent)? Does the recommendation intend to indicate that a heart failure patient with paroxysmal atrial fibrillation (AF) who is in sinus rhythm for the vast majority of the time should not be offered, and would not benefit from, a beta-blocker? Furthermore, the outcome of death or cardiovascular hospitalisation in the main evidence used to support this recommendation was borderline improved by beta-blockers (HR 0·89: 95% CI 0·80–1·01), with the wide CI and relatively small AF subgroup numbers impacting on marginal failure to achieve statistical significance.[4] Beta-blockers are also a class of medication with significant variation in their properties and mechanisms of action, including aspects such as cardio-selectivity. Does this recommendation apply to non-cardioselective beta-blockers such as carvedilol, for which there is some evidence of mortality benefit in patients with heart failure and atrial fibrillation?[5,6] The counter arguments to the draft NICE recommendation can be supported with similar weak evidence, for example a recent propensity-matched analyses.[7] All of this weak observational 'evidence' however should not be used to produce 'Do not routinely offer' recommendations due to the additional and unacceptable levels of bias.	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The meta-analysis supporting the recommendation[4] clearly shows that beta-blockers are safe and it cannot robustly refute some efficacy (as above). A 'do not routinely offer' statement also brings with it the risk of wholesale disinvestment and withdrawal of beta-blockers around the country. We do not have any evidence from beta-blocker withdrawal studies. There is real concern that patients – who have a high sympathetic drive and have blocked receptors – suddenly have catecholamine storm when beta-blockers are withdrawn. The sub-recommendation to 'manage heart rate' is also ambiguous and not necessarily evidenced based. For all of these reasons, but in particular the complete lack of evidence from randomised, controlled clinical trials, we believe this recommendation should be removed entirely. These comments also applies to Main Document P198 Lines 7-9 33. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				34. Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m 35. Yancy C, *et al.* 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation.* 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509 36. Kotecha D, et al. Efficacy of beta blockers in patients with heart failure plus atrial fibrillation: an individual-patient data meta-analysis. Lancet. 2014; 384(9961):2235-43 37. Swedberg K, *et al*. Prognostic relevance of atrial fibrillation in patients with chronic heart failure on long-term treatment with beta-blockers: results from COMET. *Eur Heart J* 2005;26:1303–1308 38. Joglar, J.A. et al. Effect of carvedilol on survival and hemodynamics in patients with atrial fibrillation and left ventricular dysfunction: Retrospective analysis of the US Carvedilol Heart Failure Trials Program. *Am Heart J;* 142 (3): 498-501 Cadrin-Tourigny J, *et al*. Decreased Mortality With Beta-Blockers in Patients With Heart Failure and Coexisting Atrial Fibrillation. *JACC: Heart Failure* 2017, 579; DOI: 10.1016/j.jchf.2016.10.015	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Wythenshawe hospital	Short	13	2	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with a preamble which explains the importance of disease modifying medications on mortality and morbidity in HF-REF. Such a message is needed to reinforce the importance of treatment.	Thank you for your comment. The short version of the guideline provides a quick reference to the recommendations therefore we do not add additional text to support recommendations. Discussion on the importance of treatments is included in the full guideline.
Wythenshawe hospital	Short	13	24	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P198 Lines 16	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Wythenshawe hospital	Short	13	27	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P198 Lines 19-22	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Wythenshawe hospital	Short	14	17	We feel that the example of 'dry cough' should be added, as essentially the side effect profile of ACEI and ARB are similar bar dry cough. This comment also applies to Main Document P199 Lines 5	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	14	19	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 6	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.
Wythenshawe hospital	Short	14	21	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 8	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					made by the health professional based on the needs of the individual.
Wythenshawe hospital	Short	14	3-12	We think these recommendations are good and we fully agree with them	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	15	10	We feel that 'symptoms' should be changed to 'any symptoms' and/or NYHA classifications added. This comment also applies to Main Document P199 Lines 23	Thank you for your comment. We consider 'symptoms of heart failure ' will be understood by health professionals treating people with heart failure, and those without expertise in managing people with this condition should refer to the specialist HF MDT.
