Perioperative Care in Adults

Consultation on draft guideline - Stakeholder comments table
07/12/2019 to 24/01/2020

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Association for Perioperative Practice	General	General	General	We will ensure that the information is included in our current review of our 2016 Standards and Recommendations for Safe Perioperative Practice, to ensure future adoption.	Thank you for your comment.
Association for Perioperative Practice	General	General	General	Thanks to the NICE review team who have worked on this significant guidance.	Thank you for your comment.
Association for Perioperative Practice	Guideline	General	General	Having reviewed the propose guideline text, I consider it a future excellent resource for our 7,000 + members. The use of this information, will I am sure benefit perioperative patients under their care across the UK operating theatre departments.	Thank you for your comment.
Association of Anaesthetists of Great Britain	Guideline	003	003	i) For many services this will be unachievable – resource implication is massive ii) Single point of contact seems sensible and will be welcomed by patients. It will require significant resourcing. I have seen use of clinical nurse specialists for this, but it was abandoned as seen as an expensive luxury. The alternative is someone in an admin role (e.g. surgeon's secretaries) but they would need clinical support for this. iii) over ambitious that there can be a single point of contact with the required availability in later lines	Thank you for your comment. The evidence review and the committee including the lay representatives highlighted the importance of giving the contact details of a person or a team of people to answer or direct specific questions about their care. We have edited this recommendation on patient information and support and now refer to a point of contact. In the rationale and impact is clear that this point of contact could be a team of people or a specific individual. This point of contact could also direct the person to someone who can answer questions about their care and may change throughout the perioperative journey. We have edited the committee's discussion of the evidence in evidence review A to make this clearer.
Association of Anaesthetists of Great Britain	Guideline	004	002	Again, over ambitious, with variable evidence to support such a strong recommendation	Thank you for your comment. There was a large body of evidence showing that hospital stays are shorter, postoperative complications less frequent and overall costs lower when people having elective major surgery follow an enhanced recovery programme (ERP). For full details of the evidence and for the committee's discussion of the evidence see evidence report B.
Association of Anaesthetists of Great Britain	Guideline	004	008	This is an opportunity missed to advance shared decision making. There is no reference to using SDM tools to ensure the patient receives what they need to decide. Only reference is to clinical tools.	Thank you for your comment. Consideration has been given to ensure that patients have the information and support they require throughout their perioperative pathway. We agree that shared decision making is pivotal; and guidance (recommendation 1.3.1) is also given to discuss the person's risks and surgical options with

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					them to allow for informed shared decision making. Shared decision making tools were not identified as a priority topic in the scope of this guideline. NICE is currently developing a guideline on shared decision making.
Association of Anaesthetists of Great Britain	Guideline	004	009	agree but to get best effect needs to be as part of an MDT discussion and for high risk cases surgeon, anaesthetist, patient and relatives all in the same room	Thank you for your comment. The potential for validated risk tools to be used by an MDT has been noted in the committee's discussion within the evidence review. The committee decided that an accurate risk prediction tool can have benefits in directing discussions between clinicians about the appropriateness of the planned surgery and whether it should proceed as planned. The committee agree this should also include patients and relatives in the decision making. The NICE guideline on patient experience is (NG138) cross referenced in the patient information section to underpin the importance of shared decision making.
Association of Anaesthetists of Great Britain	Guideline	004	018	As an example of why the guideline will not be easily implemented – all the cross referencing and linking to other NICE guidelines makes this an awkward resource to use	Thank you for your comment. A NICE pathway will be published at the same time as the guideline. The NICE pathway will bring together all NICE guidance on the topic in an interactive online flow chart.
Association of Anaesthetists of Great Britain	Guideline	004	022	Old people still have major surgery – surely the care delivered in pre-assessment clinics is suitable for patients of all age. Why are we segregating on age here? Missed opportunity again. Really important to pick up cognitive / memory issues ahead of surgery. POAC is the place.	Thank you for your comment. Older adults were included in all review protocols. The recommendation is applicable to older adults. The committee reviewed the evidence of preoperative optimisation clinics specifically for older people but were unable to make a recommendation given the lack of evidence. A recommendation for further research in this area was made.
Association of Anaesthetists of Great Britain	Guideline	005	007	oral iron poorly tolerated with a much slower loading than iv iron. Should consider iv iron for all cases needing additional iron and certainly for those who are intolerant. My trust has a good pathway. Contact Dr Lipp in anaesthetics, Norwich	Thank you for your comment. The clinical evidence included in this review did not show a clinically important benefit with IV iron compared to oral iron. Reference to people who cannot tolerate or absorb iron is included in the guidance given in NG24, referred to in section 1.3.3.
Association of Anaesthetists of Great Britain	Guideline	005	019	I can't understand why NICE hasn't taken the opportunity to lead on this area of regular poor practice	Thank you for your comment. The committee recognised that this is an important area to provide guidance. In the absence of evidence and the current variation in practice the committee were unable to make a consensus recommendation and therefore made a research recommendation. We hope that this research will benefit this decision making in the future.

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Association of Anaesthetists of Great Britain	Guideline	006	013	i) We allow milk in tea – no evidence it is an issue. We have endorsed the ESA guideline which allows milk in tea and coffee. Can't support NICE here ii) I feel you should reconsider a 'dash' of milk in tea or coffee, for many elderly patients if they cannot have milk in their tea they drink nothing	Thank you for your comment. The guidance given considers all evidence suitable for inclusion as well as expert consensus. The committee discussed this comment and reviewed the evidence and decided that the addition of a dash of milk was hard to quantify and would add ambiguity to the recommendation.
Association of Anaesthetists of Great Britain	Guideline	007	002	How did NICE manage to squeeze this in and yet missed out guidance on Vit K / POAC in the elderly? Whose agenda is being pushed here?	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Vit K/ POAC were not identified as priority areas during the scoping process. We have passed your comment about VitK/POAC onto the surveillance team at NICE to take into account when this guideline is considered for update
Association of Anaesthetists of Great Britain	Guideline	007	003	Rather than cardiac output monitoring would it not be better to look for fluid responsiveness which can be via PPV. No recommendation regarding device???	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been added to the terms used in this guideline and made clear in the cost-effectiveness and evidence reviews. The committee reviewed the evidence comparing devices but was not able to make a recommendation for any single device over another.
Association of Anaesthetists of Great Britain	Guideline	007	015	This is understandable, but the open-ended addition of items to the WHO checklist will lead to less thorough application – the impact of each individual step diminishes and the checklist speeded up. Methods to reduce never events should be formally assessed rather than assuming more checks will be successful.	Thank you for your comment. The WHO implementation manual is permissive of modifications being made to the checklist 'to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other". The committee highlighted the importance of making the checklist bespoke/relevant to your

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					environment. They also wished to incorporate local safety standards for invasive procedures. The committee considered that the recommendation is an important reminder that checklists evolve and safety alerts and learning from surgical 'never events' should be acted upon.
Association of Anaesthetists of Great Britain	Guideline	007	017	Where is the evidence for this statement	Thank you for your comment. The WHO implementation manual is permissive of modifications being made to the checklist 'to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other". The committee highlighted the importance of making the checklist bespoke/relevant to your environment. They also wished to incorporate local safety standards for invasive procedures. The committee considered that the recommendation is an important reminder that checklists evolve and safety alerts and learning from surgical 'never events' should be acted upon.
Association of Anaesthetists of Great Britain	Guideline	008	002	Define a specialist recovery unit? Completely unachievable - useless statement.	Thank you for your comment. A definition has now been added to the recommendation.
Association of Anaesthetists of Great Britain	Guideline	008	003	What does this mean?	Thank you for your comment. Definitions of major complex or high risk surgery have now been added to the section 'Terms used in this guideline'.
Association of Anaesthetists of Great Britain	Guideline	009	008	NSAIDS no comment on those with PU disease or renal impairment or sepsis which could result in renal failure see, S Cavalier	Thank you for your comment. This is covered in recommendation 1.6.1, which recommends taking into account clinical features including comorbidities and renal and liver function. The committee's discussion of the evidence has been amended in evidence review N1.
Association of Anaesthetists of Great Britain	Guideline	009	009	i) Can't support this statement. There are many situations where NSAIDs are not appropriate to use immediately post op. ii) I have NOT read the detailed evidence review on analgesics, but am surprised that NICE make such a blanket statement about the utility of NSAIDs. There are many anecdotal reports of side-effects. When one takes into account that some operations are associated with a significant risk of acute kidney injury (e.g. TKR, THR), would it not be	Thank you for your comment. NSAIDs would be prescribed in accordance with the contraindications in the BNF including acute kidney injury. This is covered in recommendation 1.6.1.

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				better to temper the recommendation with a warning about use in procedures with high-risk of AKI?	
Association of Anaesthetists of Great Britain	Guideline	009	026	Obviously not following what most centres are doing – spinal opiates and LA wound catheters.	Thank you for your comment. The committee decided that there was insufficient evidence to support a recommendation for spinal opiates but acknowledge their utility in their discussion. LA wound catheters were not prioritised by the committee for inclusion in the review protocol.
Association of Anaesthetists of Great Britain	Guideline	010	003	Decrease opioid use may well be due to increased sedation afforded by singe does gabapentin – question the evidence for immediate post op analgesia effect	Thank you for your comment. Evidence showed that a single dose of gabapentin can lessen postoperative pain and reduce the amount of opioid needed. However, the studies used a range of doses and administered the gabapentin at different times, so the optimal dose and timing of administration remain uncertain. The committee have therefore now made a research recommendation.
Association of Anaesthetists of Great Britain	Guideline	General	General	As NICE only makes a recommendation where there is definite evidence, the result is a document that is not particularly aspirational.	Thank you for your comment. The experience and opinion of the committee was used in addition to evidence to make recommendations. Research recommendations have been made on topics with limited evidence and where consensus recommendations could not be made
Association of Anaesthetists of Great Britain	Guideline	General	General	There are more than 2600 pages of supporting documents. The short version is 26 pages. Could not a summary of the evidence be produced that is less than 2600 but would be a useful resource to clinicians looking to implement the recommendations in the 26 page document?	Thank you for your comment. We acknowledge that the evidence reviews are large but the rationale and impact sections appear as drop-downs under the recommendation. These summarise the committee's discussion of the evidence and the impact of the recommendation on practice. These sections also link to the full evidence reviews
Association of Anaesthetists of Great Britain	Short version	General	General	There is much generalisation. For example, the recommendation about avoiding a tight blood glucose regime in those who are not Type 1 diabetics does not state that targets should be used in Type 2. Further, it seems to imply that the recommendation includes non-diabetics (i.e. blood sugar control in non-diabetics). Does it? At first sight it may seem that these are not included, but of course even non-diabetics may have an abnormal blood sugar, e.g. if given a large dose of dexamethasone. Some of this detail may be in the appendices/supporting documents, but there is risk of missing it if the	Thank you for your comment. The committee could not recommend a target as there was insufficient evidence (please see the committee's discussion of the evidence in evidence review K). We have edited the recommendation to make it clearer it is for people with type 2 diabetes and non-diabetics.

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				important caveats/explanations/context are not included in the short version (which is what most people will read).	
Baxter Healthcare	Guideline	006	006	Intraoperative Care Baxter believe the application of Continuous Renal Replacement Therapy (CRRT) intraoperatively should be considered. Evidence demonstrates the use of CRRT therapy can potentially improve the outcomes of patients undergoing Orthotopic Liver Transplantation (OLT) (Douthitt, L. 2012).	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Continuous renal replacement therapy was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.
Baxter Healthcare	Guideline	006	006	Baxter believes blood purification should be considered in complex patients and included in the intraoperative and postoperative care section. Blood purification within the scope of patients who have required complex abdominal care and the requirement for critical care and renal replacement therapy. The application of Endotoxin management strategies remain focused on Antibiotic treatment, fluid management and potential revisits to a surgical environment mixed with time. In reality the fragility of this patient cohort may incur a collection of complications that would impact on the morbidity, mortality and QALY. The suggestion stems from the multiple conclusions that we are seeing in literature reviews of blood purification when applied in these patient cohorts on technology that is available in 70% of Critical Care Units. Monard et al (2019) Extracorporeal Blood Purification Therapies for Sepsis provides an overall view of available literature. Alongside this Dr Broman (2019) study on Endotoxin and cytokine reducing properties of the oXiris membrane in patients with septic shock: A randomized crossover double-blind study ascertained that CRRT with the haemofilter provided effective removal of endotoxin and TNF-α, IL-6, IL-8 and IFNγ in patients with septic shock-associated acute renal failure and that this may be associated with a beneficial hemodynamic effect.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Blood purification was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.

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				This avenue of care he argues is based on Cytokines that are known to mediate the host response to infection, but their excessive release can contribute to organ damage and reduction in circulating levels may therefore be beneficial. Importantly, indiscriminate removal of all cytokines may impair immune regulation; however, when one or more cytokines is present in excess, as during sepsis, the proportion removed by adsorption will be greater than that of cytokines present at lower concentrations, thus, in theory, helping restore cytokine balance.	
Baxter Healthcare	Guideline	006	006	The intraoperative patient who becomes metabolically deranged whose status sits outside the treatment conventions of the anaesthetist and surgeon should be considered. Citrate anticoagulation CRRT should be considered for the correction of the complex patient primarily as this does not provide systemic anticoagulation. This practice appears to be growing from several interviews with senior Anaesthetists from the UK. The proposition provides opportunities where the status quo of intraoperative care may need to be questioned and supported with both Critical Care technology and experience.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Citrate anticoagulation Continuous renal replacement therapy was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.
Baxter Healthcare	Guideline	008	002	In line with specialist recovery areas, Baxter believes this should be extended to include specifics around the postoperative cardiac patient and the use of CRRT. Clinical evidence suggests in critically ill patients with Acute Kidney Injury (AKI), early Renal Replacement Therapy (RRT) compared with delayed initiation RRT reduces mortality over the first 90 days (Zarbock, A. et al, 2016).	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. The guidance given is for all people undergoing complex and major surgery. We will make the surveillance team as NICE aware of your comment.
Baxter Healthcare	Guideline	008	002	In line with the extension to include specifics around the post-operative cardiac patient, consideration should be given to the safety aspects of citrate anticoagulation and the impacts this has on the reduction in blood transfusions as discussed in the clinical evidence (Oudemans-van Straaten, HM. et al. 2011, Monchi M, et al. 2004, Kutsogiannis DJ, et al. 2005, Betjes MG, et al. 2007, Oudemans-van Straaten, HM. et al. 2009, Hetzel GR, et al. 2011, Stucker F, et al. 2015).	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We will make the surveillance team as NICE aware of your comment.

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				KDIGO guidelines also state (5.3.2.2) for anticoagulation in CRRT, we suggest using regional citrate anticoagulation rather than heparin in patients who do not have contraindications for citrate.	
British Dietetic Association	Evidence review G	005	1.1	**Review question: Does nutritional screening in preoperative assessment improve surgical outcome for adults?** We do not feel this was an appropriate question to ask as screening alone can't improve post operative outcomes, as it's the nutritional intervention that will achieve this. It would be helpful to review three things here: What is the most effective nutritional screening tool to identify those at risk of malnutrition prior to surgery? Do nutritional interventions in the pre-operative period improve surgical outcomes for adults? As research demonstrates that it does, screening should be recommended to identify those that will benefit from nutritional intervention. What nutritional intervention is most effective at improving surgical outcomes for adults?	Thank you for your comment. The committee agree that screening alone can't improve post-operative outcomes it has to be acted upon. It was outside of the scope of this guideline to comment on how to manage preoperative nutrition needs and the malnutrition NICE guideline on nutrition support for adults is cross referred to support this clinical decision making. The screening recommendations in NICE guideline on nutrition support are not specific to surgical populations and the committee decided that it was important to evaluate the appropriateness of pre-operative screening to identify the people that required intervention before surgery. Your comments have been passed on to the surveillance team to take into account when this guideline is considered for update.
British Dietetic Association	Evidence Review G	005	1.3	We feel the intervention in the PICO question should have been limited to validated screening tolls only. Albumin levels alone can't be used as a measure of nutritional status as altered due to inflammation, hepatic or renal impairments.	Thank you for your comment. The committee appreciate that there may be limitations to the use of albumin levels alone as a method of nutritional screening but recognised it may have use in nutritional assessment and so considered its inclusion .in the evidence review.
British Dietetic Association	Evidence review G	007	1.7.2	**There are no costs associated with nutritional screening as it is conducted during a preoperative assessment and it is standard practice to measure a patient's nutritional status, for example, measuring body mass index or albumin levels**. Need to remove "Or" within measuring body mass index or albumin level. Measuring albumin level is not a reliable marker for measuring nutritional status alone. We would instead recommend rewording this	Thank you for your comment. We have made the edit you suggested. We agree that these are useful research recommendations. However, the guideline's research recommendations are formed to highlight gaps in the evidence in the reviews that were undertaken for the guideline. Your suggestions have been passed to the

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				to … **patient's nutritional status using a validated screening tool, for example MUST.** Whilst it is standard practice to measure nutrition status, audits demonstrate it is not completed well or accurately. We would recommend an additional research question be added here, for example: Is nutritional screening completed consistently for pre-operative patients? How accurate are result from validated nutrition screen tools?	surveillance team at NICE to take into account when this guideline is considered for update.
British Dietetic Association	Guideline	006	001	Nutrition assessment and nutrition screening are being used interchangeably but they are very different. Nutrition assessment is a systematic process of collecting and interpreting information in order to make decisions about the nature and cause of nutrition related health issues that affect an individual (BDA), 2012). This includes interpreting anthropometry, biochemistry, clinical, environmental and social history, diet history and function tests e.g. sit to stand. Nutritional screening is a brief risk assessment which can be carried out by any healthcare professional and which may lead to a nutritional assessment by a dietitian (BAPEN, 2020). Please clarify whether you are referring to nutrition assessment or nutrition screening. It would seem from Evidence review G that the PICO question was referring to screening. In which case please change this from nutrition assessment to nutrition screening with the recommendation changing to: 'Offer preoperative nutritional assessment to people having intermediate, major or complex, surgery.'	Thank you for your comment. The wording of this recommendation has been amended.

