Rheumatoid Arthritis Update
Consultation on draft scope
Stakeholder comments table
17 June – 15 July 2016

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British Society for Rheumatology	**general**	general	The British Society for Rheumatology (BSR) considers central to the succ treatment of rheumatoid arthritis (RA) the strategy of managing the condit consequence this should take primary importance within the scope of the *Rheumatoid arthritis in adults: management* guideline, with drugs placed secondary to this approach. Yet in its current iteration, the BSR is concern the scope of the guideline is not reflective of this prioritisation, though we the inclusion of 'treat to target' in the scope.	Thank you for your comment. We agree that this is of primary importance and intend to reflect that when writing the guideline. The areas of the scope have also been reordered to place pharmacological treatment after monitoring.
British Society for Rheumatology	**general**	general	The BSR fully endorses the National Rheumatoid Arthritis Society's submission to the *Rheumatoid arthritis (update): draft scope consultation*.	Thank you for your comment.
British Thoracic Society	general		Lung disease in rheumatoid arthritis (RA) does not feature in the scope of this guideline. There is a lack of information about extra-articular manifestations of RA. The guideline scope has clearly identified prognosis as a specific aspect that needs to be addressed. Interstitial lung disease (ILD) is therefore an important area that needs to be reviewed. Approximately 10% of patients with RA develop clinically significant ILD. RA-ILD is associated with significant morbidity and mortality and contributes to premature mortality in 1 in 5 affected individuals. The median survival is 3-8 years from time to diagnosis. The presence of ILD in patients with RA is therefore of unequivocal importance. We therefore believe this should be included in the prognosis section (1.5.2), as well as the sections on monitoring (1.5.4). We suggest for example, initial screening assessment (for ILD) with CXR and PFTs; High resolution computed tomography scans (HRCT) should be reserved for those with CXR and/or PFT abnormalities. Furthermore, given the pulmonary toxicity of DMARDs, the presence of ILD at baseline and monitoring during treatment should be included (1.5.3); the importance of rheumatological-respiratory joint management	Thank you for your comment. Lung disease will be considered by the committee as a potential factor to include when agreeing the protocols within the key clinical issue of: Monitoring rheumatoid arthritis, including: what to monitor and when to monitor.

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			for patients with RA-ILD should be emphasised. The British Thoracic Society and the British Society for Rheumatology have initiated meetings between rheumatologists and respiratory physicians for 3 reasons: 1) This is an area of significant prognostic importance 2) This is an area of unmet clinical need 3) This is an area of clinical research expansion – this aspect will hopefully improve 1) and 2) above BTS would support further collaborative working between NICE, BTS and the BSR.	
College of Occupational Therapists	General	general	The College is pleased to see the SARAH trial recommendations have been added in the form of specific reference to hand exercise and would endorse the suggestion that this is provided by a practitioner with appropriate training and skills.	Thank you for your comment.
College of Occupational Therapists	4	100 (section 3)	There appears to be no specific reference to the use/ benefits/ complications of corticosteroid injections as a treatment for the complications of RA, e.g. carpal tunnel syndrome, or trigger finger. Might it be appropriate to address this?	Thank you for your comment. The scope sets out the key areas for review and draft review questions, and includes a review question on the effectiveness of steroids. These review questions will be further refined with the guideline committee when setting the protocols when more specific details will be agreed.
College of	5	117	We feel the review period recommendations are sufficiently flexible/	Thank you for your comment.

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Occupational Therapists			flexible to reflect what is a changing population and allow for individual needs assessment.	
College of Podiatry	3	57 – 60	The key issues and review questions to be updated in this section strongly relate to monitoring 'ongoing disease activity', however firstly there is evidence to indicate that patients still have persistent disease in the feet, which are not included in composite disease activity outcome measures used to monitor disease activity. Secondly patients in T2T remission or low disease activity state frequently that they have continued pain and functional limitation, which affect their daily activity. We should consider what else should be monitored i.e. the feet and when we should start asking the patients those question about the impact of their disease, even when in remission, to provide appropriate management strategies.	Thank you for your comment. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and whether they should be managed differently. The particular factors that will be considered will not be limited to existing composite scoring systems and may include lower limb disease activity. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.
Department of Health	general	general	No comments	Thank you.
Eli Lilly	5	126	We feel additional outcomes including fatigue, severity and duration of morning stiffness could also be considered	Thank you for your comment. The outcomes included in the protocol are based on the OMERACT Core Set of outcomes, as the main outcomes that are likely to be relevant to the majority of review questions. These will be further refined with the guideline committee for each review question, and the specific outcomes relevant to the particular question will be agreed.