Wythenshawe hospital	Short	15	11	The exclusion of urea from the standard monitoring requirements throughout the document is inappropriate and should be reconsidered. This comment also applies to Main Document P199 Lines 24	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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					change the wording to 'renal function profile' to reflect this.
Wythenshawe hospital	Short	15	13	We feel that an additional comment of 'disease modifying treatments in HF-REF should not be stopped due to asymptomatic low blood pressure alone' should be added. This comment also applies to Main Document P199 Lines 26	Thank you for your suggestion. The committee do not consider it necessary to apply this level of detail. Recommendations have been made for the monitoring of treatment including review of medication and any need for changes. Subsequent clinical decisions taken should be made by the health professional based on the needs of the individual.
Wythenshawe hospital	Short	15	2-4	We feel that this recommendation does not fit well at this stage (i.e. the prioritisation and it's stage in clinical reasoning) and that this recommendation should be moved to a later place in the document and amalgamated with the other statement on hydralazine-ISDN (i.e. Page 16 Line 20-24). Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines. This comment also applies to Main Document P199 Lines 15-18 5. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf Ponikowski P, *el al*. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur. Heart J*. 2016;37(27):2129-2200m	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope. The ordering of the pharmacological section has been reviewed and revised to start with treatment for HF with reduced ejection fraction followed by the management of all types of heart failure as this is a more logical order.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Wythenshawe hospital	Short	16	16-19	Sacubitril/Valsartan- 'See the recommendations in Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (NICE technology appraisal guidance 388)c': In an area of such clinical importance (i.e. mortality benefit) and change from previous NICE heart failure guidelines, why does the draft guideline not actually display these recommendations but instead leave the reader to access a NICE Technology Appraisal (TA) document? This approach is inconsistent; for example, with ivabradine (for which there is no evidence of mortality benefit compared to placebo, let alone compared to ACE inhibition), where the relevant TA recommendations are replicated in the draft guidance. Given this, we believe that the recommendations from NICE Technology Appraisal Guidance 388[1] should be replicated verbatim in this guidance to make the document easier for the reader. The guidance will be used by heart failure specialists and non-specialists – it is unrealistic to expect all readers of the document to cross reference across to TA 388. Failing to present the summary of recommendations will likely impact on many patients missing out on the opportunity to receive this life-prolonging, evidence-based intervention. Further, the Board of the BSH would also ask why the draft guideline fails to present advice as to how to initiate and monitor treatment with sacubitril/valsartan, as it does for ACEI, angiotensin receptor blockers, beta-blockers, ivabradine and MRA? Given that sacubitril/valsartan is a	Thank you for your comment. At the time of consultation it was not possible to include the recommendations within the guideline because the recommendations are within a separate publication TA 388. The sacubitril/valsartan recommendations has been included in full on publication of the guideline. As we are incorporating the recommendations made within the TA and not reviewing the evidence as part of the update of this guideline we are unable to advise on the monitoring of this medication.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				first-in-class medication with significant clinical importance, we believe that practical 'how to initiate' and monitoring recommendations, similar to every other medication with prognostic importance, should be displayed. This comment also applies to Main Document P200 Lines 20-22 National Institute for Health and Clinical Excellence. Technology appraisal guidance [TA388]. Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction, April 2016. Available at https://www.nice.org.uk/guidance/ta388	
Wythenshawe hospital	Short	16	20-24	'Considerations' for both indications for hydralazine-ISDN should be displayed at this stage: - Hydralazine and isosorbide dinitrate may be considered in symptomatic patients with HFREF who can tolerate neither an ACEI nor an ARB (or they are contra-indicated) to reduce the risk of death. - Hydralazine and isosorbide dinitrate should be considered in black patients with LVEF≤35% or with an LVEF <45% combined with a dilated LV in NYHA Class III–IV despite treatment with an ACEI, a beta-blocker and an MRA to reduce the risk of HF hospitalization and death This comment also applies to Main Document P200 Lines 24-27	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.
Wythenshawe hospital	Short	16	Before line 20	Remembering that guidelines such as this are mainly used by non-specialists, this section needs to start with	Thank you for your comment. The short version of the guideline provides a quick reference to the

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				a preamble which explains that the pharmacological treatments that come after are 'considerations' and supported with less robust evidence (i.e. less data showing beneficial effects on mortality and morbidity) and/or only applicable in small sub-groups of patients. Such a message is needed to reinforce the priorities of treatment.	recommendations therefore we do not add additional text to support recommendations. The full guideline provides detail on the evidence and discussion of the committee.