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British Geriatrics Society	Guideline	General	General	This guideline unfortunately represents a missed opportunity. The scope is too broad with the inclusion of all specialties and all types of surgery and as a result this limits the usefulness of the guideline. Essentially it recommends using several interventions which are already routine care in the majority of UK trusts and will have minimal impact as a result.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. The guideline focuses on areas that were highlighted in the scoping phase of the guideline, in particular those areas that were identified as controversial or where there is variation in care across the NHS.
British Orthopaedic Association	Guideline	003	007 - 008	This may be very difficult in unplanned care, as well as over weekends and public holidays. For unplanned care in particular, patients with multiple conditions (major trauma, polytrauma) often need more than one responsible clinician, and care may change hands throughout an admission i.e. ICU, various surgical specialties.	Thank you for your comment. In response to stakeholder comments regarding the resource implications of a single point of contact we now refer to a point of contact (which may be a person or a team of people). This allows decisions to be made locally about how to deliver this recommendation.
British Orthopaedic Association	Guideline	004	001 - 005	Enhanced recovery programmes are recommended for elective patients. Unplanned patients are often the frailer/more sickly patients and so it should be made explicit in the research recommendations that enhanced recovery programmes should be recommended for unplanned admission too.	Thank you for your comment. We have made it clear that the research recommendation includes unplanned surgery.
British Orthopaedic Association	Guideline	004	009 - 016	There have been significant improvements in outcomes from surgery in recent years. The scorings systems quotes are not validated in the recent past for the NHS within orthopaedics. We suggest the use of the term recognised rather than validated to avoid stifling innovation when big data will support better tools. In any event, pre-operative risk stratification tools are not routinely offered to most patients. It will have significant resource implications, but may be the right thing to do. We would suggest this is done for Major or complex surgery at most, and even that will be a significant change from current practice.	Thank you for your comment. The committee decided that a form of risk assessment, including a risk stratification tool, should be completed for all surgery. The committee decided that this tool could simply be recording the ASA status of the patient for lower risk, less complex surgery. This has been outlined in the committee's discussion of the evidence in evidence review C.
British Orthopaedic Association	Guideline	005	006 - 008	Low dose iron in older patients has no evidence base at all, and we are not sure this fits NICE level guidance. The fact that it is a research recommendation confirms this.	Thank you for your comment.

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British Orthopaedic Association	Guideline	005	General	This recommendation is only relevant to the elective patient and no guidance is given for the unplanned admission. The BOA would query why they were excluded as there is significant debate over the need for pre-operative transfusion in the older, frail patient.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Pre-operative transfusion was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update. The NICE guideline on blood transfusion is cross referred to. Although the evidence reviewed included cohorts of people undergoing elective surgery, the guidance given does not exclude people with unplanned admission. The recommendations made in the blood transfusion guideline account for people who are diagnosed with iron-deficiency anaemia, and for whom the interval between the diagnosis of anaemia and surgery is predicted to be too short for oral iron to be effective.
British Orthopaedic Association	Guideline	006	008 - 013	"Clear fluid until 2 hours pre-op" is an outdated statement, and European guidelines are more relaxed.	Thank you for your comment. There was insufficient evidence to support a recommendation on clear fluids for less than two hours before surgery. We have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.
British Orthopaedic Association	Guideline	008	General	The recommendation on the use of NSAIDs is not consistent with previous NICE guidelines. The recommendation in the hip fracture guideline to avoid NSAIDs was made due to the age and frailty of the patients, rather than because of the hip fracture. In the subsequent guideline on non-complex fractures, this was then made explicit. In addition, in the guideline on non-complex fractures, the use of NSAIDs was only mentioned as a possible alternative in the initial phase of management as there was concern about longer term use on fracture healing.	Thank you for your comment. As hip fracture is a current NICE guideline we have kept the cross reference.
British Orthopaedic Association	Guideline	General	General	It would be helpful if, in the introduction, it was explicit that this guideline is intended to apply to all peri-operative patients or just those with a planned admission.	Thank you for your comment. We have edited the context to make it clear that the guideline covers unplanned surgery
Centre for Perioperative Care	General	General	General	The document is very secondary care orientated but there is nothing about working with general practice to optimise things that might have an impact. For example, improving diabetic care, losing weight, improving muscle mass etc. prior to surgery. There is also nothing	Thank you for your comments. In the scope of the guideline we recognise that some aspects of pre-operative assessment could take place in the community. However, primary care was not identified as a priority area for the scope of this guideline. In the

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				from what I can see about the "hand over" back to general practice. There is a lot of work going on with the Centre for Perioperative Care and it does seem to miss many of the things being sensibly discussed there.	scope of the guideline we state that we will cross-refer to existing NICE guidance on lifestyle modifications. The committee anticipate that the recommendations on patient information and support will facilitate discharge back to community. This guideline is intended to be read alongside the NICE guideline on patient experience in adult NHS services and there is a section on the importance of transitions and continuity of care.
Centre for Perioperative Care	General	General	General	We are delighted that NICE has prioritised a guide on perioperative care. Other NICE guidance has been instrumental in changing practice by providing clear recommendations for clinicians and clear standards for Trusts and commissioners to assess against. There are, however, major concerns within the NICE guidance on perioperative care in adults as currently drafted. There is a real risk that this will not propel improvements forward and may create additional work for the wrong staff at the wrong time. 1.1 Information and support for people having surgery Recommendation 1.1.1 Single point of contact should be removed as it goes against the prevailing ethos of team-based care. Whilst it is useful to have a 'named contact', information should be available from all members of the team at different points. People will pick up things from different team-members, for example, a pre-assessment nurse may have a particular rapport with a patient. Furthermore, attention should be given to multiple other ways of accessing information that does not create an unrealistic expectation from over-worked individual staff-members. Patients and their families often have time to look at websites and/or read leaflets and find it empowering to do so. The NICE evidence review highlights that patients want information that is consistent and available when they need it and patients report difficulty recalling information given to them. Different NHS Trusts have different leaflets and electronic information available. Sometimes budgets do not prioritise printing leaflets. New staff may not be told that written information or links exist and these may not be updated.	Thank you for your comments. • Single point of contact. The evidence review and the committee including the lay representatives highlighted the importance of giving the contact details of a person or a team of people to answer specific questions about their care. We have edited this recommendation on patient information and support and no longer refer to a 'single' point of contact. and have removed reference to it remaining the same throughout.. We have edited the committee's discussion of the evidence in evidence review A to make this clearer. The committee recognise the value of the recommendations you suggest but these are not specific to perioperative care and we have cross referred to the NICE guideline on patient experience which makes specific recommendations on the provision of information. • Risk scoring wording The committee decided that an accurate risk prediction tool can have benefits in directing discussions between clinicians about the appropriateness of the planned surgery and whether it should proceed as planned. The committee accept that the examples highlighted are better suited to certain types of surgery and these have been removed to emphasise that the risk assessment is also made and discussed with the patient, rather than in an MDT based on histological and radiological features. This has been added to the 'why the committee made the recommendation' section. In the committee discussion of the evidence it outlines that being able to quantify morbidity risk allows planning for post-operative

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				It would be better to add some recommendations that could be used to monitor and improve the availability of information. NEW suggested recommendations are: • Clear information should be available for every stage of the patient's journey. This should be reviewed annually by the healthcare team with patient involvement. • Audits should be conducted on whether information is used. • Every patient should have a clear letter containing their diagnosis and the treatment plan • Each Trust should keep written and electronic information for patients up to date. Recommendation 1.1.2 'remain the same person' adds minimal value. It goes against the new ethos of respect for healthcare workers' own work-life balance; it is at odds with the new team-working ethos and perpetuates traditional hierarchical presenteeism that can limit change. For this section on information, it is welcome to have such a strong patient voice in the narrative. There is a wide range of patients, with differing needs, so a wide range of information options should be available and quality assured. Item 1.2 Enhanced recovery programmes NICE's endorsement of enhanced recovery programmes should help improve wider uptake. Item 1.3 Preoperative care The recommendation 1.3.1 on Risk scoring needs revising as it may otherwise cause increased work by the wrong staff at the wrong time to be useful. Practicalities are needed. Some operations and some patients have low operative mortality, so adding a blanket scoring requirement across adult surgery will add time and cost. Furthermore, the document suggests NICE is recommending POSSUM scoring and this can only be done after blood results are available. In the real	destination, discussions about recovery or convalescence and the anticipated clinical course. We have added the importance of using risk tools to frame discussions about reducing risks to the rationale for the recommendation on risk tools. We have added a discussion on the teachable moment to the committee's discussion of the evidence in evidence review C. The WHO implementation manual is permissive of modifications being made to the checklist 'to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other. The committee highlighted the importance of making the checklist bespoke/relevant to the local environment. The committee disagree that 1.4.9 should be removed it, it is an important reminder that checklists evolve and safety alerts and learning from surgical 'never events' should be acted upon. The committee agree that pre-implantation checks of implants and handing out of histological or other specimens is important however the committee recommendations on safety checklists are deliberately non-specific to avoid focusing on a particular area of the surgical pathway and have not added this suggested recommendation. • Non-pharmacological pain management **It was not possible to address all areas of perioperative pharmacological pain relief and this area was not highlighted as a priority area requiring guidance by the committee. The areas selected were considered to be areas where practice was controversial or there was variation across the NHS.** The guidance highlights that a key aspect of pain management is to promote DREAMING (drinking, eating, and mobilising) (see the committee's discussion of the evidence in evidence review N1)

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				world, this may mean it is not done until after pre-operative assessment by a nurse. It would be better to recommend other scoring systems that can feed into the decision-making with the patient, surgeon and team about whether to operate; for example, NICE could recommend "the SORT score" http://www.sortsurgery.com/. It would also be useful to highlight that all decisions should be made with the patient, rather than in an MDT based on histological and radiological features. In Section 1.3.2 Lifestyle modification it is disappointing that there is not greater emphasis on the 'teachable moment'. In addition, a small improvement in words would encourage the new ethos that this is everyone's responsibility and patients should get 'match fit' for their operation. SUGGEST change to: 'It is clear that complications are reduced and psychological wellbeing is improved if patients modify their lifestyle. This is often a 'teachable moment'. Health improvements can continue after the surgical episode is concluded. 1.3.2 Discuss lifestyle modifications with people having surgery, for example stopping smoking. Follow the relevant guidance. In addition, ensure that the physical demands of post-operative mobilisation are highlighted by a regular activity programme pre-operatively.' Section 1.4 Intraoperative care Regarding WHO checklists, recommendation 1.4.9 should be removed. The concept of adding items to the WHO checklist to reduce 'never events' is simplistic. Hospitals that have overly complex check lists can find these overburden staff and hinder good communication. SUGGESTED NEW possible recommendation:	

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				'A pre-implantation check of implant and the handing out of histological or other specimens (and the labelling, recording of this) should be done in a similar manner to the WHO checklist, with silence, attention and a 'sterile cockpit'. Section 1.6 In section 1.6 Pain management, it is disappointing that only pharmacological methods are included. There are many non-pharmacological methods that should be emphasised. SUGGEST addition: Post op pain: Patients should be advised on the benefits of exercise in reducing pain and swelling. Elevation and gentle moving of fingers and toes reduces swelling and pain. Advice should be given about constipation and fluid intake optimised. SUMMARY: The NICE guidance should have potential to improve care by providing guidance for clinicians and standards for quality assurance. There are several areas where this draft guidance could be greatly improved	
Centre for Perioperative Care	Guideline	General	General	I have a problem with this sort of guideline. In the same way as I have a problem with a guide we have just produced in RCS "Organising Operating Lists". We know what good looks like and I don't think NICE adds anything with this document. I don't think this is the sort of subject NICE was designed to comment on. NICE is better assessing well demarcated subjects; perioperative care is too nebulous.	Thank you for your comment. The committee recognise that this is a broad set of recommendations covering a wide range of topics. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. We have aimed to provide guidance in areas where there is current variation in practice across the NHS or uncertainty. This guideline highlights areas where research is needed to inform future guidance. Any future updates of the guideline may expand on the recommendations. We have now added this to the context section of the guideline.
Centre for Perioperative Care	Guideline	General	General	Thoughts on the first line of this NICE guidance: 2. 1.1 Information and support for people having surgery 3. 3 Single point of contact Allocate a single point of contact (such as a clinical nurse specialist or surgical team) to each person having surgery. Ensure that the allocated point of contact:	Thank you for your comment. The evidence review and the committee including the lay representatives highlighted the importance of giving the contact details of a person to answer or direct specific questions about their care. The committee have edited the recommendation and now recommend a 'point of contact' to reflect that there are a variety of different ways that this could be provided. In the rationale section we explain that the point

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				· remains the same throughout the person's surgical care whenever possible · is available before, during and after surgery to discuss queries or concerns the person and their family and carers (as appropriate) have. Thoughts on one of the last lines: DRAFT FOR CONSULTATION 1. 1 Context 2. 2 Approximately 11 million people have surgery each year in the NHS. Over half are 3. 3 having elective (non-emergency) procedures. 1.1. NICE needs to give guidance on how to implement this. Most people will read 1., laugh and then dismiss this as impossible.	of contact could be a team of people or an individual and may vary throughout the perioperative journey. This point of contact could also direct the person to someone who can answer questions about their care. We have edited the committee's discussion of the evidence in evidence review A to make this clearer. The committee confirmed the importance of providing people with a point of contact to improve patient outcomes and to reduce unnecessary admissions. In addition to highlight this good practice the NICE guideline on patient experience has been cross referred to.
Centre for Perioperative Care	Guideline	General	General	The pages from 12 onwards that list recommendations and guidance on additional evidence stands out as an opportunity for the input of the Centre for Perioperative Care (CPOC) and could align well with the Guidelines for the Provision of Anaesthetic Services (GPAS) scoping document on research topics. In particular, it would be helpful to match their suggestions on lack of evidence with knowledge that we already have in the following areas: · optimisation clinics for older persons · iron supplementation · ERP and specialist recovery areas · risk assessment and SDM · fluid management Overall, the focus is too much on increased/decreased staffing issues; cost escalation/reduction; reduced hospital stay times - rather than centred on what the patient would benefit from throughout the perioperative care pathway. The document would be additionally strengthened by hyperlinks to Fitter Better Sooner and Doug which give both patients and healthcare professionals a solid and practical overview of Perioperative Care.	Thank you for your comment. The research recommendations were made when the evidence reviews resulted in limited evidence such that the committee could not make a recommendation. NICE guidelines make research recommendations only on topics where the evidence review has been conducted and the evidence has been searched for. The committee are pleased to see that some of the research recommendations in the guideline do overlap with the ones you highlight (optimisation clinics, iron supplementation, ERP and specialist recovery areas). The outcomes for each evidence review included quality of life and other patient related outcomes. All of the evidence reviews evaluate both clinical and cost effectiveness and these are both taken into account in the committee's decision making. The recommendations in the guideline are developed using the methods outlined in Developing NICE guidelines: the manual (2018) and are quality assured through that process. Non-NICE guidelines are not linked to in NICE guidelines. The NICE implementation team will be looking at how to support the implementation of the guideline.

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				This is a typical overview guideline by NICE which tries to deliver a rational for perioperative care, reveals the (apparent) lack of evidence that is currently available as a backstop to progress but ultimately is short on the 'how to implement', on a day to day basis, the recommendations. And, the recommendations are actually quite small in number!	
Centre for Perioperative Care	Guideline	General	General	The format is so uneasy. NICE think this will have sway - I very much doubt it. Simple things like the fasting recommendations quoted are out of date and what they have decided to recommend or not seems less than rationale despite the link to same. Don't mention never events. Why bring in such a controversial and totally random thing such as never events (we all know they are random events because we have followed the science) and expect clinicians to take this credibly. The WHO safety checklist could have been cited for so much more good and been left credibly alone. These guidelines will seem in the main irrelevant to many colleagues.	Thank you for your comment. The guidance given has been developed with consideration for clinical and cost-effectiveness data and expert consensus. The interventions and outcomes included in each review were considered to be priority areas requiring guidance.. Never events were considered to be an important outcome in the review of efficacy of surgical safety checklists. The committee decided that Never Events apart from other types of serious incidents are regarded as being wholly preventable when appropriate safety protocols are followed by healthcare professionals.
Centre for Perioperative Care	Guideline	General	General	Sadly I found this to be an example of a NICE guideline that is uninspiring, unwieldy and which will fail to capture the attention or significantly influence the practice of clinicians delivering perioperative care on a daily basis.	Thank you for your comment. The committee recognise that this is a broad set of recommendations covering a wide range of topics. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. We have aimed to provide guidance in areas where there is current variation in practice across the NHS or where there is uncertainty. Any future updates of the guideline may expand on the recommendations. We have now added this to the context section of the guideline.
Centre for Perioperative Care	Guideline	General	General	Although NICE guidance is mainly aimed at health care professionals, my understanding is that it is also intended that patients should read the guidance. This document states ' nice guidelines should help patients make informed decisions and specifically includes on the first page under 'Who is it for" Adults having surgery, their families and carers I have just tried reading the document as ' an adult having surgery ', deliberately putting aside any knowledge I already have of NICE	Thank you for your comment. We aim for the rationale and impact sections of the guideline to be accessible for all readers. On the NICE website there is a section entitled 'information for the public'. As well as summarising what the guidance covers it will also provide links to websites that can provide further information.

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				guidelines from my years working in the health service. Unfortunately, unless I have missed something, my conclusion is that the document is difficult for patients to navigate and understand and very unlikely to add to any understanding by someone approaching surgery, indeed for some patients and their families it may well increase their worry and apprehension. I don't think this is unique to this particular NICE guidance and fully recognise that patients are not the key target for the document. However, given the growing number of supportive and helpful documents available elsewhere for patients, and their families, including some produced by RCoA, I would recommend a maximum one page specifically for patients with a very brief and easy to read document linking to other patient friendly sources of information and support. If this is outside the remit of NICE then I suggest this should be made clear to patients and their families early on in the document.	
Cochrane Pain, Palliative and Supportive Care Review Group]	Evidence Review A	054 - 055	012 - 013	Joanne Abbott: The MEDLINE strategies appear to have gone rather haywire. In Evidence Review A, search strategy lines 16-30 are a repetition of lines 1-15, which means that lines 35, 37, 45 and 71 don't work. I suspect that it's – hopefully – a mistake in transferring the strategy to paper, rather than in the actual running of the search, but it needs to be corrected. I haven't looked at all the documents but the first 3 all have similar problems with the MEDLINE strategy so they should check them all.	Thank you for your comment. The search strategies have been checked and there was an error with the formatting which has now been corrected.
Cochrane Pain, Palliative and Supportive Care Review Group]	Guideline	General	General	Dr Amanda C de C Williams: I think an opportunity has been missed to integrate a large and consistent literature (which does not appear to have been searched) on reducing pre-operative and post-operative anxiety improving patient experience and often reducing analgesia use, use of sleep medication, and length of hospital stay. Information giving is a very brief part of this, and the guidelines as far as they go are fine, but they just don't recognise the extent to which anxiety needs more than single delivery of information, often without written backup.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Pre and post-operative anxiety was not identified as a priority area during the scoping process but this area has been acknowledged within the guidance on patient information and support in the committee's discussion of the evidence in evidence review A.