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HQT Diagnostics	3	72	There is very good evidence that diet contributes to the Inflammation that presents as Rheumatoid Arthritis GP to refer patient at first presentation to a Dietitian or Nutritional Therapist who can review the current diet and suggest changes Dietitians https://www.bda.uk.com/ Nutritional Therapists http://bant.org.uk/ Sources: http://www.ncbi.nlm.nih.gov/pubmed/16194694 http://rheumatology.oxfordjournals.org/content/38/11/1039.full http://www.semarthritisrheumatism.com/article/S0049-0172(05)00087-9/abstract	Thank you for your comment. CG79 includes recommendations on dietary modifications. The surveillance review did not identify any new evidence in this area that would change these recommendations and therefore this area will not be updated but the existing recommendations will still stand.
HQT Diagnostics	3	73	There is very good evidence that increasing Vitamin D levels of 25(OH)D to 100-150 nmol/L helps to prevent and treat Rheumatoid Arthritis - in the early stages GP to prescribe Vitamin D to adjust level and review after 3 months Source: http://www.vitamindwiki.com/Overview+Rheumatoid+Arthritis+and+vitamin+D http://www.ncbi.nlm.nih.gov/pubmed/24907153	Thank you for your comment. CG79 includes recommendations on dietary modifications. The surveillance review did not identify any new evidence in this area that would change these recommendations and therefore this area will not be updated but the existing recommendations will still stand.

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HQT Diagnostics	3	73	There is very good evidence that adjusting Omega-3 and Omega-6 levels helps to prevent and treat Rheumatoid Arthritis - in the early stages **Key Indicators**……**Target**…**Comments** **Omega-3 Index**…..>8%.....Is the Omega-3 level high enough ? **Omega-6/3 Ratio** <3:1……Is the Inflammation low enough ? Increasing Omega-3 may need 2-5 grams of Omega-3 per day. Reducing Omega-6 needs advice about diet and lifestyle from a Dietitian or Nutritional Therapist Source: http://www.expertomega3.com/omega-3-studies/inflammatory-diseases http://www.ncbi.nlm.nih.gov/pubmed/12442909 http://www.ncbi.nlm.nih.gov/pubmed/22765297 http://www.greenvits.eu/pages/omega-3	Thank you for your comment. A number of small studies on omega-3 supplementation were identified in the surveillance review. However, the evidence was limited by a small number of participants. The conclusion of the surveillance review was that more large studies examining omega-3 in this population are needed before it can be considered for inclusion in the guideline.
HQT Diagnostics	2	44	Investigate biomarkers for the Inflammation that is the basis for Rheumatoid Arthritis Source: http://www.greenvits.eu/blogs/news/90038403-what-to-do-about-inflammation http://www.expertomega3.com/omega-3-studies/inflammatory-diseases http://www.ncbi.nlm.nih.gov/pubmed/22765297	Thank you for your comment. A number of small studies on omega-3 supplementation were identified in the surveillance review. However, the evidence was limited by a small number of participants. The conclusion of the surveillance review was that more large studies examining omega-3 in this population are needed before it can be considered for inclusion in the

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			http://www.greenvits.eu/pages/omega-3	guideline.
Laughter Yoga ball	General	16	'include Citiizens and Citizen Patients" who do not want DMARDs and pharmaceutical drugs but use NHS 'complementary health' services.	Thank you for your comment. CG79 includes recommendations on complementary therapies. The surveillance review did not identify any new evidence in this area and therefore these areas will not be updated and the existing recommendations will still stand.
Laughter Yoga ball	3	73	To include' Mind Body Medicine'	Thank you for your comment. CG79 includes recommendations for complementary therapies. The surveillance review did not identify any new evidence in this area that would change these recommendations therefore this area will not be updated but the existing recommendations will still stand.
Laughter Yoga ball	3	61	Should be updated to include innovative mind body medicines & therapies like Laughter Ball Yoga which is effective, low cost & practical without contraindications.	Thank you for your comment. CG79 includes recommendations on complementary therapies. The surveillance review did not identify any new evidence in this area that would change these recommendations, therefore the existing recommendations will be retained in this area.
Laughter Yoga ball	3	57	Should include treat to find cause	Thank you for your comment. The remit of the commissioned update is for the diagnosis and management of rheumatoid arthritis, therefore finding the cause is beyond the remit we are able to