Wythenshawe hospital	Short	17	1-3	Digoxin is recommended for worsening or severe heart failure with reduced ejection fraction despite first and second line treatment for heart failure: We feel that this should be re-worded to 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in…..' 'Severe heart failure' is also ambiguous (i.e. Severe LVEF? Severe symptoms?) and should be changed to 'patients with symptomatic heart failure with reduced ejection fraction' Digoxin is also only indicated in such patients with sinus rhythm. The final wording should be 'on a background of 1st, 2nd and 3rd line treatments digoxin can be considered in patients with symptomatic heart failure due to reduced ejection fraction in sinus rhythm' Such an approach would be consistent with other recent national[1] and international[2] heart failure guidelines and the evidence base[3]. This comment also applies to Main Document P200 Lines 31-33 9. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 10. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1997;336:525–533	
Wythenshawe hospital	Short	17	13-22	(Section 1.6.1) This recommendation in the current NICE draft Guideline is contrary to evidence from the a priori trial protocols of all of the clinical studies underpinning the evidence base for the treatments that we know to improve outcomes for patients with heart failure due to Left Ventricular Systolic Dysfunction (LVSD). The recommendation has the clear potential to cause harm to patients, as it will without doubt encourage a conservative approach to the use of disease modifying therapies, in particular angiotensin-converting enzyme (ACE) inhibitors and mineralocorticoid antagonists (MRA), in the setting of a condition for which outcomes are poor and for which there is evidence from multiple randomised, controlled, clinical trials, of benefits to patients in both life expectancy and quality of life. Further, the Board of the British Society for Heart Failure is not aware of any	Thank you for your comment. In general, the committee felt the evidence showed the efficacy and safety of ACE, Beta-blockers and MRA drugs in patients with renal impairment. Patients with HFREF and CKD stage IIIa or less should be offered standard therapies with appropriate modifications to dosing and careful monitoring. The evidence in stage IIIb patients was more limited, and while this group would also benefit from standard HFREF therapies, the committee agreed that standard HFREF drugs should be considered in this group. In CKD stage IV, the side effects of all of these medications is likely to be increased. While there is not a substantial evidence base in this population, the committee agreed that standard HFREF treatment recommendations should generally be applied, subject to the consideration

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				published scientific evidence to support the apparently arbitrary thresholds presented in the draft guideline. We are concerned that the recommendation as presented in the current NICE guidelines document is not evidence-based, goes against the recommendations presented in all other recent national[1] and international[2,3] guidelines for the management heart failure, is likely to lead to inappropriate reduction or withdrawal of treatments which confer survival and symptomatic benefit on patients with LVSD. We believe this recommendation (Section 1.6.1) should be removed entirely. References 1. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 147- Management of chronic heart failure: A national clinical guideline. March 2016 Available at http://www.sign.ac.uk/assets/sign147.pdf 2. Ponikowski P, el al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur. Heart J. 2016;37(27):2129-2200m 3. Yancy C, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509	of individual risk factors and liaison with renal specialists as appropriate. The committee have reconsidered and revised the recommendations as follows: • offer the treatment outlined in section 1.4 **and** • if the person's eGFR is 45 ml/min/1.73 m^2 or below, consider lower doses and/or slower titration of dose of ACE inhibitors, mineralocorticoid receptor antagonists and digoxin. For people who have heart failure with reduced ejection fraction and chronic kidney disease with an eGFR below 30 ml/min/1.73 m^2, the specialist heart failure MDT should consider liaising with a renal physician. Monitor the response to titration of medicines closely in people who have heart failure with reduced ejection fraction and chronic kidney disease, taking into account the increased risk of hyperkalaemia. The committee considered eGFR to be the most appropriate way to direct treatment.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Wythenshawe hospital	Short	17	23-25	(Section 1.6.2) We are concerned that this recommendation may lead to inappropriate referral to renal services of some patients with heart failure and LVSD. We suggest that this recommendation (section 1.6.2) should be combined, in an amended recommendation, with section 1.6.4 (see below)	Thank you for your suggestion. The recommendations have been combined to consider liaising with a renal physician if the person has reduced ejection fraction and CKD with eGFR below 30 ml/mib/1.73 m2.