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Cochrane Pain, Palliative and Supportive Care Review Group]	Guideline	General	General	Professor Andrew Moore: The guideline covers a lot of ground with a lot of (mainly small) trials for each of the topics, but with some comparisons there is almost no information, for example 1 trial with 24 patients is not evidence.	Thank you for your comment. In accordance with Developing NICE guidelines: the manual (2018) all evidence that meets the protocol criteria is included and assessed using the GRADE approach or similar. The experience and opinion of the committee can be used to make recommendations where there is limited evidence.
Deltex Medical	Comment form question 1	General	General	**Q. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.** A. Currently NICE is heavily promoting 'Connect multi-year project to transform the way advice is produced and presented, making it easier to use and ensuring people receive evidence-based high-quality care in the right place at the right time'. However, this review clearly does not meet these high expectations. The conclusion that 'The recommendation on cardiac output monitoring reflects current practice and is not expected to lead to major changes in practice' is clearly wrong. This analysis shows that even on the most conservative approach, including all 'COM' technologies there is a reduction in post-op complications and a positive QALY impact. Currently less than 10% of applicable patients receiving these COM technologies in the UK, so 100,000's of patients are getting avoidable complications after surgery. Why is NICE not doing more to get this implemented whilst also clearly defining which of the COM technologies have a robust evidence base and which have no outcome evidence at all.	Thank you for answering this question. The committee stated that although cardiac output monitoring is not used for all surgeries, it is regularly used for people undergoing major, complex or high-risk surgery. This was the opinion of the committee members who undertake these surgeries, but also a UK survey on the trends in cardiac output monitoring in ICU units (1) found that out of those that responded, 96% routinely use cardiac output monitoring. Whilst this is in ICU and not in surgery, the committee view was that if a hospital has the monitors then they are often shared resource between departments. (1) Current trends in cardiac output monitoring in UK intensive care units A Labib et al; 2010; the intensive care society.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical	005	006	There is absolutely no evidence to show that 'Cardiac output monitoring is used to guide fluid replacement during surgery'. There is a very clear evidence base for the optimisation of Stroke Volume, but nothing for cardiac output. Our major concerns here are that if NICE	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This

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	assessment during surgery			do not appreciate the basic terminology within this recommendation, no clinicians will take it seriously.	has now been added to 'terms used' in the guideline and has been made clear in the cost-effectiveness and evidence reviews.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	005	009	The sentence 'However cardiac output monitoring devices are expensive and also have an added cost per patient from the additional cost of a probe' has several issues. The term 'expensive' is relative. When NICE recommended the use of the CardioQ-ODM with a cost saving of over £1000 per patient in over 800,000 surgical procedures it highlighted within a NICE designed business case that payback could be achieved by treating just 10 patients. Also 30% of CardioQ-ODM's within the NHS are placed on loan, which now much more a regular practice due to severe cuts to capital budgets. Therefore, there is no cost associated to these, making them very 'inexpensive'. Secondly in this sentence you are using the word 'probe' which is generally associated to the ODM and would not be used in reference to COM's	Thank you for your comment. The committee are referring to the upfront cost of purchasing or loaning the equipment irrespective of the downstream savings the monitors may lead to due to the reduction in complications. The wording has been edited to '*cardiac output monitoring devices are expensive as well as the added cost per patient associated with disposables.'* The word 'probe' has been removed and disposables has been used instead. Using the purchase price of the monitors is a conservative approach, however, a threshold analysis has been added to assess at what cost per patient the monitors would no longer be cost-effective and text has been added to acknowledge that some of these monitors will be on loan instead of purchased. The results from the threshold analysis show that the cost per person would have to be extremely high in order for cardiac output monitoring to no longer be considered cost effective.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	005	017	It is stated in line 17 that since the publication of MTG3 in 2011 there have been improvements in other areas of the standard perioperative care pathway, which have resulted in reductions in complications and overall length of stay. Whilst Deltex agree there have been significant improvements, what data are you providing to demonstrate that this has had a direct impact on post-operative complications and hospital length of stay. On several occasions since MTG3 was published Deltex analysed the publicly available HES data and demonstrated that there had been no significant reductions nationally in hospital length of stay in major surgery. Therefore, please reference the evidence you have to support your comment related to the improvements?	Thank you for your comment. The committee highlighted that there have been improvements such as an increase in minimally invasive procedures which leads to a quicker recovery and shorter length of stay. Examples from the recent National Emergency Laparotomy Audit 2017/18 and the National Oesophago-Gastric Cancer Audit 2018 have been added to the introduction to support this statement.

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Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	006	005	'Cardiac output monitoring' is not also known as goal-directed therapy. Reference comment 7	Thank you for comment. This has been removed.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	006	011	Deltex believe you need to clearly define what is considered to be Conventional Clinical Assessment (CCA) within this section as this is the main comparator against COM. Stating that it can include 'heart-rate, blood pressure and urinary output' is not clear enough and does not define what is actually happening across the NHS.	Thank you for your comment. The phrase conventional clinical assessment was taken from research papers. The committee acknowledge this may not reflect the current practice within the NHS and recognise this as a limitation. To clarify how conventional clinical assessment is used in the evidence a definition has been added into the glossary and into the committee's discussion of the evidence.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	006	028	There is a major flaw in the modelling. The assumption that are 'cardiac output monitoring' as equivalent is clearly wrong. A 'similar' device to the Oesophageal Doppler Monitor (ODM) would be another device that uses ultrasound to measure blood flow velocity not a device that uses an algorithm based on blood pressure measured peripherally. Without completing a meta-analysis of the RCT evidence base for each of the different 'COM's' then you do not have the evidence to state this. This is a major flaw and consequently makes all the calculations invalid.	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been added to 'terms used' in the guideline and has been made clear in the cost-effectiveness and evidence reviews. Pooling data from varying COM methods did not cause heterogeneity of meta-analysed results, showing consistency of results. The committee decided that the process of combining data to increase the statistical power of data was valid.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	010	021 - Table 2	Age (entering model). Why has the age been set to 60 when the 'perioperative care in adults' pathway is for patients over the age of 18? The FEDORA study (which has been omitted from your evidence review – see comment 29) was published in the BJA in March 2018. This was a large multi-centre RCT of haemodynamic monitoring using ODM during surgery and is our 24th published RCT. What FEDORA shows was a 75% reduction in total complications after surgery (both	Thank you for your comment. The clinical review included all adults undergoing major or high risk surgery. However, the average age of the populations in the included trials was 67. Every study will have a range of ages included, however when looking at evidence and making decisions on a population level, aggregate data is usually used.

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				minor and majors) including AKI's and SSI's. This was completed on ASAI&II patients and included patients under the age of 60 years. The total reduction in complications for AKI was 92% and for deep SSI 76%. Is NICE not concerned that this evidence, which was not included within the review (even though it was submitted by Deltex), clearly demonstrates that patients who receive sub-optimal haemodynamic management during surgery are getting avoidable post-operative complications?	When conducting a health economic model with a lifetime horizon, an average starting age is needed in the model so that age related mortality can be applied as people age in the model. As the average age of people in the RCTs was 67, and also given that the average age of people undergoing surgery in the NHS in England is 57, an average age of 60 was used as the starting age in the lifetime model. This age was used to obtain the risk of mortality in the long-term extrapolation in the model, and therefore does not impact the data used in the short-term model, which is based on the clinical review. As with any review, the resulting recommendations made are based on the populations of the evidence identified. The committee felt that this evidence, as well as the economic modelling based on this, can be generalised to rest of the adult surgical population because the review captured the typical population that would be undergoing major or high risk surgery. A sensitivity analysis was undertaken which used a starting age of 67 (to match the treatment effect population), and this showed COM was still highly cost effective. Using an age younger than 60 like age 57 identified from UK data being the average surgical population, is also likely to make little difference to the results. The FEDORA study was excluded from the clinical review because it did not meet the protocol due to the inclusion of starches.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	010	021 – Table 2	The fact that probability of complications at 30 days is 44% clearly shows there is a major problem post-operatively within the NHS and therefore stronger guidance on how to reduce post-op complications is required, which is not being conveyed in this document.	Thank you for your comment. The probability of complications is taken from the conventional clinical assessment arm from the systematic review of RCTs. This is based on a number of different studies which are conducted across different countries. Specific data which showed the probability of complications in an NHS setting for people undergoing major, complex or high risk surgery and only receiving conventional clinical assessment could not be identified. As a result, a decision was made to the use the data from the systematic review. Conducting the sensitivity analysis which only included studies conducted after the publication of MTG3 addressed this and showed that the probability of complications was 29% in the conventional clinical assessment arm, and this did not impact the conclusions on cost effectiveness.

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Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	013	006	'It was agreed that a large proportion of adults undergoing high risk surgery would have cancer and therefore this population was more reflective of the population considered'. Where is the evidence to support this statement? The evidence base reviewed covers multiple different surgical specialities including colorectal, urology, gynaecology, orthopaedics and shows a similar benefit across all surgical specialities.	Thank you for your comment. The review question covers multiple different surgical specialities, and this is covered in the 30 day decision tree which utilises data from the systematic clinical review. In order to extrapolate the long-term survival, a proxy population was chosen as the committee decided that the general population mortality was not reflective of a population undergoing major, complex or high risk surgery. The committee agreed that a large proportion of major surgery in England is for treating people with cancer, and the studies in the review also showed that around 75% were likely to be cancer related from the description of the populations. As some of the studies included in the clinical review were for adults undergoing major surgery for cancer and were bowel or gastrointestinal related, bowel cancer mortality was used in the model as a proxy for a high-risk surgical population. The bowel cancer statistics were used to obtain yearly mortality probabilities to model people's survival beyond 30 days. It is acknowledged that this may overestimate mortality for some people undergoing major, complex or high risk surgery, therefore a sensitivity analysis was conducted using the general population mortality, and this did not impact conclusions on cost effectiveness.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	016	028	The creation of SA2 requires evidence to demonstrate that clinical practice has improved since the publication of MTG3.	Thank you for your comment. The data from this sensitivity analysis showed that the probability of complications is lower in the conventional clinical assessment arm compared to the base case analysis where all studies were included. Also, examples from the recent National Emergency Laparotomy Audit 2017/18 and the National Oesophago-Gastric Cancer Audit 2018 have been added to the introduction to support the reason for conducting this sensitivity analysis.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	016	032	Monitor Costs. This section does not take into account the majority of monitors now installed into the UK are placed on loan to the NHS and not purchased; therefore there is no capital cost.	Thank you for your comment. The committee are aware that there are several other monitors used in the NHS, however, we were only able to obtain the costs of the monitors listed in the report. Also, the recent COMET-UK survey showed that the most commonly used monitors were the Oesophageal Doppler, LiDCO and PiCCO. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating

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				Deltex did not provide pricing information as part of this review as we fundamentally disagree with the assumption that all cardiac monitor are similar. A 'similar' device to the Oesophageal Doppler Monitor (ODM) would be another device that uses ultrasound to measure blood flow velocity, not a device that uses an algorithm based on blood pressure measured peripherally. Without completing a meta-analysis of the RCT evidence base for each of the different 'COM's' then you do not have the evidence to state this. This is a major flaw and consequently makes all the calculations invalid.	volume status of a patient, used to guide decision making regarding fluid replacement therapy. Pooling data from varying COM methods did not cause heterogeneity of meta-analysed results, showing consistency of results. The committee decided that the process of combining data to increase the statistical power of data was valid. The capital costs of the machines were used in the model as this was also the more conservative way to cost the intervention. Using loan costs is only likely to make CoM even more cost effective, if it is cheaper to get the machines on loan. Some discussion on how machines may be bought on loan rather than bought outright has been added to the model write-up to acknowledge this alternative method of purchasing.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	021	010	Where is the evidence to support the average number of uses per year would be 150?	Thank you for your comment. This was based on the committee's assumptions due to the lack of data available on the average number of uses in a surgical setting. This was tested as part of a sensitivity analysis, using a lower estimate (50 uses) and a higher estimate (250). These estimates did not impact conclusions on cost effectiveness.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	023	005	Where is the evidence to support the decision to only include patients over 60 years?	Thank you for your comment. The clinical review included all adults undergoing major or high-risk surgery. However, the average age of the populations in the included trials was 67. When conducting a health economic model with a lifetime horizon, an average starting age is needed in the model so that age related mortality can be applied as people age in the model. As the average age of people in the RCTs was 67, and also given that the average age of people undergoing surgery in the NHS in England is 57, an average age of 60 was used as the starting age in the lifetime model. This age was used to obtain the risk of mortality in the long-term extrapolation in the model, and therefore does not impact the data used in the short-term model, which is based on the clinical review. As with any review, the resulting recommendations made are based on the populations of the evidence identified. The committee felt that this evidence, as well as the economic modelling based on this, can be

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					generalised to rest of the adult surgical population because the review captured the typical population that would be undergoing major or high-risk surgery. A sensitivity analysis was undertaken which used a starting age of 67 (to match the treatment effect population), and this showed COM was still highly cost effective.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	030	023	'Another limitation is that there had been a limited number of studies published since MTG3'… This statement is not true. There have been multiple positive studies published since MTG3 on all 'COM's', but NICE either excluded them due on an irrational basis i.e. conducted with starch or missed them when conducting the evidence review. Deltex requests that the evidence review is completed again and includes all the relevant RCT's/	Thank you for your comment. This has been reworded to state that there have been a limited number of studies published since MTG3 that met the inclusion criteria. The committee noted the resolution of the Committee on Pharmacovigilance Risk Assessment of the European Medicines Agency/606.303 of October 2013 recommended not to use 6% HES in septic, burned, and critically ill patients, and in clinical trials and in situations of hypovolaemia, and agreed it inappropriate to consider the inclusion of studies with interventions including starch.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	030	027	'Also the introduction of enhanced recovery programmes has improved surgical outcomes'… Whilst this may be true is some NHS hospitals in the UK it is only a relatively small percentage. Can NICE provide the evidence to support this statement and demonstrate nationally the number of hospitals that have successfully implemented an enhanced recovery programme which is then supported by outcome benefit?	Thank you for your comment. The committee decided that although there is variation across specialities and hospitals there has been an overall increase in the implementation of enhanced recovery programmes. The PQIP 2017/18 report showed that 61% of patients were enrolled on an enhanced recovery programme. This reference has been added to the report. In terms of outcome benefit, the review undertaken for this guideline on enhanced recovery programmes identified a large volume of evidence (76 trials). The committee's view of the evidence was that there a large body of evidence showing a benefit with ERP in reducing complications and length of hospital stay. Showing that there is benefit where these programs are used.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	030	027	'The cost and utility data used in the model for minor complications was specific to a chest infection'. With the focus on SSI's and AKI's why were these not included?	Thank you for your comment. All complications (including SSI and AKI) were included in the clinical review, however for the purposes of modelling, example costs and utilities were used. The committee decided to use the costs and utilities associated with a chest infection as an example of a minor complication. Using higher complication costs would have led to COM being more cost

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					effective (lower cost per QALY for COM), therefore using lower complication costs is more conservative. The cost of SSI's was explored and were higher than the cost of a chest infection, therefore, using the chest infection cost was conservative towards cardiac output monitoring, but still showed it to be cost effective. Also, the utility associated with SSI's was lower than for chest infections, therefore using the chest infection utility was the conservative approach. For major complications, the costs and quality of life associated with being admitted to an intensive care unit (ICU) was used as an example. The cost of AKI was also explored and was less than the cost of ICU used in the model, however, various deterministic sensitivity analyses were conducted reducing the cost of ICU and this did not impact conclusions. The utility associated with AKI was similar to that used for ICU and therefore would not result in an impact on conclusions.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	031	003 - 007	When calculating the cost implications of post-operative complication why was the Khuri paper not included within the review – 'Determinants of Long-Term Survival After Major Surgery and the Adverse Effect of Postoperative Complications'. This looked at over 105,951 patients and demonstrated the significant implications of getting either a minor or major complication post-operatively. • 24.3% of patients suffering a deep wound infection were dead within a year versus 10.5% without; • 25.4% of patients suffering AKI were dead within a year versus v 10.3% without	Thank you for your comment. Although the Khuri paper looked at a large number of people, it was published in 2005 and included data that was collected in 1991. The committee decided that this doesn't reflect current practice as practice has improved in that time. Also, the Khuri study was conducted in the USA which may not accurately reflect UK practice in the NHS. The Moonesinghe study that was used to determine long-term survival in the model was conducted in the UK and was also conducted more recently, and therefore considered appropriate to use in the model due to it being more relevant to current UK practice.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs.	031	045	Please explain the decision behind removing any RCT that used 'starch boluses' and the supporting evidence why these cannot be used within a surgical haemodynamic protocol?	The committee noted the resolution of the Committee on Pharmacovigilance Risk Assessment of the European Medicines Agency/606.303 of October 2013 recommended not to use 6% HES in septic, burned, and critically ill patients, and in clinical trials

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	clinical assessment during surgery			This decision excluded positive ODM 11 RCT's from the evaluation process and we question the science and evidence behind that decision?	and in situations of hypovolaemia, and agreed it inappropriate to consider the inclusion of studies with interventions including starch.
Deltex Medical	Cost-effectiveness analysis: cardiac output monitoring vs. clinical assessment during surgery	032	044	Deltex disagree that further research is required, which would take a huge amount of time and energy to perform. What we do request is that a better analysis of the existing evidence is conducted on each individual COM.	Thank you for your comment. The committee disagree as some of the trials included in the clinical review were carried out many years ago and do not accurately reflect current practice. The committee decided that conducting new trials in a current UK NHS context would be beneficial to assess the benefits of using cardiac output monitoring during surgery.
Deltex Medical	Evidence Review J	005	002	Deltex fundamentally disagree with the assumption that all cardiac monitor are similar. A 'similar' device to the Oesophageal Doppler Monitor (ODM) would be another device that uses ultrasound to measure blood flow velocity, not a device that uses an algorithm based on blood pressure measured peripherally. Without completing a meta-analysis of the RCT evidence base for each of the different 'COM's' then you do not have the evidence to state this. This is a major flaw and consequently makes all the calculations invalid.	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been added to the 'terms used' in the guideline and has made clear in the cost-effectiveness and evidence reviews. Pooling data from varying COM methods was considered to be clinically appropriate and this assumption was supported by the lack of heterogeneity in the meta-analysed results, showing consistency of results. The committee decided that the process of combining data to increase the statistical power of data was valid.
Deltex Medical	Evidence Review J	005	006	There is absolutely no evidence to show that 'Cardiac output monitoring is used to guide fluid replacement during surgery'. There is a very clear evidence base for the optimisation of Stroke Volume, but nothing for cardiac output. Our major concerns here are that if NICE do not appreciate the basic terminology within this recommendation, no clinicians will take it seriously.	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been added to the 'terms used' in the guideline and has been made clear in the cost-effectiveness and evidence reviews.
Deltex Medical	Evidence Review J	005	008	'More recently there has been a trend to less liberal fluid management'. Where is the evidence for this statement and then the	Thank you for your comment. The review introduction wording has been revised and this sentence removed.