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				cover.
Laughter Yoga ball	4	101	In adults with RA what are the complementary treatments for managing RA such as Laughter Ball Yoga, its effectiveness and costs vs. conventional pharmaceutical treatments, DMARDs et al.	Thank you for your comment. CG79 includes recommendations on complementary therapies. The surveillance review did not identify any new evidence in this area that would change these recommendations therefore this area will not be updated but the existing recommendations from CG79 will still stand.
Laughter Yoga ball	4	140	Triggers: what causes flare-ups	Thank you for your comment. The outcomes included in the scope are based on the OMERACT Core Set of outcomes as the main outcomes that are likely to be relevant to the majority of review questions. These will be further refined with the guideline committee for each review question, and the specific outcomes relevant to the particular question will be agreed.
Laughter Yoga ball	2 3	32 53 54	Laughter Ball Yoga (LBY) is used as 'exceptionally outside licensed indications'. LBY is supported by evidence. E Mortlock is the expert witness.	Thank you for your comment. CG79 includes recommendations on complementary therapies. The surveillance review did not identify any new evidence in this area that would change the recommendations. The existing recommendations from CG79 will be retained in in the guideline.
MSD	3	62	The draft scope currently states that biological DMARDs for managing rheumatoid arthritis will not be reviewed as part of this clinical guidance review. MSD believes that the use of biological DMARDs in patients with	Thank you for your comment. Biological DMARDs (including any biosimilars) are covered by existing TAs and therefore are outside the remit of this

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			moderate rheumatoid arthritis (RA) should be reviewed, in light of the recent availability of biosimilar treatments since the publication of NICE TA375. Moderate Rheumatoid Arthritis (defined as a DAS28 range of 3.2 to 5.1 [1]) is a highly debilitating condition, which can have a severe impact on the lives of patients. The current NICE guidance does not recommend the use of biological treatments for this indication, leading to delayed access to effective medicines at the severe disease stage. As a consequence there is high inconsistency across European countries in the level of access to TNF-α inhibitors for RA patients. The UK provides the lowest access amongst European countries in the management of moderate RA, for which the use of TNF-α Inhibitors has been recommended for several years. The delayed access provided by the UK is exacerbated by the progressive and debilitating nature of RA, which can significantly add to the costs associated. The recent RA MTA (TA375) included analyses for the use of biologics in the moderate RA population, where the mean ICERs for anti-TNFs were approximately £51,000/QALY for moderate patients, versus £41,000/QALY for severe patients. These figures have been disputed by professional patient groups, as well as the ERG, who believe that the ICERS should be much lower for moderate patients, at £28,500/QALY, decreasing to £20,462/QALY when including infliximab biosimilar in the analysis [2]. These ICERs indicate that TNF-α Inhibitors are a cost-	guideline. Any concerns regarding the accuracy or currency of the TAs should be raised through the appropriate TA channel.

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			effective treatment option for moderate RA patients. Since the publication of NICE TA375, the market for biologics in RA has undergone large disruption, most notably due to the loss of exclusivity for etanercept (Enbrel®), where clinicians and patients gained access to biosimilar etanercept which received marketing authorisation in January 2016. Etanercept is a commonly used biologic in RA, and as the increased competition in the market for biologics drives down acquisition costs, the value of treating the moderate RA population with all TNF-α inhibitors increases, and the ICERs will fall. The cost-effectiveness analysis conducted in TA375 was based on the cost of originator biologics, and with the introduction of biosimilars to the market, MSD feels that the analysis is no longer a true reflection of clinical practice. As such, MSD feels there is an opportunity to revisit the analysis in calculating ICERs for the moderate RA population, in order to provide greater access for patients with RA. MSD supports the appeal against the outcome of the RA MTA driven by NRAS, and joins several other stakeholders in calling for the consideration of biologic DMARDs for moderate RA in this clinical guideline.	
National Rheumatoid Arthritis Society	1	9/10	The NICE Quality Standard 33 already exists – do we assume from this that a revision of QS33 will follow publication of the new Guideline in 2018?	Thank you for your comment. QS33 will be revised following publication of the new guideline – please see section 2.2 of the scope.
National	2	33	Should include diagnostic stratification using all potential biomarker tests	Thank you for your comment. The guideline scope