Wythenshawe hospital	Short	18	1-3	(Section 6.1.3) The Board of the British Society for Heart Failure agrees with this recommendation	Thank you for your comment.
Wythenshawe hospital	Short	18	19	We are concerned that the requirement to measure urea has been dropped from the 2010 guidelines. We are aware that in some primary care settings urea is no longer routinely measured with standard electrolytes and as such this suggestion may have been made to simplify electrolyte monitoring. However we firmly believe that to monitor heart failure patients safely urea needs to be measured. Heart failure management is dependent on treating congestion with diuretics and starting neurohumoral antagonists which have been shown to prolong life. The key to managing congestion is to give the correct amount of diuretics. In advanced heart failure with cardiac cachexia it is not unusual to have a normal or only mildly raised creatinine (the patients have reduced muscle mass) and the urea can seem disproportionately high. When patients dehydrate urea rises before creatinine and so we judge the need to alter diuretic therapy based on relative changes in urea and creatinine from baseline. We believe omitting the measurement of urea leaves patients at increasing risk of becoming dehydrated, which can lead to	Thank you for your comment. The committee noted that there is variation in the name (urea & electrolyte being a historical term) and components of a renal function test profile. The committee noted that many places in the NHS urea testing is no longer routinely available. The committee acknowledged that these tests might provide useful information but that this was outside the remit of this guideline. The committee agreed that the main focus of these tests is to assess renal function and noted associated guidance from NICE about the diagnosis of acute kidney injury (CG189). Therefore it agreed to change the wording to 'renal function profile' to reflect this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				hypotension, falls (and potentially limb fractures) and if an acute kidney injury (AKI) is diagnosed this may lead to withdrawal of life prolonging heart failure medication. The alternate scenario is that patients receive insufficient diuretic based on concerns regarding renal function; if the creatinine is seen to rise but the urea doesn't change this would suggestion a reduction in diuretic therapy is not required. Specialist expertise is often required to interpret the changes in electrolytes and make decisions about up-titrating or down-titrating medications. Whilst GPs may find this challenging at times the Heart Failure team have the necessary expertise to do this assuming they receive the necessary information (ie measuring urea as well as creatinine and eGFR).	
Wythenshawe hospital	Short	18	4-7	(Section 6.1.4) We are concerned that this recommendation is likely to lead to involvement of renal physicians in patients showing "deterioration" in renal function while prescribed RAAS inhibitor treatment, and indeed other treatments for heart failure. We are concerned at the use of the wording "……deterioration in kidney function that may be *caused by* heart failure medicines…", which is likely to lead to under-dosing of disease-modifying therapy in patients with LVSD. Reduction in eGFR is expected as part of ageing, and thus such changes are likely to occur in patients with heart failure. We are also aware that clinical trials have shown that in the context of deteriorating renal function, patients have better	Thank you for your suggestion and the references to other sources of information. The committee have reconsidered the recommendations and have removed recommendation 1.6.4. The committee have also revised the recommendation to offer people with heart failure with reduced ejection fraction and chronic kidney disease with an eGFR of 30 ml/min/1.73 m2 or above the same treatment as other HEFREF patients and if the person's eGFR is 45 ml/min/1.73 m2 or below to consider lower doses and/or slower titration of dosages of treatments.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				outcomes when prescribed a RAAS inhibitor, as compared to those who are not[1]. Thus there is compelling evidence to encourage continuation of these medications in these patient. Further, advice as to how to respond to changes in renal function, in particular eGFR, in patients currently prescribed RAAS blockers, are presented in the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. The recommendations presented in that document are based on the Renal Association/Resuscitation Council guideline on hyperkalaemia section on primary care (p78), on Think Kidneys Acute Kidney Injury guidance, on ESC guidelines, on the British National Formulary, and, in the context of the current NICE guideline, on NICE Clinical Knowledge Summaries. We suggest that Sections 6.1.2 and 6.1.4 should be amalgamated in to a statement along the following lines: "In patients showing deterioration in renal function during treatment with heart failure medications (in particular ACE inhibitors, angiotensin receptor blockers, mineralocorticoid antagonists and angiotensin receptor/neutral endopeptidase inhibitor), consideration should be given to alterations in the doses of these medications. Advice on this is given in	