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				data to demonstrate that giving less fluid improves outcome? The largest study ever completed by P Myles group in Australia titled 'restrictive vs liberal fluid for major abdominal surgery' showed that there was a worse outcome for patients who had restricted fluids. The point here is that the ODM ensures the patient does not receive either too much or too little fluid and is individualised for each patient.	
Deltex Medical	Evidence Review J	006	002 - 013	Included studies. Deltex believe that the evidence included within the review is not comprehensive. There are major studies that have not been reviewed: Studies not included are: • Kaufmann KB, Steil L, Ulbrich F, Kaifi JT, Hauschke D, Loop T, Goebel U. Oesophageal Doppler guided goal-directed haemodynamic therapy in thoracic surgery - a single centre randomized parallel-arm trial. Br J Anaesth. 2017 Jun 1;118(6):852-861. doi: 10.1093/bja/aew447. • Calvo-Vecino JM, Ripollés-Melchor J, Mythen MG, Casans-Francés R, Balik A, Artacho JP, Martínez-Hurtado E, Serrano Romero A, Fernández Pérez C, Asuero de Lis S; FEDORA Trial Investigators Group. Effect of goal-directed haemodynamic therapy on postoperative complications in low-moderate risk surgical patients: a multicentre randomised controlled trial (FEDORA trial). Br J Anaesth. 2018 Apr;120(4):734-744. • Szturz P, Folwarczny P, Kula R, Neiser J, Ševčík P, Benes Multi-parametric functional hemodynamic optimization improves postsurgical outcome after intermediate risk open gastrointestinal surgery, a randomized controlled trial. Minerva Anestesiol. 2018 May 11. doi: 10.23736/S0375-9393.18.12467-9	Thank you for providing these references. All have now been reviewed and the Kaufmann and Szturz studies have been added to the clinical evidence review. The Calvo-Vecino study intervention included a starch bolus and was subsequently excluded. The committee noted the resolution of the Committee on Pharmacovigilance Risk Assessment of the European Medicines Agency/606.303 of October 2013 recommended not to use 6% HES in septic, burned, and critically ill patients, and in clinical trials and in situations of hypovolaemia, and agreed it inappropriate to consider the inclusion of studies with interventions including starch.

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Deltex Medical	Evidence Review J	006	002 - 013	Included studies. With the included studies there are ones conducted on technologies that would never be used as a 'COM' within the operating theatre environment, such as TOE. If NICE is going to include TOE devices into the evaluation they should also be included in the cost evaluation?	The committee acknowledged that TOE may not be a routine modality for COM but has potential use within this setting and so considered its inclusion as an intervention valid. The evidence from the two trials (Dhawan 2018 and Shillcutt 2014) comparing TOE to conventional clinical assessment were considered in a balance with the rest of the evidence presented for COM when considering recommendation for practice. Both these studies were also informing the overall clinical effectiveness of CoM and therefore are also part of the pooled treatment effect that fed into the model. In terms of the devices that informed the weighted average cost of the intervention in the model, these were based on the top three most popular monitors as reported in the COMET-UK survey. These were oesophageal doppler (cardioQ), The PiCCO, and the LiDCO.
Deltex Medical	Evidence Review J	006	015 - 017	Excluded studies. Deltex believe that the exclusion criteria for studies has not clearly been evidence based and therefore significantly reduces the financial impact of the cost savings. The decision to remove any RCT that includes the use of 'starches' is not evidence based. In total the following 11 RCT's have been removed for this reason:- 1. Mythen MG, Webb AR. Perioperative plasma volume expansion reduces the incidence of gut mucosal hypoperfusion during cardiac surgery. Arch Surg 1995; 130: 423-9 2. Sinclair S, James S, Singer M. Intraoperative intravascular volume optimisation and length of hospital stay after repair of proximal femoral fracture: randomised controlled trial. Br Med J 1997; 315: 909-12	The committee noted the resolution of the Committee on Pharmacovigilance Risk Assessment of the European Medicines Agency/606.303 of October 2013 recommended not to use 6% HES in septic, burned, and critically ill patients, and in clinical trials and in situations of hypovolaemia, and agreed it inappropriate to consider the inclusion of studies with interventions including starch. The studies previously included in the evidence review have been reviewed and revised to exclude two further studies (Senagore 2009 and Smetkin 2009) that included starch as part of the intervention.

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				3. Conway DH, Mayall R, Abdul-Latif MS, Gilligan S, Tackaberry C. Randomised controlled trial investigating the influence of intravenous fluid titration using oesophageal Doppler monitoring during bowel surgery. Anaesth 2002; 57: 845-9 4. Gan TJ, Soppitt A, Maroof M, El-Moalem H, Robertson KM, Moretti E, Dwane P, Glass PSA. Goal-directed intraoperative fluid administration reduces length of hospital stay after major surgery. Anesthesiol 2002; 97: 820-6 5. Chytra, I., Pradl, R., Bosman, R., Pelnar, P., Kasal, E., Zidkova, A., *Esophageal Doppler-guided fluid management decreases blood lactate levels in multiple-trauma patients: a randomized controlled trial.* Crit Care, 2007. **11**(1): p. R24 6. Challand C, Struthers R, Sneyd JR, Erasmus PD, Mellor N, Hosie B, Minto G. Randomized controlled trial of intraoperative goal-directed fluid therapy in aerobically fit and unfit patients having major colorectal surgery. Br J Anaesth 2012; 108(1): 53-62 7. Brandstrup B, Svendsen PE, Rasumssen M, Belhage B, Rodt SÅ, Hansen B, Møller DR, Lundbech LB, Andersen N, Berg V, Thomassen N, Andersen ST, Simonsen L. Which goal for fluid therapy during colorectal surgery is followed by the best outcome: near maximal stroke volume or zero fluid balance? Br J Anaesth 2012; 109(2): 191-9 12 8. McKenny M, Conroy P, Wong A, Farren M, Gleeson N, Walsh C, O'Malley C, Dowd N. A randomised prospective trial of intra-operative oesophageal Doppler-guided fluid	

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				administration in major gynaecological surgery. Anaesthesia 2013 9. El Sharkawy OA, Refaat EK, Ibraheem AEM, Mahdy WR, Fayed NA, Mourad WS, Abd Elhafez HS, Yassen KA. Transoesophageal Doppler compared to central venous pressure for perioperative hemodynamic monitoring and fluid guidance in liver resection. Saudi J Anaesth 2013; 7(4): 378-86 10. Phan TD, D'Souza B, Rattray MJ, Johnston MJ, Cowie BS. A randomised controlled trial of fluid restriction compared to oesophageal Doppler guided goal directed therapy in elective major colorectal surgery within an Enhanced Recovery After Surgery program. Anaesth Intensive Care 2014 Nov; 42 (6);752-60 There are then studies included that do use starches.	
Deltex Medical	Evidence Review J	032	Table 7 (a)	It is stated that for MTG3 'measure of effect is not in line with NICE reference case methods as the analysis does not measure QALY's'. This is correct as when MTG3 was completed by NICE it did not include looking at QALY's, it looked at cost consequences. It is clear however (then and now) that if it had there would have been a much larger benefit demonstrated than by using this 'COM' model now, where there is still limited evidence for the other devices included. Despite this the 'COM' has still shown to be cost effective no matter how extreme the scenarios have been set to	Thank you for your comment. The NICE manual for developing guidelines states that a cost-utility analysis is the preferred form of economic evaluation and therefore the preferred measure of health benefit is QALYs.
Deltex Medical	Evidence Review J	032	Table 7 (b)	It is interesting that they very critical of how MTG3 was conducted seeing as it was an independent evaluation completed by NICE.	Thank you for your comment. A part of the NICE checklist for assessing economic evaluations involves a question on whether a conflict of interest has been declared. A relevant conflict of interest

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				There is a comment at the end of this point regarding potential serious limitations- 'Funded by Deltex Medical'. Please explain what is meant by this?	would be the source of funding for undertaking the study. In the case of MTG3, although it was an independent evaluation by NICE, the main piece of evidence submitted to NICE on cost effectiveness was the model by the manufacturers of the device and therefore there is a relevant conflict of interest as this could influence the inputs chosen in the model.
Deltex Medical	Evidence Review J	037	005	'Since the publication of this medical technology guidance in 2011 there have been improvements in the perioperative pathway which have resulted in reductions in complications and length of stay'. What evidence to support this comment?	Thank you for your comment. The committee highlighted that there have been improvements in the pathway such as an increase in minimally invasive procedures, which leads to a quicker recovery and shorter length of stay. More detail has been added to the evidence review to support this statement with references.
Deltex Medical	Evidence Review J	039	018	There are no references number attributed to any of the clinical evidence statements so difficult to verify what has been stated.	Thank you for your comment. The evidence statements provide a succinct summary of the body of evidence presented in the clinical evidence summary tables and reflected in the forest plots. The references for the source of the evidence can be found there.
Deltex Medical	Evidence Review J	041	005 - 034	There are no references number attributed to any of the health economic evidence statements so difficult to verify what has been stated.	Thank you for your comment. The evidence statements reflect the body of evidence presented in the health economic evidence profiles and health economic evidence tables in appendix H. The references for the source of the evidence can be found there.
Deltex Medical	Evidence Review J	041	035 - 036	'The commit agreed cardiac output monitoring is primarily used within perioperative practice……'. As stated previously there is no evidence for 'cardiac monitoring in surgery'.	Thank you for your comment. The text has been amended and primarily has been removed. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been added to the 'terms used' in the guideline and has been made clear in the cost-effectiveness and evidence reviews.
Deltex Medical	Evidence Review J	042	010 - 030	Not all the evidence has been reviewed with regard to comparing technologies. There are multiple studies published highlighting that all the 'COM' technologies have very different modalities and algorithms and provide very different values. The RCT completed by Chiati - 'Comparison of two versions of the Vigileo-FloTracTM system (1.03and 1.07) for stroke volume estimation: a multicentre, blinded comparison with oesophageal Doppler measurements' is the first of the many that highlight the COM technologies are very different and the outcome data is not transferable between devices.	The noted study compares an updated version of the same method and so this would not have been included as a comparison between different intervention methods.

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Deltex Medical	Evidence Review J	043	009	Where is the evidence studies that included 'starches' can not be used within the operating room?	The committee noted the resolution of the Committee on Pharmacovigilance Risk Assessment of the European Medicines Agency/606.303 of October 2013 recommended not to use 6% HES in septic, burned, and critically ill patients, and in clinical trials and in situations of hypovolaemia, and agreed it inappropriate to consider the inclusion of studies with interventions including starch.
Deltex Medical	Evidence Review J	075	Appendix D: Clinical Evidence Tables: Bartha study	It is listed on several occasions that this study was conducted by Oesophageal Doppler which is in-correct.	Thank you for your comment. This has been amended to pulse contour analysis
Deltex Medical	Methodology	007	Bullet 1	It states that within the guideline that it does not cover 'preventing infection', apart from …prevention of surgical site infections. Obviously preventing SSI's is a key metric within the NHS, but these are not covered at any point within the Appendix J - Non-invasive cardiac output monitoring. Within this section the cost benefits are based around chest infections. Why is this not more desire to focus on SSI's and AKI's within these guidelines?	Thank you for your comment. Surgical site infection and acute kidney injury were included as clinical outcomes of evidence reviews where considered appropriate. For the purposes of modelling a specific cost had to be attributed to minor and major complications. As a result, the committee chose chest infections as an example of a common minor complication and intensive care admission was chosen as an example cost of major complications.
Deltex Medical	Methodology	012	Evidence Report 11	The review question is 'what is the clinical and cost effectiveness of non-invasive cardiac output monitoring during major, complex and high-risk surgery in adults'. Deltex has repeatedly stated that this question is not a valid one for several reasons. There are no published RCT's that look at the clinical benefit of 'cardiac output'. All of the current RCT's use algorithms based on the patients Stroke Volume (SV) in combination with blood pressure. The second major point is that not all the 'cardiac output' devices that measure either 'cardiac output' or 'stroke volume' are 'similar' as they use different methods and different algorithms. A 'similar' device to the Oesophageal Doppler Monitor (ODM) would be another device that uses ultrasound to measure blood flow velocity (such as the USCOM), not a device that uses an algorithm based on blood pressure measured peripherally. Virtually all of the positive evidence showing outcome benefit within surgery is based on the ODM, not on the 'similar' devices	Thank you for your comments. The committee considered cardiac output monitoring an umbrella term to encompass interventions monitoring stroke volume / cardiac output / central venous pressure for the purposes of evaluating volume status of a patient, used to guide decision making regarding fluid replacement therapy. This has now been made clear in the cost-effectiveness and evidence reviews. Pooling data from varying COM methods did not cause heterogeneity of meta-analysed results, showing consistency of results. The committee decided that the process of combining data to increase the statistical power of data was valid.

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Deltex Medical	Methodology	012	Evidence Report 11	The review question is 'what is the clinical and cost effectiveness of non-invasive cardiac output monitoring during major, complex and high-risk surgery in adults' does not have any age restrictions applied to it (like >60 years of age for the pre-optimisation clinics). Given the reduction in complications for ODM (and consequently COM) has been proven in large RCT's in patients of all ages why did an age restriction get added into the 'Non Invasive Cardiac Output monitoring guidance.	Thank you for your comment. Please note that no restriction on age was used for this review (other than including adults aged >17 only). Age, stratifying adults aged <60 and older adults aged >60 was only considered for further investigation in the case of heterogeneity of results. For the purpose of the economic model, an average age had to be used in order to model over a lifetime. As the average age of people in the RCTs was 67, and also given that the average age of people undergoing surgery in the NHS in England is 57, an average age of 60 was used as the starting age in the lifetime model. This age was used to obtain the risk of mortality in the long-term extrapolation in the model, and therefore does not impact the data used in the short-term model, which is based on the clinical review. As with any review, the resulting recommendations made are based on the populations of the evidence identified. The committee felt that this evidence, as well as the economic modelling based on this, can be generalised to rest of the adult surgical population because the review captured the typical population that would be undergoing major or high risk surgery. A sensitivity analysis was undertaken which used a starting age of 67 (to match the treatment effect population), and this showed COM was still highly cost effective.
Deltex Medical	Methodology	039	Glossary	There are numerous references to Conventional Clinical Assessment (CCA) for COM within this recommendation, but very few references as to what that actually is. There is no reference for this within the Glossary even though it is one of the main comparators? Please include CCA within the glossary with references to how this has been agreed.	Thank you for your comment. A definition of CCA has now been added to the guideline.
Deltex Medical	Methodology	039	Glossary	There is no definition for 'starches' which is used within the Non Invasive Cardiac Output monitoring guidance as one of the filters when reviewing the evidence base.	Thank you for your comment. A definition has now been added to the guideline.
Deltex Medical	Methodology	040	Glossary	The definition for 'pulse contour analysis' is a marketing description of what it is intended to do, not how it actually is done.	Thank you for your comment. This has been amended.

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Diabetes UK	Guideline	007	006 - 007	This recommendation implies that tight glucose control, defined as 4-6 mmol/litre, is recommended for people living with type 1 diabetes, although this is not explicit. However, the evidence for this recommendation is limited. While we recognise there is evidence for tight glucose control for some surgery, cardiac for example, the same evidence is not available for other types of surgery, such as orthopaedic, gynaecological and vascular surgery. The *Joint British Diabetes Society's* (JBDS) guidelines on the management of adults with diabetes undergoing surgery and elective procedures recommends that blood glucose levels should be maintained between 6-10mmol/litre. We support this recommendation and suggest that the recommendation proposed here has the potential to put patients at risk of hypoglycaemia, as per the conclusions of Levy N et al Diab Med 2019;36(1):120-121.	Thank you for your comment. The wording of the recommendations has been revised.
Diabetes UK	Guideline	007	009 - 010	We note the reference to NG17 in this draft guideline, but would highlight that NG17 is in the process of being updated – meaning recommendations in this guideline that reflect those in NG17 may well be out-of-date and not fit-for-purpose soon after it is published.	Thank you for your comment. The impact of any updates to the recommendations in NG17 on this guideline will be assessed when an update is considered.
Diabetes UK	Guideline	General	General	We are concerned that this guideline makes no reference to consulting with inpatient specialist diabetes teams before and after surgery. This should be standard practice in all inpatient settings and will help guarantee the safety of patients. Further, this approach would reflect the broader **move towards personalised care planning** within our health services, as detailed in the NHS Long Term Plan (2019). The JBDS has produced detailed guidelines on inpatient care for older people living with diabetes, for example, which outline how personalised care planning should take place in this context. While we appreciate some recommendations to this effect feature in NG17, we suggest that the same should be said for other types of	Thank you for your comment. The clinical and cost effectiveness of the input of inpatient specialist teams for specific conditions was not prioritised for inclusion in the guideline. Evidence review K evaluates glucose control and the importance of inpatient specialist diabetes teams in preoperative assessment was recognised by the committee and has now been added to the write up of the committee's discussion of the evidence in evidence review K.