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Rheumatoid Arthritis Society			available – we should be treating those with poor prognostic markers differently.	highlights Identifying the prognostic factors that indicate which people are at greatest risk of disease progression as a key area to update. The committee will consider which prognostic factors to review when developing the protocol for this question.
National Rheumatoid Arthritis Society	3	60	Conducting holistic annual reviews for patients with existing disease as recommended in CG79 has not been widely adopted since 2009 when CG79 was published. Given the recommendations to better integrate primary and secondary care, as well as the government's desire to see as many patients with long term conditions (LTCs) being treated more in the community, we think there is an opportunity for certain aspects of annual review to be conducted in primary care, such as risk assessment for heart disease and osteoporosis. We therefore strongly believe that annual review monitoring, particularly the 'when' should be included. Although the HQIP early RA audit data would indicate that the majority of rheumatology units are conducting such annual reviews, evidence we have from talking to patients and health professionals across England would indicate that this is not the case. I am not aware of any audit data of such annual reviews being undertaken anywhere, with the exception of the Freeman Hospital in Newcastle who run a nurse led annual review clinic in the community. The audit they have done of their service shows clear evidence of catching the start of co-morbid conditions at a stage where something can be done to prevent chronicity which would not have been caught at such an early stage without such a clinic. In the presentations done by the NICE team in May, it was made clear that you were looking for areas of variation in practice and this is a huge one.	Thank you for your comment. No new evidence was identified that would change the recommendation on CG79 for the annual review therefore it has not been prioritised for update. The existing NICE Quality Standard QS33 states that "People with rheumatoid arthritis have a comprehensive annual review that is coordinated by the rheumatology service." Implementation of these recommendations is the responsibility of commissioners.

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			Something needs to be done. Line 65 re location of review on page 3 should be included in line 60. We also think that an additional item should go under this which should review and consider primary preventative measures.	
National Rheumatoid Arthritis Society	3	63/64	It is easy for a rheumatology unit to tick a box to say that they have provided education, self-management and the provision of information and advice. This could be anything from giving the patient a leaflet on methotrexate to providing a group session with the multi-disciplinary team and there is a huge difference between the two. What patients really need within a month of diagnosis is the kind of emotional support and information that organisations like NRAS can provide. We are providers of self-management programmes and support, yet we would not recommend putting someone on a self-management programme within 1 month of diagnosis because people are generally not ready or in a headspace to take on board a lot of detailed information. I believe we need to be more specific about what the current recommendations stipulate and require units to detail what kind of education, self-management, information and advice has been given and be less prescriptive that it must be within 1 month of diagnosis. Within 3 months of diagnosis would be more appropriate. A stronger recommendation to sign-post patients to the relevant patient organisations who can help would make more sense within that one month timeframe. One of the frequent things we do for patients who contact us immediately on diagnosis is to help them to translate the information they have been told or given by health professionals into something meaningful by talking them through this again in simple	Thank you for your comment. Any changes to the recommendations have to be based on published evidence. The surveillance review did not identify any new evidence that would change the current recommendations in this area, and so it was not identified as a priority area for update.

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			language and making it relevant to them and to their lives. We reinforce messages around adherence to medication and help them to normalise their fears and anxieties. We have an opportunity to define the kind of support people need on diagnosis more helpfully, all of which aligns with the Five Year Forward View. Also it was made clear that you were looking for areas of variation in practice and this is a major one.	
National Rheumatoid Arthritis Society	3	66	It was felt at the stakeholder meeting that non-specialist referral to specialist services should be included in items up for review	Thank you for your comment. All areas of CG79 were considered in the surveillance review to identify whether there was any new evidence. Only areas with new evidence likely to have an impact on the current guideline recommendations are priorities to be updated. This process did not identify any new evidence in this area that would impact upon current recommendations. The existing recommendations on this topic from CG79 will be retained.
National Rheumatoid Arthritis Society	3	67-74	I think there was quite substantial support for reviewing the importance and effectiveness of the multidisciplinary team input from everyone who attended the stakeholder event in May. It was also strongly felt that there should be full MDT representation on the committee. Other non pharmacological issues which need to be reviewed I believe are things like access to psychological and talking therapies (anxiety and depression prevalence in newly diagnosed is approx. 40%), sleep disturbance which we know has negative long term health impact	Thank you for your comment. We agree that the multidisciplinary team is an important factor and this was noted from the stakeholder discussion. However, no new evidence was identified in this area that would change the recommendations that were in CG79. Therefore, this area will not be updated, but the existing recommendations will still stand. Non-pharmacological treatment (including psychological therapies) was also not prioritised for