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				the document "Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure"[2]. Reference: 1. Clark H, Krum H, Hopper I. Worsening renal function during renin-angiotensin-aldosterone system inhibitor initiation and long-term outcomes in patients with left ventricular systolic dysfunction. Eur J Heart Fail. 2014 Jan;16(1):41-8. doi: 10.1002/ejhf.13. Epub 2013 Dec 11. 2. Changes in kidney function and serum potassium during ACEI/ARB/diuretic treatment in primary care: A position statement from Think Kidneys, the Renal Association, and the British Society for Heart Failure. https://www.thinkkidneys.nhs.uk/aki/news/changes-kidney-function-serum-potassium-aceiarbdiuretic-treatment-primary-care/	
Wythenshawe hospital	Short	19	12	Section 1.8.1. This statement does not make sense as it is worded. It should be specified that you are referring to patients who have heart failure with reduced ejection fraction that is due to coronary artery disease. We thought this might be changed to read: 'In patients with HFREF and coronary artery disease consideration of revascularisation should be through a	Thank you for your comment. The committee reviewed the evidence for coronary artery bypass grafting and noted that only a small well defined population was potentially eligible for this intervention despite the high frequency of coronary artery disease as concomitant co-morbidity in patients with HFREF. It also noted

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				formal revascularisation MDT. Whilst it should not be routinely offered it might be appropriate in carefully selected patients.'	that clinical practice had moved on in this field and that trials of other interventional therapies were underway. The wording has been amended to reflect the presence of significant coronary artery disease.
Wythenshawe hospital	Short	19	16	Section 1.8.2. We are concerned that this recommendation implies that a patient needs to be 'failing' on inotropic or intra-aortic balloon pump (IABP) support before specialist referral for transplantation is considered. Cardiogenic shock carries a very poor prognosis and should be a trigger for consideration of referral, irrespective of whether the cardiogenic shock is 'refractory' or has been stabilised with inotropic or IABP support.	Thank you for your comment. The sections shaded in grey were not included in the scope for the update of this guideline and are therefore not part of this consultation. For details on what areas are included in this update please refer to the NICE website https://www.nice.org.uk/guidance/gid-cgwave0817/documents/final-scope
Wythenshawe hospital	Short	19	26	Section 1.8.3. Bullet point 2. It is unclear what is meant by the term 'partially deactivate'. The tachycardia treatment functions of a defibrillator are either on or off. A reader might think the authors are advocating turning off ICD shocks but leaving on anti-tachycardia pacing – this is generally inadvisable because anti-tachycardia pacing may be pro-arrhythmic. If the authors are referring to deactivation of tachycardia treatment function of CRT-D devices, then this should be more clearly worded.	Thank you for your comment. The committee agree the term is unclear and have revised this to remove fully and partially and have removed reference to potential harms of unnecessary shocks.
Wythenshawe hospital	Short	19	29	Section 1.8.3. Bullet point 3. Unnecessary shocks is not a recognised term. One assumes that the authors are referring to appropriate shocks that occur in the minutes, hours or days before an expected death in a patient with heart failure. These might be better	Thank you for your comment. The committee agree this term is unhelpful and have removed this.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				described as 'futile' shocks but this may only be apparent in retrospect.	
Wythenshawe hospital	Short	20	26	Section 1.10.1. This statement may be mis-interpreted. It only applies to patients with advanced heart failure who do not have hypoxaemia. As discussed in the full version, there is clear guidance from the British Thoracic Society that home oxygen should be offered to patients with advanced heart failure who have symptoms and a low resting pO2.	Thank you for your comment. We think the wording of the recommendation is clear. Whilst the Committee acknowledged the guidance made by the British Thoracic society, they made the recommendation based on the evidence reviewed for the guideline which did not demonstrate a benefit for the key pre-specified outcomes. However the committee did recognise there may be other comorbid conditions where people may benefit from oxygen therapy and this has been stated in the recommendation.