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				diabetes, not least type 2 diabetes. A recommendation on **consulting with an inpatient specialist diabetes team** before decisions around blood glucose monitoring and diabetes management are made during perioperative surgery should be explicitly included in this guideline, for **all** people living with diabetes.	
Diabetes UK	Guideline	Guideline	Guideline	Nearly 1 in 6 hospital beds are occupied by someone living with diabetes at any one time, and it is reasonable to conclude that this will include people living with type 2 diabetes. However, and further to the above comment (3), we are concerned to note there are no recommendations surrounding the management of type 2 diabetes in perioperative care in this guideline. This approach risks sending the message to clinicians that type 2 diabetes is a uniform condition that can be managed in a routine way and that people living with type 2 are at a lower risk of hypo- and hyper-glycaemia in hospital. We know, however, that people living with type 2 diabetes **are** at risk of hypo- and hyper-glycaemia in hospital (see, for example: Lake A et al. The effect of hypoglycaemia during hospital admission on health-related outcomes for people with diabetes: a systematic review and meta-analysis. Diab Med. 2019;36(11):1349-1359). Around 90% of people with diabetes are living with type 2 and the treatment of the condition can vary extensively from person to person. What we do know is that many people living with type 2 diabetes take blood-glucose lowering medications, including some who use insulin intensive therapy (4 of more insulin injections per day) to manage their condition. This puts them at risk of hypo- and hyper-glycaemia. To make no reference to type 2 diabetes in this guideline at best risks perpetuating myths about the condition amongst clinicians and at worst risks causing serious harm to people living with diabetes in an inpatient setting. We would strongly urge the committee to revisit this	Thank you for your comment**.** The management of diabetes was outside of the scope of the guideline. The focus of the blood glucose control evidence review (evidence review K) and subsequent recommendations was on intraoperative glucose control. This was the topic identified during the scoping process as an area where there is variation in practice. Your comments have been passed on to the surveillance team to take into account when this guideline is considered for update.

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				guideline and ensure appropriate recommendations are included for people living with **all** types of diabetes who are using insulin or taking blood glucose lowering medications.	
Edwards Lifesciences	Evidence Review J	General	General	The evidence only covers non-invasive COM. Current practice uses invasive, minimally invasive and non-invasive processes. The support information is not reflective of current practice.	Thank you for your comment. The committee considered the main interventions for comparison to be non-invasive cardiac output monitoring, pulmonary artery catheter monitoring, and conventional clinical assessment. All evidence on these interventions was considered for inclusion.
Edwards Lifesciences	Guideline	007	001	Monitoring: • We feel there is insufficient mention of intraoperative monitoring. This is a critical area of the perioperative care pathway in which the major patient safety issues arise and consequentially litigation burden. • It is an area of innovation which can assist in the reduction of these issues but is not encouraged neither supported by the innovation process and funding, particularly with digital and AI – machine learning technologies such as predictive monitoring • The coverage does not expand on haemodynamic monitoring, pressure and oximetry	Thank you for your comment. The committee recognise the utility of intraoperative monitoring. This has been noted within the record of the committee's discussion. The committee were only able to discuss the evidence available for the areas prioritised for guidance, and cannot inform innovation and future funding for development. The guideline could only focus on the areas of perioperative care and monitoring that were raised during guideline scoping and development. Areas of monitoring outside of this were not within the scope of the guideline.
Edwards Lifesciences	Guideline	008	001	Postoperative care: Monitoring should be included in the recovery stage otherwise this is not reflective of current practice.	Thank you for your comment. The committee recognise that monitoring is continued into the post-operative period. This is acknowledged in the committee's discussion of the evidence in evidence review J.
Edwards Lifesciences	Guideline	General	General	Edwards commend NICE for the extensive work and the production of this guideline. • We didn't see any involvement of the GIRFT Clinical Leads: o Anaesthesia and perioperative medicine - Dr Chris Snowden / Dr Mike Swart o Intensive and critical care - Dr Anna Batchelor We feel their involvement would give a good picture of current practice and variation.	Thank you for your comment. The committee was recruited according to NICE's recruitment policy and all the professional committee members are currently practising in the NHS and either specialise in or have a particular interest in perioperative care. They used this knowledge of current practice and variation to support their decision making. The consultation processes, for both the guideline scope and the guideline itself also provide opportunities for registered stakeholders to comment on the committee's decision making. Outcomes relevant to patient safety were included on a number of reviews including the review on safety management systems. Any

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				• Whilst clinical evidence is of utmost importance, we believe it doesn't tell the real story of this pathway and real-world assessment needs to be included in the guideline to show current practice • The areas mentioned and those not didn't seem to adequately consider patient safety, which is a key area of the NHS Long Term Plan • The guideline doesn't mention innovation which is sadly missing in perioperative care and not encouraged by the capital funding system, but which could have impacts on workforce, patient safety and litigation issues	future updates of this guideline may explore other topics in more detail. Any future updates of the guideline may expand on the recommendations. We have now added this to the context section of the guideline.
Faculty of Intensive Care Medicine	Guideline	004	016	As the guideline includes high-risk surgery with a mortality of >5% it's seems unusual that there is no mention of discussion regarding levels of care, patient wishes etc. There is an assumption that the pathway will be smooth which for high risk groups will not necessarily be the case. It would be reasonable for the guideline to make some comment about exploring patient wishes and understanding of the risks associated with the procedure so the patient could express a view about their treatment and properly understand what's involved. Especially in older, frailer patients (no mention of that group other than recommending research).	Thank you for your comment. Consideration has been given to ensure that patients have the information and support they require throughout their perioperative pathway. The committee agree that shared decision making is pivotal; and guidance (recommendation 1.3.1) is also given to discuss the person's risks and surgical options with them to allow for informed shared decision making.
Faculty of Intensive Care Medicine	Guideline	009	008	NSAIDs – although good for acute post -op pain there is not suggestion to consider any underlying kidney or liver disease which may influence that decision	Thank you for your comment. This is covered in recommendation 1.6.1. The committee's discussion of the evidence has been amended in evidence review N1.

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Faculty of Intensive Care Medicine	Guideline	011	005	Specialist recovery suggestion for major and complex surgery: includes prostate which may be undertaken as day surgery these days	Thank you for your comment. The committee confirmed that there will be some exceptions to this recommendation but this would be for a very small minority of major and complex surgery.
Faculty of Pain Medicine – Royal College of Anaesthetists	Evidence review N1	330	009 - 011	Incomplete sentence 'As such, the committee considered that a choice of PCA or epidural should be [given?] and …'	Thank you for your comment. This has been added.
Faculty of Pain Medicine – Royal College of Anaesthetists	Evidence review N1	331	015	Incomplete sentence.	Thank you for your comment. This has been amended.
Faculty of Pain Medicine – Royal College of Anaesthetists	Evidence review N1	333	014 - 017	Including overall kit in using IV paracetamol, seems double accounting as rarely do patients not have IV fluids attached (so these costs are irrespective of the paracetamol) - NICE cost indicated £5, but noted the average of a single dose to be £1.79 (p333)	Thank you for your comment. The wording has been changed to state that disposable costs would not always be included as people may already have IV fluids attached.
Faculty of Pain Medicine – Royal College of Anaesthetists	Evidence review N1 - Management of pain	333	012 - 038	The argument against IV paracetamol seems largely economic and the arguments seem to have excluded single or two doses given at surgical onset and perhaps a second dose in a prolonged procedure. The assumptions of 4 doses seem erroneous.	Thank you for your comment. The committee decided that the evidence shows no clear clinical benefit of IV paracetamol over oral paracetamol. Given the cost of intervention and absence of evidence on intraoperative use of IV paracetamol, no recommendation was made for this scenario. =
Faculty of Pain Medicine – Royal College of Anaesthetists	Evidence review N2	280-285	D.3 – D.5	In the evidence appendix there is discussion about neuroaxial blocks but this does not appear to lead to a comment in the final summary.	Thank you for your comment. The page number and sections referred to are the forest plots on the delivery method of opioids; PCA versus epidural, PCA versus spinal epidural and spinal epidural versus continual epidural. The discussion on this evidence and reference to neuraxial analgesic techniques is in evidence review N1 in section 6. 'The committee's discussion of the evidence'.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	008	007 - 021	'Discharge analgesia planning and transition to community after surgery' should be a recommendation under managing pain [recommendation 1.6.1-1.6.14]. There is now enough high grade evidence to support this statement. The guidelines should recommend	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We will make the surveillance team at NICE aware of your comment.

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				an appropriate plan should be in place especially as an increasing amount of surgery is done as day case or 23hr stay.	
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	008	007 - 021	1.6.1- Under planning pain management, it will be useful to include 'psychological assessment and optimisation' as currently the plan appears very focussed on the 'biological' aspect.	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We now acknowledge the importance of the non-pharmacological management of pain in evidence review N1. We will make the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	008	008 - 021	1.6.1 Planning pain management. There is no mention of complex patients with coexisting pain conditions or those already on significant doses of analgesics who should be highlighted as higher risk patients to manage. They may be a group where reassessment would be more beneficial or worth considering for research.	Thank you for your comment. This has been considered in the recommendation for planning pain management under the patient's pain history. We now acknowledge the importance of involving the pain clinic in people with pre-existing pain in the committee's discussion of the evidence in evidence review N1. We are unable to make a research recommendation on topics where we have not conducted an evidence review. We have made the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	008	008 - 021	The planning pain management section should be expanded. It touches on the impact of a procedure on a 'person's pain'. Does that mean pain they already have? It definitely doesn't make comment on those already on long term analgesia. It should also expand on 'plans for discharge' to cover de-escalation and what to do if pain persists.	Thank you for your comment. This has been considered in the recommendation for planning pain management under the patient's pain history and discussion section. In the committee's discussion of the evidence in evidence review N1 we discuss the importance of –de-prescribing and have added that they should be given information what to do if pain persists. We have made the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	008 - 010	001 - 013	No mention of regional anaesthesia +/- continuous infusions in the post-operative period. Regional block catheters are routinely used in reverse shoulders, amputations, breast reconstructions, emergency laparotomies etc.	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We will make the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	009	009 - 012	1.6.6 states 'offer oral Ibuprofen to manage immediate postoperative pain'. Does this a] include post op ward care and b] does this apply to elderly with propensity for AKI perioperative with NSAIDs on top of multiple drugs they usually take. Clarity is needed.	Thank you for your comment. This is covered in recommendation 1.6.1 under what factors should be taken into account. The committee discussion has been amended. NSAIDs would be prescribed in accordance with the BNF including contraindications.

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Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	009	018 - 028	The guideline recommends no intravenous opioids unless the patient is unable to take oral medication. Does this include in recovery? Onset for IV opioids is quicker and may be more appropriate in that setting.	Thank you for your comment. Upon reviewing the evidence comparing efficacy of IV and oral opioids, the committee decided to recommend oral opioids where they can be taken. This will include the recovery period. The committee acknowledge that a number of patients will not be able to take oral opioids while in recovery and IV opioids may apply in this scenario.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	009 - 010	018 - 002	Oral opioids where possible are a good idea because the propensity to use a PCA for 'big operations' even when patients are eating and drinking can slow them down tying them to a bed with oxygen and a drip.	Thank you for your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	009 - 010	027 - 002	Recommendation 1.6.10 is concerning: '… Take into account the benefits of a continuous epidural for people who … have cognitive impairment.' Epidurals require detailed consent with discussion of risk and benefit ratio; this is a possible issue for people with cognitive impairment and we would have welcomed guidance that would point towards less intrusive techniques (e.g. peripheral nerve blocks; rectus sheath catheters) also. The need for competent consent is important and requires consideration.	Thank you for your comment. In the committee discussion of the evidence in evidence review N we discuss the issue of cognitive impairment and informed consent. The recommendation highlights to take into account cognitive impairment as the committee recognised that this is a very important issue and would lead to a detailed discussion on consent.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	010	007 - 012	1.6.12 Intravenous ketamine '… given either during or immediately after surgery … if … an intravenous opioid alone does not provide adequate pain relief'. How can you assess the effect of the opioid given? Unless this is aimed at guiding perioperative pain management. We have no issue with the potential benefit for ketamine but more clarity is required in the wording.	Thank you for your comment. The committee considered that the effect of an opioid given intraoperatively can be assessed by physiological indications. This has been added to the report of the committee discussions.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	010	007 - 012	IV Ketamine point needs to be clearer. It doesn't take into account its use with intrathecal opioids and no IV opioid and that is part of some enhance recovery protocols. 'If IV opioids are not enough' should be removed. It can be instead of or reduce opioids required.	Thank you for your comment. The addition of IV Ketamine to IV opioid was noted as the area of practice prioritised for guidance and so evidence in this area was reviewed. The committee agree that ketamine may be used to prevent additional opioid administration, and this is captured in the committee's discussion of the evidence in evidence review N1. The committee also note that ketamine may

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					have benefits in people with opioid sensitivity and that this is the main reason for using ketamine instead of opioids.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	010	007 - 012	The guideline doesn't mention using oral ketamine post operatively, though we are aware of a number of trusts that do use this.	Thank you for your comment. The focus of this was review was the addition of IV ketamine to a pain management intervention of IV opioid, primarily with one administration of ketamine intraoperatively in addition to IV opioid to manage post operative pain relief. Oral ketamine was not identified as a priority area requiring guidance by the committee and so the evidence on oral ketamine was not included in the review protocol for this question. We have made the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	010 024	003 - 006 005 - 006	We are concerned by the recommendations regarding the use and dose of Gabapentin - the level of evidence was generally very poor and the dose ranges substantial (100-1200mg) which seem to make the headline suggestion of limited value. There may be a benefit but better studies are needed, especially considering some of the other research questions.	Thank you for your comment. Evidence showed that a single dose of gabapentin can lessen postoperative pain and reduce the amount of opioid needed. However, the studies used a range of doses and administered the gabapentin at different times, so the optimal dose and timing of administration remain uncertain. The committee therefore now made a research recommendation.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	015	013	It will be very useful if 'Preoptimisation of complex pain patients/those on significant analgesia or opioids' is added as a key recommendation for research. [Assessing risk of surgery -1.3.1]	Thank you for your comment. This is outside of scope of the guideline and an evidence review was not conducted on this topic. We are therefore unable to make a research recommendation.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	NICE should clearly state in the "Short Version" or "Executive Summary", when a suggestion is due to positive evidence (for/against), lack of evidence or due to economic reasons (despite positive evidence).	Thank you for your comment. The recommendations link to a rationales and impact on practice section which summarise the committee's discussion of the evidence. The discussion comments on both clinical and cost effectiveness
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	On the whole, the draft guideline seems fairly aligned to current practice though there is a clear underlying theme of cost cutting. From a Pain Management Service perspective, it does present an incomplete picture of perioperative care.	Thank you for your comment. NICE guidelines do consider both clinical and cost effectiveness. NICE's report 'Social value judgements: principles for the development of NICE guidance' (2nd edition) http://www.medicine.mcgill.ca/epidemiology/courses/EPIB654/Summer2010/NICE/Social%20value%20judgements.pdf sets out the principles that committees should consider when judging whether an intervention offers good value for money. The criteria we use is outlined in the methodology chapter. It was not possible to address

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					all areas of perioperative pain relief. The areas selected were considered to be areas where practice was controversial or there was variation across the NHS. The pharmacological management of pain was highlighted as a priority area during the scoping process. The guidance highlights that a key aspect of pain management is to promote DREAMING (drinking, eating, and mobilising) (see the committee's discussion of the evidence in evidence review N1)
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	We were surprised not to see local anaesthetic or nerve blocks included in the scope of the guidelines.	Thank you for your comment. It was not possible to address all areas of perioperative pharmacological pain relief and this area was not highlighted as a priority area requiring guidance by the committee. The areas selected were considered to be areas where practice was controversial or there was variation across the NHS. We will make the surveillance team at NICE aware of your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	Agree to advocating multimodal analgesia in the management of postoperative pain, and agree on the need for patient involvement and cost effectiveness.	Thank you for your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	The use of Magnesium and intravenous LA has been about for some time but it makes no reference to this. There could have been something about the strength of evidence/ lack of evidence to support this.	Thank you for your comment. It was not possible to address all areas of perioperative pharmacological pain relief and this area was not highlighted as a priority area requiring guidance by the committee. The areas selected were considered to be areas where practice was controversial or there was variation across the NHS.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	We are supportive of the comparisons between oral paracetamol vs IV paracetamol, as IV tends to be used as default – the less a patient feels like a patient the better. Likewise, the comparison of Cox 2 versus Nonselective is useful because parecoxib is another drug given to many and there probably isn't the need.	Thank you for your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	Not mentioned in the guidance and should be mentioned: • Lignocaine infusions • IV magnesium	Thank you for your comment. Unfortunately, it was not possible to include all of the interventions and these were not highlighted as a priority area requiring guidance by the committee. The committee

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				IV clonidine	prioritised the areas that were considered to be controversial or where there was variation in practice across the NHS.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	We welcome the preoptimisation of patients with pre-existing pain problems, opioid use and those at high risk of persistent post-surgical pain	Thank you for your comment.
Faculty of Pain Medicine – Royal College of Anaesthetists	Guideline	General	General	There has been a lot in the acute pain world about how psychology both pre and post op reduces pain and bed stays post operatively. This does not appear to be covered.	Thank you for your comment. This has been discussed by the committee and text about the importance of non-pharmacological interventions in the management of pain has now been added to the write up the committee's discussion of the evidence. It was not possible to address all areas of perioperative pain relief and this area was not highlighted as a priority area requiring guidance by the committee. The areas selected were considered to be areas where practice was controversial or there was variation across the NHS. We have passed your comment onto the surveillance team to consider when this guideline is updated.
Intensive Care Society	Guideline	008	001 - 025	General comment - I think the definitions of what counts as major surgery are going to vary greatly across organisations.	Thank you for your comment. Definitions were used from the NICE preoperative tests for elective surgery guideline categorization. A table has been added into the glossary section to show different categories of surgery. The glossary can be found in the methods chapter. Major complex surgery is defined in the 'terms used; section of the guideline
Medtronic	Guideline	General	General	The continuous monitoring of cerebral desaturations during general anaesthesia has been shown to reduce the incidence of Post-Operative Cognitive Dysfunction (POCD). Studies into POCD have concluded that it is associated with an increase in the patient's length of stay in the hospital[1,2]. Further, there is evidence to support the reduction of postoperative complications. We therefore feel that it is important to include Cerebral Oximetry Monitoring within this Clinical Guideline and request that the committee consider the inclusion of Cerebral Oxygen Desaturation monitoring. 1. Lopez, O., Gollaher, T. and Riddle, D. (2014) 'Cerebral oxygen desaturation monitored by intraoperative near-infrared spectroscopy and incidence of post-operative cognitive dysfunction: a systematic review', *JBI Database of Systematic*	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result,areas to be included in the guideline had to be prioritised. The continuous monitoring of cerebral desaturations was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.

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				Reviews and Implementation Reports, 12(8), pp. 145–192. doi: 10.11124/jbisrir-2014-1163. Zorrilla-Vaca, A. *et al.* (2018) 'Intraoperative cerebral oximetry-based management for optimizing perioperative outcomes: a meta-analysis of randomized controlled trials', *Canadian Journal of Anesthesia/Journal canadien d'anesthésie*, 65(5), pp. 529–542. doi: 10.1007/s12630-018-1065-7.	
Medtronic	Guideline	General	General	We are concerned that the guidelines imply that cardiac monitoring is the only monitoring system recommended during intraoperative care. We therefore would recommend that the committee considers the inclusion of depth of anaesthesia monitors. Studies have shown that monitoring the depth of anaesthesia to an optimal level improves the patient's emergence, recovery and discharge from the post anaesthesia care unit[3,4]. Significant evidence exists regarding the benefits which depth of anaesthesia monitors have in elderly patients[5], aligned to the scope outlined in Section 3.1. We therefore feel that it is important to explicitly include depth of anaesthesia monitors within this clinical guideline. 1. Punjasawadwong, Y., Phongchiewboon, A. and Bunchungmongkol, N. (2014) 'Bispectral index for improving anaesthetic delivery and postoperative recovery', *Cochrane Database of Systematic Reviews*. John Wiley & Sons, Ltd, (6). doi: 10.1002/14651858.CD003843.pub3. 2. Chan, M. T. V. *et al.* (2013) 'BIS-guided Anesthesia Decreases Postoperative Delirium and Cognitive Decline', *Journal of Neurosurgical Anesthesiology*, 25(1), pp. 33–42. doi: 10.1097/ANA.0b013e3182712fba. Quan, C. *et al.* (2019) 'BIS -guided deep anesthesia decreases short-term postoperative cognitive dysfunction and peripheral inflammation in elderly patients undergoing abdominal surgery', *Brain and Behavior*, 9(4), p. e01238. doi: 10.1002/brb3.1238.	Thank you for your comment. Cardiac output monitoring is included in the scope of this guideline. Depth of anaesthesia was not identified as a priority area during the scoping process.

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National Axial Spondylarthritis Society	Guideline	004	007	Discussion of current medications should take place. Patients who are prescribed biologic drugs will need to stop medication a set number of weeks before an operation and will not be allowed to begin administering again immediately following an operation. Surgeons should be fully aware. Alternatives for pain management should be discussed in full.	Thank you for your comment. We expect that current medications would be discussed a part of good practice in preparation for surgery. Contraindications for medications are not routinely included in NICE guidance but healthcare professionals should be aware of these and refer to guidance from the BNF.
National Axial Spondylarthritis Society	Guideline	004	007	Patients have reported that it is important for the pain clinic / team to be involved with perioperative care throughout the process.	Thank you for your comment. This was considered by the committee and we have added this to the committee's discussion of the evidence in evidence review N1
National Axial Spondylarthritis Society	Guideline	004	009	We are concerned that the risk stratification tools do not include any which consider fusion of the axial skeleton which can occur in people with axial spondyloarthritis including ankylosing spondylitis, leading to issues with chest expansion, lying flat during an operation. Cardiac risks may also occur.	Thank you for your comment. The committee acknowledge the use of surgery or disease specific risk tools, but within the scope of the guideline were required to review and consider general risk tools for people undergoing all forms of surgery. Reference to specific tools has been removed to avoid inference that these are the only appropriate risk assessment tools. Professionals should use their judgement to decide if a surgery or disease specific tool is appropriate for the individual having surgery.
National Axial Spondylarthritis Society	Guideline	008	001	People with axial spondyloarthritis including ankylosing spondylitis may suffer spinal fusion. This means that they are unable to turn their head or lie flat. There is also an increased risk of spinal fracture and should be handled carefully.	Thank you for your comment. The group of people you identify would be covered by the current recommendation.
National Axial Spondylarthritis Society	Guideline	008	001	Patients with spinal fusion can miss meals due to being unable to turn their head.	Thank you for your comment
National Axial Spondylarthritis Society	Guideline	008	007	Consider physiotherapy and hydrotherapy as an alternative for pain relief for those who cannot tolerate additional medication.	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We now acknowledge the importance of the non-pharmacological management of pain in evidence review N1.
National Axial Spondylarthritis Society	Guideline	008	007	Patients with axial spondyloarthritis must be able move as soon as possible. Laying still is likely to cause more pain and stiffness.	Thank you for your comment. Guidance is given to encourage mobilisation post-surgery. For example, promoting the use of oral pain medication instead of IV. We also discuss the importance of mobilisation in evidence review N1.

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National Axial Spondylarthritis Society	Guideline	008	018	Consider other conditions which may cause pain other than the condition being treated by the operation.	Thank you for your comment. This has been considered in the recommendation for planning pain management under the patient's pain history. We now acknowledge that i the pain clinic may be involved in people with pre-existing pain in the committee's discussion of the evidence in evidence review N1.
National Axial Spondylarthritis Society	Guideline	008	022	Consider additional analgesia may be necessary if a patient has an underlying condition or medication which was stopped to receive surgery eg biologic drugs.	Thank you for your comment. This has been considered in the recommendation for planning pain management under the patient's pain history. We now acknowledge the that the pain clinic may be involved in people with pre-existing pain in the committee's discussion of the evidence in evidence review N1.
National Axial Spondylarthritis Society	Guideline	General	General	There is no mention of preoperative home assessments with occupational therapy.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Preoperative home assessments were not identified as a priority area during the scoping process; your comments have been passed on to the surveillance team to take into account when this guideline is considered for update
National Axial Spondylarthritis Society	Guideline	General	General	There is no consideration of post-operative rehabilitation using physiotherapy and hydrotherapy if they have had any imposed bed rest and/or suspension of their biologic. It is common place to utilise water proof dressings or aqua shields to facilitate patients in the water and they can then address overall mobility exercises.	Thank you for your comment. Guidance is given to encourage mobilisation post-operatively and to adopt a multi-modal approach to enhancing recovery, including aspects of physiotherapy where appropriate. The scope of the guideline was limited to the perioperative period and did not include post-operative rehabilitation. In this guideline the perioperative period starts when the patient is booked for surgery and ends when the patient is discharged from care following surgery.
NHS England and NHS Improvement	General	General	General	Research recommendation re: preoperative optimisation clinics. I would prefer if the call included older patients and/or those with multimorbidity of any age. (SRM)	Thank you for your comment. The research recommendation has been edited to make it clearer that people with multimorbidities are included as a subset of older people Younger people with multimorbidity were not included in the review protocol. The research recommendation should reflect the population in the evidence review.
NHS England and NHS Improvement	General	General	General	Cost implications of guidelines: none major; likely increased costs associated with ensuring adherence to smoking cessation guidance	Thank you for your comment. The committee agree with your comment and have outlined the costs associated with cardiac output monitors in Appendix 1. Cost effectiveness-cardiac output monitoring.

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				(but this is obviously a good thing), and use of cardiac output monitors in high risk patients as not all hospitals will use the latter (SRM)	
NHS England and NHS Improvement	General	General	General	Implementation challenges: enhanced recovery implementation remains a challenge despite it generally being accepted to be evidence based. CQUIN/BPT related to this, perhaps measured through www.pqip.org.uk and appropriate specialty specific audits would help. Shared resources would also help. (SRM)	Thank you for your comments. The committee agree and PQIP is referred to in the committee's discussion of the evidence in evidence report B. The potential benefits of speciality specific audits and shared resources have been added to the write up of this discussion.
NHS England and NHS Improvement	Guideline	003	003 - 014	It would be helpful to be clear about when the single point of contact should be allocated. The guidelines cover the period from when the patient is listed for surgery until discharge from hospital. While there may not be evidence to support this, a patient-centred approach would be to allocate the single point of contact at the time that the decision for surgery is taken and for that to last until after the first post-surgical discharge outpatient review (or discharge from hospital for procedures not requiring post-discharge follow-up by secondary care). (SRM)	Thank you for your comment. When the point of contact should be allocated has been added to recommendation and to the committee's discussion of the evidence in evidence review A. We no longer refer to a single point of contact.
NHS England and NHS Improvement	Guideline	004	001 - 006	Enhanced recovery: findings from the Perioperative Quality Improvement Programme plus research findings from the UK and internationally, indicate that adherence to ER pathways remains a challenge for many hospitals. This is reflected in the continued wide variation in length of stay between institutions identified in GIRFT reports. There is a research opportunity to investigate methods which support implementation and adherence to ER pathways – something which has been neglected in the literature so far. (SRM)	Thank you for your comment. Adherence to Enhanced Recovery programmes was not highlighted as an area of practice prioritised for guidance. As the evidence on this area was not looked at with an evidence review, the committee are unable to make a recommendation for further research. The implementation team at NICE will provide support for this guideline.
NHS England and NHS Improvement	Guideline	006 012	014 020	Would the committee consider that the issue of carbohydrate loading for (a) other specialties and (b) in patients with diabetes might be worth research recommendations? (SRM)	Thank you for your comment. The committee considered where further research could be beneficial and agreed that further research on pre-operative carbohydrate drinks is needed, but with a priority on reviewing the timing of administration.
NHS England and NHS Improvement	Guideline	007	003	I am concerned that there is insufficient detail in this recommendation, given the level of equipoise in the literature for perioperative haemodynamic optimisation. It may help to provide a little more detail – e.g.	Thank you for your comment. The recommendation focuses on what action to take and a brief explanation for the recommendation is in the rationale section. More detail is provided in the committee's

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				- cardiac output monitoring may considered as an adjunct to help anaesthetists determine the cause of reduced blood pressure (i.e. low CO vs low vascular resistance) further evidence on how cardiac output monitors should be used to haemodynamic optimisation for both elective and emergency abdominal surgery is being gathered through large clinical trials	discussion of the evidence. The points you have raised have been added (see evidence review J).
NHS England and NHS Improvement	Guideline	008 012	002 - 005 013	I found the term 'specialist recovery area' confusing. I think the committee was referring to ICS defined Level 2 and 3 units and if so it would be helpful to use this terminology (SRM)	Thank you for your comment. A definition has now been added to the recommendation.
NHS England and NHS Improvement	Guideline	009	009 - 017	I am concerned that the NSAID guidance is too broad. There are concerns in some types of surgery (orthopaedics and colorectal in particular) about the risks of NSAIDs for bone healing and anastomotic breakdown for example. I think therefore this section needs some refinement / mention of caveats / exceptions / areas of uncertainty. (SRM)	Thank you for your comment. The use of NSAIDs is for the perioperative period only and not for long term use and the contraindications specified in the BNF should be followed. The specific NICE guidelines on NSAIDs should be followed for example non-complex fractures NG38.
NHS England and NHS Improvement	Guideline and Evidence review – preoperative risk tools	004 and general feedback	009 - 017 and general feedback	Assessing the risks of surgery: I am surprised at which risk stratification tools were named in the guideline – the P-POSSUM is regularly found to be poorly calibrated; the NSQIP tool has never been validated in a large UK cohort; and both the E-PASS and P-POSSUM require intraoperative variables to be guessed in order to complete preoperatively. Doing a systematic review of this area is extremely challenging, and perhaps for this reason, a number of relevant manuscripts have also been omitted – e.g. a previous systematic review of this field (Moonesinghe et al Anesthesiology 2013). Options other than risk tools for preoperative risk stratification (e.g. functional capacity assessment) have also not been mentioned, and nor have condition / surgery specific tools such as the EuroSCORE for cardiac surgery or Nottingham Hip Fracture Score. I think that this area is worthy of its own NICE guidance in order to provide more detailed recommendations (SRM)	Thank you for your comment. The committee acknowledge the existence and utility of surgery specific risk scoring systems but given the broad nature of the guideline and the extensive list of surgery specific tools, were limited to focus on the utility of general risk tools for people undergoing surgery. Specific named examples have been removed. Thank you for the reference provided. This has been reviewed and additional studies added.
NHS England and NHS Improvement	Guideline and Evidence review C	General	General	New evidence which should be published within 3 months indicates that in fact formal risk stratification is not commonly undertaken in practice, despite lots of previous guidelines. I don't think that	Thank you for your comment. The expectation is that the current guidance will improve the access to and uptake of risk stratification

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				implementation need necessarily be challenging though; hospitals / individual consultants simply need to be able to access the appropriate websites or mobile apps to be able to access the calculators for tools such as P-POSSUM, ACS-NSQIP or SORT. (SRM)	tools. We have passed your comment on to the implementation team at NICE.
Resuscitation Council UK	Guideline	018	013 - 018	Fully support that checklist should and must be used, but we wish to raise concerns about modifying the process. Checklists are an essential feature of safe practice in complex circumstances. That said, adding items to the checklist can be seen as an easy fix to demonstrate that 'something has been done' without thinking critically whether this is the right tool for the job. Adding complexity can make systems less safe, particularly if they are not designed with careful thought.	Thank you for your comment. The WHO implementation manual is permissive of modifications being made to the checklist 'to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other. The committee highlighted the importance of making the checklist bespoke to your environment. They also wished to incorporate local safety standards for invasive procedures.
Royal College of Anaesthetists	Comment form question 1	General	General	**Q. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.** A. As stated in the document, the provision of specialist recovery will have significant upfront costs in terms of staff, equipment and location. This will make them difficult to implement but this is possibly the intervention that would have the greatest impact on outcome.	Thank you for answering this question. We have acknowledged that there may be significant costs. However, there may also be savings achieved by reducing the occurrence of postoperative adverse events and the need to manage these.
Royal College of Anaesthetists	Comment form question 2	N/A	N/A	**Q. Would implementation of any of the draft recommendations have significant cost implications?** A. Specialist recovery areas	Thank you for answering this question.
Royal College of Anaesthetists	Comment form question 5	N/A	N/A	**Q. Due to a lack of evidence the committee has not made a recommendation on anticoagulation bridging treatment in people taking a vitamin K antagonist with a target INR of more than 3, and has instead made a research recommendation. We would welcome your view on whether this research recommendation appropriately addresses the uncertainly in practice in this area.** A. I think the research recommendation for anticoagulant bridging needs looking at more closely. I could not find evidence submitted to show great variation in practice and I would be surprised to find may	Thank you for your comment. Due to recent local policy initiatives the committee agree that the original research recommendation is now unlikely to be conducted. The research recommendation has been edited to focus on the consensus of haematologists through a Delphi survey. This approach would identify current practice and support consensus based recommendations.

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				units using UFH for bridging. It might be worth trying to get a more accurate picture of current practice before recommending research in this area. My personal opinion is that the research would be extremely difficult to do and might not make the picture any clearer. In addition, the use of UFH in a research setting would be very different to its use in an ordinary clinical setting particularly with regard to measurement of APTT and ensuring that anticoagulation is adequate.	
Royal College of Anaesthetists	Guideline	003	004	I strongly support the proposals on single point of contact, based on practical experience of other services eg cancer, renal services. It can be expected that this will have resource implications, frequently requiring staff expansion	Thank you for your comment. In response to stakeholder comments regarding the resource implications of a single point of contact we now refer to a person or a team of people. This allows decisions to be made locally about how to deliver this recommendation.
Royal College of Anaesthetists	Guideline	004	002	1.2.1- ERP. A clear focus on Enhanced Recovery needs to be maintained as it is easy for staff to lose track of this in the light of competing operational clinical pressures. It is likely this would have additional staffing implications. The guideline suggests that research is required on emergency surgery and given the proven value with elective ERP, there would seem value in exploring the potential for emergency surgery	Thank you for your comment.
Royal College of Anaesthetists	Guideline	004	009	1.3.1 Risk Assessment- the National Emergency Laparotomy Audit (NELA) provides additional evidence to support the requirement for risk assessment	Thank you for your comment.
Royal College of Anaesthetists	Guideline	006	002	1.3.7 – nutritional assessment- this can be an overlooked factor and it is good to see it given prominence	Thank you for your comment.
Royal College of Anaesthetists	Guideline	006	009	Oral fluids- I support the promotion of a newer approach to fluids. Patients often have strong preconceptions relating to 'nil by mouth' and need new advice. This has been highlighted by the promotion of new policies at recent ACSA visits e.g. at Leeds.	Thank you for your comment.
Royal College of Anaesthetists	Guideline	007	013	1.4.8 WHO checklist- it is important that this is emphasised as the significance of the checklist has been supported by clear evidence for many years but experience, including Anaesthesia Clinical Services Accreditation (ACSA) reviews, indicates a continuing variation in practice	Thank you for your comment.

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Royal College of Anaesthetists	Guideline	008	003	1.5.1 Specialist Recovery areas – the guideline outlines evidence in support of this development. I think this proposition in particular could have very considerable resource implications, with increasing costs of care resulting from the introduction. However, there could be some offsetting savings resulting from shorter lengths of stay, more effective use of specialist resources etc	Thank you for your comment. The committee agree with your summary and discuss the resource impact of this recommendation in the impact section of the guideline and in the committee's discussion of the evidence (see evidence review M).
Royal College of Anaesthetists	Guideline	008	009	1.6.1 Pain management- information for patients on options for pain management is important and needs to be supported by adequate written information; possibly patients may be more engaged or even concerned, given the publicity on potential opioid dependency	Thank you for your comment. This has been considered in the recommendation for planning pain management under the patient's pain history and discussion section. The recommendation on providing a point of contact will also support the patient if they have any questions regarding pain management. We cross-refer to the NICE guideline on patient experience for recommendations on information and support in recommendation 1.1.2
Royal College of Anaesthetists	Guideline	009	009	I do not think that there is adequate warning about the problems associated with NSAIDs in the perioperative period. I accept that people are encouraged to take comorbidities into account by the reference to point 1.6.1 but I do not think this is strong enough and would like to see something in the paragraph on NSAID prescription along the lines of "when considering offering these drugs it is important to take all comorbidities, concurrent medication, age and operation type into consideration".	Thank you for your comment. The factors you suggest are referred to in recommendation 1.6.1. The committee discussion has been amended in evidence review N1 to reflect your comment.
Royal College of Anaesthetists	Guideline	009 - 010	026	Whilst I can see why the compilers have put the recommendation for PCA or epidural in based on the evidence they have looked at, it remains difficult to run continuous epidural infusions in many hospitals. For that reason, if no other, I would have liked the authors to consider other pain relief methods such as TAP blocks or rectus sheath catheters either alone or in combination with PCA. They have also discounted spinal analgesia due to lack of evidence but again this is often used in combination with TAP blocks rectus sheath catheters and or PCA. Whilst the literature is clear that epidural analgesia is superior to rectus sheath catheters or TAP blocks, I think this guideline should at least mention them as they are widely used.	Thank you for your comment. The committee decided that there was insufficient evidence to support a recommendation for spinal opiates but acknowledge the utility of other techniques of pain management in their discussion.