Wythenshawe hospital	Short	20	5	Section 1.8.4. There are two additional time points where the benefits and potential harms of a cardioverter defibrillator remaining active in a person with heart failure should be reviewed 1. After any appropriate or inappropriate ICD therapy 2. Before any planned replacement of the ICD pulse generator	Thank you for your comment. The focus of the review undertaken was specifically on discussing deactivation of ICDs with patients. Decisions around the management of ICDs is outside the scope of this guideline.
Wythenshawe hospital	Short	21	1	Section 1.10.2. It would be useful for the reader to include positive guidance about how to decide which patients should be offered referral to palliative care services.	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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Wythenshawe hospital	Short	21	10	Section 1.10.5. The NICE guideline does not specify that the patient must be in the last 2-3 days of life. We would suggest that the wording 'last 2-3 days of life' is replaced with 'last days of life' as per the NICE guideline	Thank you for your suggestion, however the guideline states it 'covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life'.
Wythenshawe hospital	Short	21	3	Section 1.10.3. This section should be expanded to include clinical triggers for consideration of a palliative care referral, such as , 1. More than 3 unplanned hospital admissions in the last 12 months 2. Important therapies are being withdrawn in the face of worsening heart failure and renal function	Thank you for your comment. The review question considered the use of prognostic tools to support decisions about involving palliative care services. Unfortunately no tool demonstrated sufficient accuracy to support their use. Other referral criteria was not considered therefore the committee were unable to make recommendations in this area other than general principles based on consensus opinion.
Wythenshawe hospital	Short	25	14-15	The statement "Intravenous and subcutaneous diuretics need to be administered by nursing or healthcare staff, whereas oral formulations do not" is not true in that a self-adhesive subcutaneous pump has been developed to be self-administered by patients.	Thank you for your comment and this information. We have updated this statement to reflect this.
Wythenshawe hospital	Short	27	3	We are concerned about the research question "Risk tools for predicting **non-sudden** death in heart failure". BNP/NT-proBNP are excellent markers of pump failure death. Predicting sudden death is far more of a challenge, and relevant when considering who to consider for expensive device-based therapies. Only one study found BNP to be predictive of sudden death (Berger *et al.* Circulation 2002;105:2392-7), a finding that has not been replicated. We would suggest that	Thank you for your comment. The question addressed by the guideline was to determine which are the most accurate prognostic risk tools at predicting patient mortality in the short term, to support decisions about involvement of palliative care services and the use of palliative care processes. The guideline did not consider tools to predict sudden death and therefore cannot widen the question.

Chronic heart failure in adults: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
13/03/2018 - 26/04/2018

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				the question should then be "Risk tools for predicting **sudden and** non-sudden death in heart failure'.	

Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links
Short	**Bayer plc**	**Current Situation** • Bayer does not have direct or indirect links with, or funding from, manufacturers, distributors or sellers of smoking products but Bayer provides pesticides for crops, which would therefore include tobacco crops. • Bayer is a member of the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) (http://www.coresta.org/) within the scope of recommendations of pesticides used for protection of tobacco plants. • It is also a member of country and EU business federations such as the Confederation of British Industry (CBI) and 'Business Europe', which include tobacco companies. **Past Situation** In 2006, Bayer and its subsidiary Icon Genetics piloted a new process for producing biotech drugs in tobacco plants. Icon Genetics was acquired by Nomad Bioscience GmbH from Bayer in 2012.

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Full	Alliance for Heart Failure	The Alliance for Heart Failure is not linked or funded by the tobacco industry. It is supported and funded by Bayer, Medtronic Limited, Novartis Pharmaceuticals UK Ltd, and Roche Diagnostics Ltd. XXX has received honoraria from Novartis and from Servier for participation in educational events and advisory boards. His department is in receipt of research funding from Novartis.
Full	Worcestershire Acute hospitals NHS trust – Dept of Cardiology	We have received a grant from Vifor Pharma to be used towards the development of an acute heart failure service.
Full	UK Clinical Pharmacy Association (UKCPA) Heart Failure Group	Members of the group that have contributed to this response have received honorarium from Novartis, Vifor and Servier