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Royal College of Anaesthetists	Guideline	General	General	I find this guideline is rather bland and not very progressive. I think it needs balancing against what CPOC advises and where it varies should be highlighted.	Thank you for your comment. The guidance is based on up to date reviews of the clinical and economic evidence on areas that were prioritised during the scoping process. The guidance provides recommendations on areas of uncertainty or where there is variation in practice across the NHS Any future updates of the guideline may expand on the recommendations. The guideline doesn't highlight differences to other guidelines. However, the committee discussions describe how the committee evaluated the evidence and outlines their decision making to develop the recommendations.
Royal College of Anaesthetists	Guideline	General	General	I found this quite difficult to comment on, largely because it is clinically-based with many technical terms and refers regularly to other guidelines. I just have a few comments: · On p4 of the Summary, 1.3.2 Lifestyle modifications · Could we ask them to reference our Fitter Better Sooner and the Centre for Perioperative Care (CPOC). CPOC is a new cross-organisational, multidisciplinary initiative led by the Royal College of Anaesthetists to facilitate cross-organisational working on perioperative care for patient benefit. CPOC is a partnership between patients and the public, other professional stakeholders including Medical Royal Colleges, NHS England and the equivalent bodies responsible for healthcare in the other UK devolved nations. · Section D Evidence Review for preop optimisation clinics for older people · I am not surprised NICE were unable to make firm recommendations. It seems totally unnecessary to me. Their criteria is "aged over 60". Given that people are living and working longer past former retirement age of 60/65 years, I feel this is verging on discriminatory. The criteria should be based on need, not age. I know two people over 80 who regularly play tennis.	Thank you for your comment. We are unable to reference non-NICE guidance. However, on the website there will be a section on 'information for the public' where we can highlight organisations that provide information. The focus of evidence review D was preoptimisation clinics for older people. Recognition of deficits in routine pathways of care has led to the development of new models of care; Enhanced Recovery after Surgery (ERAS) and 'Perioperative medicine for Older Patients undergoing Surgery' (POPS). ERAS employs a standardised approach to preoperative, intraoperative and postoperative care, whilst POPS delivers care throughout the surgical pathway underpinned by comprehensive assessment and optimisation methodology. POPS clinics were therefore specifically designed for older adults. Where these exist, all older adults undergoing planned surgery would be seen in the clinics to ensure optimal outcomes after surgery. The committee recognised that health may vary significantly in older people and some people aged over 60 may be fit and well but considered this a suitable threshold to identify a general population of older people who may benefit from preoperative optimisation. We have made the edits you suggested.

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				· 1.2 Introduction to above, line 14 quotes "optimise the patient" – surely this should be "optimise the care/recovery of the patient". · Similarly line 1.7.1.1 on p14, line 21 quotes "optimising older people". I think this should be "optimising the care/recovery of older people".	
Royal College of Anaesthetists	Guideline	General	General	Although NICE guidance is mainly aimed at health care professionals, my understanding is that it is also intended that patients should read the guidance. This document states ' nice guidelines should help patients make informed decisions and specifically includes on the first page under 'Who is it for" Adults having surgery, their families and carers I have just tried reading the document as ' an adult having surgery ', deliberately putting aside any knowledge I already have of NICE guidelines from my years working in the health service. Unfortunately, unless I have missed something, my conclusion is that the document is difficult for patients to navigate and understand and very unlikely to add to any understanding by someone approaching surgery, indeed for some patients and their families it may well increase their worry and apprehension. I don't think this is unique to this particular NICE guidance and fully recognise that patients are not the key target for the document. However, given the growing number of supportive and helpful documents available elsewhere for patients, and their families, including some produced by RCoA, I would recommend a maximum one page specifically for patients with a very brief and easy to read document linking to other patient friendly sources of information and support. If this is outside the remit of NICE then I suggest this should be made clear to patients and their families early on in the document. The document is very secondary care orientated but there is nothing about working with general practice to optimise things that might have an impact. For example, improving diabetic care, losing weight, improving muscle mass etc. prior to surgery. There is also nothing from what I can see about the "hand over" back to general practice.	Thank you for your comment. On the NICE website there will be a section entitled 'information for the public'. As well as summarising what the guidance covers it will also provide links to websites that can provide further information. The rationale and impact sections of the guideline aim to be understandable to all readers and explain why the recommendations were made. In the scope for this guideline we state that modifications of lifestyle prior to surgery will be cross-reference (recommendation 1.3.2). The committee anticipate that the recommendations on patient information and support will facilitate discharge back to community. This guideline is intended to be read alongside the NICE guideline on patient experience in adult NHS services. There is a section on the importance of transitions and continuity of care.

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				There is a lot of work going on with the Centre for Perioperative Care and it does seem to miss many of the things being sensibly discussed there.	
Royal College of Anaesthetists	Guideline	General	General	Lay comments are invited but the format for putting forward comments is not 'lay friendly'. I understand why NICE wants to encourage structured responses. I can see that this will make it easier and more efficient for them to analyse contributions. However, it seems to me that the strict approach to submitting comments and the didactic, rather bossy tone of the instructions is likely to deter lay people and lay groups from making contributions. It is clear that major effort and resource has been committed to looking at the information and support required by patients in the perioperative period. The evidence considered and the conclusions reached are clearly set out and people who want to interrogate the rationale for the recommendations are directed towards detailed source material. The recommendations include specific reference to communication with people with learning disabilities e.g. 1.1.3 which is certainly to be welcomed. What about others whose circumstances impact on their ability to communicate - for example those with hearing and visual impairments or those for whom English is not their first language? This may be included in the links to other documents but I have not noticed it in the summary recommendations. The guidance is clearly mainly aimed at health professionals. However, it also says specifically that it is aimed at 'Adults having surgery, their families and carers.' With this in mind I think more terms should be explained or plain English versions offered. This is especially the case in sections which patients and carers are most likely to access - for example those about information and support, pain management and single point of contact. A couple of examples of technical terms and words which I noticed are: · off-label use · multimodal · preoperative optimisation	Thank you for your comment. We are sorry that you found it difficult to provide comments on the guideline. We have passed your comments to the Public Involvement Programme at NICE more details can be found at https://www.nice.org.uk/about/nice-communities/nice-and-the-public/public-involvement This guideline is intended to be read alongside the NICE guideline on patient experience of adult NHS service. This makes a recommendation on the format of information and support including how it should be tailored to the individual. On the website there will be a section on 'information for the public' which summarises what the guideline covers and signposts people to further sources of information The definition for multi-modal has been provided in the recommendation. Definitions of the terms noted have been added to the glossary which can be found in the chapter on methodology.

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Royal College of Nursing	Guideline	003	004	Increasingly AHPs are working as Advanced Clinical Practitioners as well. When discussing single point of contact, does this need to be a registered practitioner, as the surgical teams secretaries fulfil this role already, referring the patients' queries to the appropriate staff member when required.	Thank you for your comment. The evidence review and the committee including the lay representatives highlighted the importance of giving the contact details of a person or to a team of people to answer or direct specific questions about their care. We have edited this recommendation on patient information and support and now refer to a point of contact. In the rationale and impact is clear that this point of contact could be a team of people or a specific individual. This point of contact could also direct the person to someone who can answer questions about their care and may change throughout the perioperative journey. We have edited the committee's discussion of the evidence in evidence review A to make this clearer.
Royal College of Nursing	Guideline	004	002	How is major or complex surgery defined?	Thank you for your comment. Definitions for major and complex surgery have now been added in the terms used in the guideline.
Royal College of Nursing	Guideline	004	008	Who is best to assess the risks of surgery? No mention of profession.	Thank you for your comment. The focus of this review was whether risk assessments should be performed. Who performs the risk assessment is a decision that will vary according to local service configuration.
Royal College of Nursing	Guideline	006	001	Who is best to perform nutritional assessment?	Thank you for your comment. Who performs the nutritional assessment is a decision that would be taken locally.
Royal College of Nursing	Guideline	006	007	It is good to have clarity on oral fluids but what about food? Guidance on chewing gum?	Thank you for your comment. The committee were unable to make recommendation on food restriction prior to surgery due to a lack of evidence to guide a recommendation and were not confident to make a consensus recommendation given the wide variation in current clinical practice. We have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update.
Royal College of Nursing	Guideline	007	012	When discussing the Surgical Safety Checklist, there could be reference made to NatSIPs, and the opportunity to standardise the checklists.	Thank you for your comment. We now refer to NatSIPs in the committee's discussion of the evidence in evidence review L.
Royal College of Nursing	Guideline	008	002	Define of specialist recovery area. What about reference to FICM Enhanced Care? No mention of Emergency Laparotomy pathway and direct admission to ICU.	Thank you for your comment. A definition has now been added to the recommendation. The committee considered that FICM is a bespoke/localised pathway and that the ELP would fall under the SRU umbrella.
Royal College of Nursing	Guideline	008	007	Why is there no mention of regional anaesthesia?	Thank you for your comment. It was not possible to cover the entire perioperative pathway and the scope focuses on areas of clinical

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					uncertainty or variation in practice. This was not highlighted as a priority area requiring guidance. We will make the surveillance team at NICE aware of your comment.
Royal College of Nursing	Guideline	General	General	Guidance on antibiotics intra and post operatively may be helpful.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas included in the guideline had to be prioritised. Guidance on antibiotics was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team to consider when this guideline is updated.
Royal College of Nursing	Guideline	General	General	The significance of Post-Operative Nausea and Vomiting as a barrier to early mobilisation and discharge. Its management is not addressed.	Thank you for your comment. The committee agree that nausea and vomiting has a significant impact and accordingly is recognised as an important outcome across the post-operative management evidence reviews. As a result the impact of nausea and vomiting was taken into account in all the committee's decision making on interventions. The management of the nausea and vomiting itself was not identified as a priority area during the stakeholder consultation of the scope
Royal College of Nursing	Guideline	General	General	Surgical wound care is not mentioned.	Thank you for your comment. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. Surgical wound care was not identified as a priority area during the scoping process but we have passed your comment onto the surveillance team at NICE to take into account when this guideline is considered for update. Surgical site infection was included as an outcome for evidence reviews throughout the guideline where this was deemed to be an important outcome.
Thrombosis UK	Guideline	General	General	We thank you for the opportunity to comment on this guideline. There are several general comments that we would like to make and also some links to patient information materials which we hope will prove useful.	Thank you for your comment.
Thrombosis UK	Guideline	General	General	It is vitally important that patients and their family/carers are aware of the risk of developing thrombosis both during and following their hospital admission and are reliably informed about risk, prevention and self-help.	Thank you for your comment. The recommendations on assessing and reducing the risk of venous thromboembolism for people having surgery in the NICE guideline on venous thromboembolism in over 16s are cross referred to in the guideline. We recognise the importance of providing information and the main theme emerging from the evidence review was the importance of providing people

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				We welcome the reference to NICE guidelines but would like to stress that information should be shared both in written form and verbal, throughout the treatment and recovery pathway, with plenty of opportunity for an individual and their family / close support, to discuss, be reminded and ask questions. In collaboration with VTE exemplar lead nurses we have developed an information booklet for the general hospital population 'Lowering your risk of blood clots' https://thrombosisuk.org/admin/resources/downloads/tuk-lowering-your-risk-of-blood-clots.pdf and also for high risk groups including cancer patients, 'Cancer and the risk of blood clots]', who are statistically at higher risk of thrombosis.	with a point of contact to answer any question they may have about their care. We also cross-refer to the NICE guideline on patient experience which makes recommendations on information provision. Thank you for the link to the patient information resource.
Thrombosis UK	Guideline	General	General	It is important to inform patients about the signs and symptoms of blood clots in an accessible and simple format that includes verbal and written information and can be shared with close family/support. For example: https://thrombosisuk.org/admin/resources/downloads/tuk-a5-vte-general-leaflet-final.pdf	Thank you for your comment. Recommendation 1.1.3 cross-refers to the NICE guideline on patient experience in adult NHS services. The patient experience guideline includes recommendations on communication and giving information, including the format of information
Thrombosis UK	Guideline	General	General	Patient groups at increased risk and those who may be vulnerable, frail or find recalling information difficult, should be given opportunity for a named healthcare professional to liaise with them and their family/support and ensure continuity of care after discharge.	Thank you for your comment. This guideline is intended to be read alongside the NICE guideline on patient experience in adult NHS services.
Thrombosis UK	Guideline	General	General	The opportunity to discuss prescribed medication, how to take it and who to contact should the patient have any questions with a named HCP is also of great importance.	Thank you for your comment. This was considered by the committee and has been added to the committee discussion of the evidence in evidence report N1.
UK Clinical Pharmacy Association	Guideline	General	General	Overall, we feel there is very little substance to the recommendations in this guidance. As such we find it disappointing and are not sure it adds anything to current practice; in fact in some areas more comprehensive documents from reputable societies already exist. We think the scope of the guidance is too broad as it covers many topics in minimal detail and as such the content feels diluted and disjointed and	Thank you for your comment. The committee recognise that this is a broad set of recommendations covering a wide range of topics. Perioperative care encompasses many different areas of care and, as a result, areas to be included in the guideline had to be prioritised. We have aimed to provide guidance in areas where there is current variation in practice across the NHS or uncertainty.

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				leaves many questions unanswered. No rationale is provided for why the guidance focuses on part of a topic and the rest of the topic was not addressed i.e. it feels like each of the sections could be a guideline in its own right with several review questions for each mini topic.	The guideline highlights areas where research is needed to inform future guidance. Any future updates of this guideline may explore other topics in more detail. Any future updates of the guideline may expand on the recommendations. We have now added this to the context section of the guideline.
UK Clinical Pharmacy Association	Section A – Information	General	General	We agree with the named point of contact in pre-operative assessment team for pre-op concerns, outcome of investigations and discussions regarding optimisation etc to ensure continuity of care and improve patient experience. This is already implemented within some trusts, although current practice is that this named point of contact covers the time from initial contact with the pre-operative assessment clinic up until the point of the actual operation (including any cancellations etc and answering any questions about post-op expectations e.g. when can fly, when can return to work) but doesn't extend into the postoperative period (e.g. patients concerns post-op – do they have a DVT? Do they have a wound infection?). The surgical team / ward will be better placed to answer any concerns post-operatively e.g. post-op wound care (mentioned page 32/line 40) so feel that the named point of contact should only cover up until time of surgery and a further person/ward to contact should be given as part of the discharge from hospital. It's disappointing that the guidance doesn't actually indicate what information should be provided to patients. As lines 6 and 7 on page 15 mention that patients couldn't recall information from pre-surgical consultations after surgery and that lines 24/25 on page 16 mention that some patients feel overwhelmed by the information given we strongly feel that patients should be provided with written instructions about any changes to their medication that are required pre-operatively to reinforce the verbal information provided. The JBDS guidance 'Management of adults with diabetes undergoing surgery and elective procedures: Improving standard' states on page 21 that "patients undergoing investigative procedures requiring a period of	Thank you for your comment. We have edited this recommendation and no longer refer to a 'single' point of contact and have removed reference to it remaining the same throughout. In the rationale we explain that this could be a team of people or an individual. The point of contact may also be to someone who can signpost to the most appropriate person. We have added this to the committee's discussion of the evidence in evidence review A. We also now recognise in evidence review A that this point of contact may change throughout the perioperative journey. The focus of this guideline was the perioperative phase rather than on post-operative recovery. This guideline cross-refers to NICE guideline on patient experience NG138 which makes recommendations on for example enabling patients to actively participate in their care

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				starvation should be identified and provided with written information about diabetes management".	
UK Clinical Pharmacy Association	Section B – enhanced recovery	120	037 - 040	ER protocols are also beneficial in other types of surgical procedures other than those mentioned to include Upper Gastro-intestinal surgery. The principles can be extended to other major elective surgery procedures to include specialities such as renal transplant, head and neck related surgical procedures and urology. ER is difficult to implement in emergency surgery as it is not possible to optimise the patient for the procedure prior to surgery. Agree that ER is not applicable to day case and dental surgery. There have been a couple of papers published in the UK highlighting role of pharmacists along enhanced recovery pathways. These studies demonstrate impact of optimising patients prior to surgery and more pro-active involvement post-operatively leading to a reduction in overall length of stay and post-operative complications. These could be considered by the committee as examples of innovative practice which could potentially be adopted by other NHS Trusts: Bansal N, Tai WT, Chen LC (2019). Implementation of an innovative surgical pharmacy service to improve patient outcomes – twelve-month outcomes of the Enhanced Surgical Medicines Optimisation Service. Journal of Clinical Pharmacy and Therapeutics. Available online at: https://onlinelibrary.wiley.com/doi/10.1111/jcpt.13014 Bansal N, Morris J (2019). Pharmacist involvement in Elective Enhanced Recovery Pathways to improve patient outcomes in Lower Gastrointestinal Surgery. A Prospective before and after study. International Journal of Clinical Pharmacy. Available online at: https://rdcu.be/bPCSJ	Thank you for your comment. The committee agree that ER protocols may have benefit in other types of surgery, but just wished to highlight where they are recognised to have clear and significant benefit from the evidence. The committee also recognise the potential benefit of pharmacist intervention and highlight that enhanced recovery should be multimodal and flexible to the institution and patient. We have made the surveillance team at NICE aware of the references.

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UK Clinical Pharmacy Association	Section C - Preoperative Risk Stratification Tools	General	General	In the initial PICO question SORT is listed as one of the risk stratification tools but then it is not mentioned in recommendation 1.3.1 or in the committee's discussion of the evidence – we note that there were limitations to the quality of evidence for the study(s) that used SORT. Does this mean use of SORT is not recommended as it is not reliable or that there is insufficient evidence to support its use? This would have implications within some Trusts as SORT is perceived as easier to complete / requiring less data so is routinely completed for all patients by the Pre-assessment nurses and escalated to anaesthetist for further discussion if SORT risk is high. P-possum, includes more variables and whilst this probably makes it a better tool it is more difficult to complete and tends to be reserved for use in anaesthetic consultations either electively or as justification/decision making for potential emergency surgery.	Thank you for your comment. The committee accept that the specific tool used may vary between centres. There was insufficient evidence to recommend a specific tool and we have now removed the examples from the recommendation.
UK Clinical Pharmacy Association	Section D – Preoperative Optimisation	General	General	We appreciate that there is limited evidence about POPS clinics and that they are associated with a significant resource implication - but did the committee consider any benefits of optimisation of some clinical conditions (e.g. reflux, anaemia, hypertension, diabetes) by staff working in the pre-operative assessment clinic rather than referring patients back to primary care? This is likely to have less resource implications than the POPS clinics and will still improve patient experience and enable optimisation of issues that could otherwise delay surgery in a timely manner (lines 4-7 of page 16). For example, some nurse-led clinics include pharmacist/nurse independent prescribers and have facilities such as 24-hour ABPM to enable further investigation of hypertension. Page 16 lines 17-18 – we would like to see pharmacists mentioned as a profession rather than grouped under allied health professionals. Pharmacists may not be involved in all clinics but we strongly feel that the presence of a pharmacist, in whatever format resources allow, contributes to patient safety and reduces the risks involved with surgery by encouraging evidence-based medication advice and	Thank you for your comment. The committee recognised the potential for POPS clinics but were unable to make any formal recommendation given the lack of clinical and cost-effectiveness data. The optimisation of pre-existing conditions prior to surgery is, in the experience and opinion of the committee, highly variable and the scope therefore focused on POPS clinics which address this issue. Pharmacists have now been recognised in the discussion of this evidence review in evidence review D.

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				encouraging patients to take their medications correctly. The Royal College of Anaesthetists specifically advocate pharmacy involvement in pre-assessment in their GPAS documents: "A process of medicines reconciliation by a pharmacist or pharmacy technician should be in place preoperatively".	
UK Clinical Pharmacy Association	Section E – Anaemia	General	General	The summary document (page 16 lines 7-13) states "Oral iron supplements are usually taken daily but some people have unpleasant side effects from daily iron. The committee thought that, for these people, switching to an alternate-day regimen should be considered as a means of reducing side effects and encouraging adherence. They noted that this potential benefit needs to be balanced against the potential risk that an alternate-day regimen might be more complicated for people taking multiple daily medicines". Some Trusts' preassessment clinics have already adopted the alternate day dosing for oral iron, and whilst it was partly to reduce side effects, in the main it was linked to the finding that an increased fractional absorption of iron occurs with alternate day dosing of iron due to differences in hepcidin production (https://ebm.bmj.com/content/23/6/228). Did the committee consider the impact on hepcidin production when advising on the merits of daily versus alternate-day regimens? The traditional male and female cut-off values for haemoglobin are used in the NICE document; however, these figures have been disputed in a recently published review article in the Anaesthesia journal (https://onlinelibrary.wiley.com/doi/full/10.1111/anae.14466) which proposes that "the cut-off value/trigger be changed to a haemoglobin > 130 $g.l^{-1}$ for both men and women. Women with haemoglobin levels between 120 and 129 $g.l^{-1}$ are not considered to be anaemic according to the WHO definition, leaving them at a potential disadvantage when undergoing major surgery. These women will not undergo further investigation or treatment of their reduced haemoglobin, even though they are more likely to need peri-operative red cell transfusion due to their lower circulating volume, despite losing	Thank you for your comment. The committee were unable to make recommendation on the routine use of daily or alternate-day administration of oral iron due to the lack of evidence. However, a research recommendation was made which may be able to capture both the side effects and impact on and of hepcidin production. The traditional thresholds of haemoglobin levels were used to review evidence. As the guideline did not focus on the specific target haemoglobin levels, no deviation from these recognised thresholds was made.

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				similar amounts of blood during surgery as men. A large multi-centre cardiac surgery study showed that, regardless of sex, lower haemoglobin was associated with increased transfusion requirements, prolonged hospital stay and higher mortality. Any reduction below 130 $g.l^{-1}$ was associated in a linear manner with worse outcomes. Furthermore, women with haemoglobin levels between 120 and 129 $g.l^{-1}$ undergoing cardiac surgery are more likely to be transfused, and are transfused more units of red cells and stay longer in hospital".	
UK Clinical Pharmacy Association	Section F – Management of Anticoagulant Medication	General	General	Although this section is entitled 'Management of anticoagulant medication', it doesn't cover management of DOACs or patients on warfarin with target INR<3 – these patients also need advice preoperatively – why weren't the management of these patients considered within the scope of this title? If the intention was not to include these situations the wording needs to change in the title for this section to prevent confusion. In addition, different wording is used in the summary document as page 5 lines 19-20 refer to this section as "people taking a vitamin K antagonist who need bridging therapy". It is acknowledged from the BRIDGE trial that not bridging was non-inferior to perioperative bridging with LMWH for the prevention of arterial thromboembolism and reduced the risk of major bleeding. However, the British Committee for Standards in Haematology advocate bridging for some indications other than mechanical valve replacement. Did the committee consider these other indications or are they stating that only patients with a target INR>3 require bridging? The focus of this section is the research recommendation (page 42, lines 6-9) to compare outpatient LMWH bridging with inpatient UFH. Is this relevant? (the above-mentioned BRIDGE trial only looked at LMWH). Given the pressures on the NHS are there going to be beds for patients to be admitted for UFH several days pre-operatively – e.g. a daycase hernia repair could then result in a week's stay in hospital?	The committee noted that the area prioritised for guidance was for people who require bridging of anticoagulant medication (warfarin) for surgery and agreed that there is no need to be bridged on DOACs. The focus of the review question was people with an INR > 3. The reason for this was that people taking vitamin K antagonists (VKA), with an international normalised ratio (INR) target greater than 3, are at a particularly high risk of developing deep vein thrombosis, pulmonary embolus or stroke. These are often people with mechanical heart valves and therefore require a greater level of blood thinning than other people using anticoagulant therapies, such as VKA with an INR target lower than 3 or a direct oral anticoagulant (DOAC). The committee were therefore unable to make recommendations on people with a target INR < 3. The research recommendation has been revised and is now a formal consensus survey instead of an RCT. This survey will explore if there are any groups of people when UFH should be offered. The cost effectiveness of any recommendation may be explored if there are future updates of this guideline. The role of CHADVASC and HASBLED for bridging was not prioritised during scoping for inclusion in the guideline.

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				Therefore, even if UFH was shown to be superior would it be implemented in practice? We also disagree with the choice of wording on page 17, lines 4-7 of the summary document: "People who take a vitamin K antagonist are at high risk of venous thromboembolism or stroke and therefore it is **usual practice** to provide bridging anticoagulation **during surgery** with either subcutaneous low molecular weight heparin (LMWH) or intravenous unfractionated heparin (UFH)". The above quoted sentence could cause confusion as it is not usual practice to bridge <u>all</u> patients as outlined above due to the BRIDGE study. Bridging is also not 'during surgery'; it is prior to and after surgery with a sufficient gap to allow the LMWH to wear off so the procedure can happen safely. Consideration should be also given to the use of CHADVASC and HASBLED scores for bridging. The BSH consensus statement in the BJH oct 2016 on peri-operative management of anticoagulation and anti-platelet therapy also makes reference to the fact that CHAD2 scores ≥4 require bridging. There is also no mention of the use of UFH for patients with renal impairment – reference How to bridge by tan et al, British journal of thoracic and cardiovascular surgery, July 2019.	
UK Clinical Pharmacy Association	Section G – nutrition	General	General	The major problem with pre-operative nutrition is that generally there isn't a large enough timeframe between pre-operative assessment and the surgery to significantly improve any nutritional markers.	Thank you for your comment. The committee agree with your comment and recognise the challenges of nutritional screening and preoperative intervention. This has been highlighted in the committee discussion in evidence review G.
UK Clinical Pharmacy Association	Section I - IV fluids	General	General	Based on the poor quality available evidence, cost implications and current practice, the recommendations are reasonable.	Thank you for your comment.
UK Clinical Pharmacy Association	Section J – Non invasive cardiac output monitoring	General	General	We agree that non invasive COM is added to the guidelines allowing clinicians to use this according to their clinical judgement and is definitely less invasive than PA catheter monitoring. However, PA	Thank you for your comment. Given the lack of evidence the committee were unable to comment on the utility of PA catheters. The committee made a recommendation to consider COM, which will still allow for the use of PA catheter monitoring where

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				catheter monitoring should not be ruled out as it is invaluable for cardiac surgery where PA catheters are used for monitoring the PA pressures and oxygen extraction necessary during cardiac surgery.	appropriate. PA catheter monitoring is considered as a type of COM. We have added a definition of COM to the 'terms used' section in this guideline.
UK Clinical Pharmacy Association	Section K – Blood Glucose Control	General	General	The guideline specifically mentions blood glucose control in hospital but does not address the pre-operative assessment of patients with diabetes (HbA1c review and optimisation of diabetic medication). Neither does it discuss the importance of appropriate management of medication and the need to ensure patient's receive written confirmation of this information (in the JBDS guidance on managing patients with diabetes undergoing surgery it specifies ensuring patients receive written information). There is no discussion around how to manage day case vs. those missing more than one meal or appropriate management of variable rate intravenous insulin infusion. The current JBDS guidance does not advocate tight BM control in BOTH type 1 and type 2 diabetes and specifies the range as 6 – 10 mmol/l for patients in both groups due to the risks associated with hypoglycaemia in the anaesthetised patient. Lower BMs (down to 3.5) are only suggested as acceptable in awake patients on non-glucose lowering agents. Overall, we don't think this adds anything to the current guidance already available and widely adopted by many Trusts from the JBDS.	Thank you for your comment. The pre-assessment of people with diabetes was outside of the scope of this guideline. The wording of the recommendations for blood glucose control has now been revised.
UK Clinical Pharmacy Association	Section L - Safety management systems	069	General	We would suggest that you consider expanding the research recommendation to asking for good quality studies on the impact/outcome of other safety management systems in theatres (in addition to the WHO checklist) as listed in the PICO table 1.3 in this chapter. In particular the National Safety Standards for invasive procedures as these are vigorously rolled out across the country.	Thank you for your comment. The committee sought to make a research recommendation that would inform and update the recommendation on the WHO checklist. The committee focused on this checklist because its use is mandatory.
Vifor Pharma UK Ltd.	Evidence Review E	007	001	In Table 2 "PICO characteristics of IV iron", health-related quality of life (QoL) is listed as a critical outcome. In Table 3, the Keeler et al 2017 reference does not include quality of life. However the Keeler et al 2019 publication, from the IVICA Trial	Thank you for providing this reference. The quality of life data from this trial has now been added to the evidence review. The committee considered the addition and agreed that it did not alter their recommendations made.

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				Group, was a follow up study and did compare the efficacy of intravenous and oral iron at improving quality of life. These findings indicate that intravenous iron is more efficacious at improving quality of life scores than oral iron in anaemic colorectal cancer patients. It is our view that the Keeler et al 2019 study should be considered in a review of the evidence in Appendix E.	
Vifor Pharma UK Ltd.	Evidence Review E	008	001	In Table 2 "PICO characteristics of IV iron", change in healthcare management (for example delayed surgery or surgery cancellation) is listed as a critical outcome In Table 3, there is an omission of delays in surgery as an outcome from the Kim study. Kim et al 2009 reported that "because intravenous iron sucrose was significantly superior to oral iron treatment in preoperative anaemia correction, delays in surgical procedures were also significantly reduced".	Thank you for your comment. The change in healthcare management outcome data has now been added to the evidence review. The committee considered the addition and agreed that it did not alter their recommendations made.
Vifor Pharma UK Ltd.	Evidence Review E	013	018	It is unclear why such different doses were used for cost comparison in Table 7. Iron isomaltoside and ferric carboxymaltose should be dosed as per each product's summary of product characteristics (SmPC), which would result in same or similar dose prescriptions in the majority of patients. We feel the table should be amended to reflect a consistent approach for the dosing models across the different products.	Thank you for your comment. The doses have been changed so that 1000mg is administered for all of the IV iron products.
Vifor Pharma UK Ltd.	Evidence Review E	013	018	Factual inaccuracies and incorrect data have been used for normal UK usage of ferric carboxymaltose. There are also a number of assumptions made and derived figures that we feel to be erroneous. Corrected figures are listed below which should be used in a revision of the information presented in Table 7. 1. Ferric carboxymaltose is supplied in 500mg and 1000mg vials. A 1000mg dose can therefore be delivered using one	Thank you for your comment. this has been corrected and the dose for ferric caboxymaltose has been changed to 1000mg and therefore a 1000mg vial has been costed using the drug tariff price of £154.23. These costs have been edited in the table and also in the conclusions in the committee discussion of evidence.

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				vial in one visit at with a drug cost of £154.23 at list price, although tender prices are available locally. 2. The list price of a 500mg vial of ferric carboxymaltose is £95.50, again with locally available tender prices. 3. The adjustment of the data presented in Table 7 will have knock-on effects for other conclusions drawn elsewhere in Appendix E, including Table 8 and further discussions on cost effectiveness.	
Vifor Pharma UK Ltd.	Evidence Review E	014	001	In Table 8, incorrect data for the administration of ferric carboxymaltose (see above comment) has led to a miscalculation in the "Total costs, inc. drug" column.	Thank you for your comment. Table 8 has been corrected based on the changes made in table 7 regarding the cost and administration of ferric carboxymaltose.
Vifor Pharma UK Ltd.	Evidence Review E	014	012	We feel it is insufficient to just use excess bed days in the calculation of downstream costs for cardiothoracic surgery, where cost savings may also include a day in an intensive care bed (Klein 2016, Onwochei 2019). One day saved in intensive care or coronary care, per anaemic patient successfully treated pre-operatively may equate to more than £1000, rather than the £260 currently listed. An alternative approach should be used to calculate in-hospital costs of cardiothoracic surgery (eg. NHS reference costs), rather than simply modelling the number of excess bed days under the national tariff.	Thank you for your comment. We are aware that downstream costs can vary between surgery and people and can vary from being admitted to ICU or having a longer stay in hospital. The costs associated with an excess bed day from two examples of major surgery were chosen however these costs were not used in any cost calculations or modelling, they were used for illustrative purposes. The NHS Reference Costs for excess bed days were used instead of the overall in-hospital costs associated with cardiothoracic surgery as they reflect the additional cost per day to the NHS for a hospital stay that exceeds the maximum expected length of stay.
Vifor Pharma UK Ltd.	Evidence Review E	020	013 - 014	The comments referring to no longer considering intravenous iron where time to surgery is short reflect a contradiction to NICE guidance NG24, and could lead to confusion among clinicians and possibly even lead to patients being sub-optimally treated.	Thank you for your comment. This section has been edited to highlight that the committee were aware of the recommendation in NG24 on IV iron.
Vifor Pharma UK Ltd.	Evidence Review E	General	General	Vifor Pharma UK recognise that the appendices to the consultation reflect the committee's reviews of evidence, rather than guideline recommendations. However, we feel that a number of factual	Thank you for your comment.

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				inaccuracies appear and therefore have made some additional comments.	
Vifor Pharma UK Ltd.	Guideline	005	004 - 005	We note that NG24 states that intravenous iron should be considered when patients cannot tolerate or absorb oral iron, or are unable to adhere to oral iron treatment. There is no dosing recommendation for oral iron, or for follow up of patients to assess their response.	Thank you for your comment. NG24 is cross referred to referred to in section 1.3.3 and includes this information. This was considered by the committee and the committee's discussion of the evidence in evidence review E section has been amended to reflect the need for follow up after commencement of treatment. However, no recommendation could be made as follow up was not included in the review protocol.
Vifor Pharma UK Ltd.	Guideline	005	006 - 008	1.3.4 Following the recommendation to **"Consider an alternate day oral iron regime",** we feel that there should be a **recommendation for healthcare professionals to follow up patients after commencement of treatment for iron deficiency anaemia to assess their response**. Response to treatment can be affected by a number of factors including food intake and concomitant medication that can affect absorption (Ferrous sulfate summary of product characteristics), as well as side effects. Non-compliance as a result of side effects is a common problem (Tolkien 2015, Markowitz 1997) and will also affect response. We feel that the omission of any guidance to ensure follow up of patients and assess their response to treatment with oral iron could lead to some patients being suboptimally treated if, as per NG 24 1.1.3, oral iron is not tolerated, not absorbed, ineffective or insufficient.	Thank you for your comment. This was considered by the committee and the committee's discussion of the evidence in evidence review E section has been amended to reflect the need for follow up after commencement of treatment. However, no recommendation could be made as follow up was not included in the review protocol
Vifor Pharma UK Ltd.	Guideline	005	006 - 008	Alongside the recommendations in GID-NG10072, we feel that a recommendation should be included to ensure that where oral iron is still considered inappropriate for some patients, IV iron therapy should still be considered (eg. in cases where alternate day dosing with oral iron is still inappropriate).	Thank you for your comment. This is included in the guidance given in NG24, referred to in section 1.3.3.
Vifor Pharma UK Ltd.	Guideline	005	009	Regarding "When to start oral iron supplementation", Vifor Pharma UK recognise that there has been uncertainty over timing between the	Thank you for your comment. The committee were keen to evaluate this evidence. However, the dearth of evidence on this topic meant they were unable to determine the timeframe of which the interval

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				commencement of iron therapy and surgery. With urgent surgery, the timescale pre-surgery is often limited. Whilst we recognise the role of alternate day dosing with oral iron, we note that the time for such treatment may take longer (in Stoffel 2017, patients on an alternate day regimen were treated for twice as long compared to those on a consecutive day regimen). We therefore feel that there should be some reminder that **where the interval between diagnosis and surgery is short, intravenous iron may be appropriate,** as per NG24 1.1.3. Currently, the 'International Consensus Statement on Perioperative Management of Anaemia and Iron Deficiency' recommends offering intravenous iron if surgery is planned within 6 weeks. This is mirrored by the 'Scottish Standard for the Optimisation of Preoperative Anaemia' which states that "IV iron should ideally be given 4-6 weeks before surgery. We therefore feel that if there is to be a recommendation for the use of oral iron, it should be commenced at least 6 weeks before surgery.	between diagnosis and surgery would be too short to treat pre-operative anaemia with oral iron. As such, a research recommendation was made to inform future practice.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

Registered stakeholders