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				updating and therefore the recommendations from CG79 will remain. Because these areas are not being updated, a decision was made that one allied health professional would provide adequate representation for the topics under consideration on the GC. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression. The particular factors that will be considered may include depression or other co-morbidities. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.
National Rheumatoid Arthritis Society	4	96-99	Have already mentioned this earlier but worth reinforcing here. Should include diagnostic stratification using all potential biomarker tests available – we should be treating those with poor prognostic markers differently.	Thank you for your comment. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and whether they should be managed differently. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.

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National Rheumatoid Arthritis Society	4	104-105	Need to ensure that the true cost to patients of side effects from long term steroid use is taken into account, especially if patients on long term steroids are unable to meet the current criteria to access biologic/biosimilar treatment	Thank you for your comment. As part of our review of the effectiveness of steroids, we will consider the adverse effects.
National Rheumatoid Arthritis Society	5	131	One of the astonishing things given the impact of RA on quality of life, is that (outside of the HQIP audit) rheumatology units do not routinely measure quality of life except through the patient global part of the Disease Activity Score and that is just a visual analogue scale of 0-10 or 0-100. We would like to address this as part of the review if possible.	Thank you for your comment and for highlighting this. The outcomes listed are the core set that are expected to be relevant to the majority of the questions. Quality of life data for all reviews, as reported in the literature, and specific outcomes relevant to the particular questions will be agreed by the guideline committee when setting the protocols.
NHS England	general	general	No comments	Thank you.
Nordic Pharma	2	3	There is evidence of continued use of 'specials' manufactured methotrexate pre-filled syringe in rheumatoid arthritis patients, despite licensed presentations of methotrexate pre-filled syringe in doses relevant for rheumatoid arthritis patients, incorporating a needle-protection device being introduced in February 2016. The guidance should advise healthcare professionals with regard to MHRA Guidance Note 14 that an unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient.	Thank you for your comment. This is beyond the remit of NICE guideline.
Nordic Pharma	2	3	With reference to NICE guidance CG76 (Medicines Adherence) there is little made of the need of a significant minority of patients who would prefer to have choice of injection device (auto-injector pen / pre-filled syringe) – Demary *et al* 2014. Where choice is available it would seem	Thank you for your comment. The committee will consider different modes of administration when developing the protocols for the review questions on pharmacological interventions.

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			appropriate to offer the choice to patients of a pre-filled syringe to patients who would prefer more control over their injection.	
Pfizer	general	general	No comments	Thank you.
Podiatry Rheumatic Care Association	3 5	57-60 117-125	In considering 'treat to target', what and when to monitor , my concern is around the current assessment and monitoring of the lower limb in terms of active disease and impact on daily activity. Clinical experience and research highlight that there is a group of patients who have globally stable or in remission disease (as assessed by DAS28 &T2T) but continue to experience foot related active disease and as a result disease activity is undermanaged. The current composite scores used within in monitoring do not reflect persistent foot related disease activity across the RA group.	Thank you for your comment. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression. The particular factors that will be considered will not be limited to existing composite scoring systems and may include lower limb disease activity. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.
Roche Products	2	33	The draft scope states it covers adults with RA, however, adolescents and those transitioning from paediatric to adult services may be at risk of an interruption to their care. Therefore we would support provisions to be made in this Guideline to cover the adolescent population.	Thank you for your comment. We recognise this is an important issue to be considered, however there is existing NICE guidance on the transition of care services (NG43: Transition from children's to adults' services for young people using health or social care services).
Roche Products	4	98 & 113	Patients identified as being at risk of rapid progression may require a different approach to the management of their disease. We would suggest the Guideline update makes explicit treatment recommendations	Thank you for your comment. The guideline will include a review on how the pharmaceutical management of patients identified to have a poor

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			for the patient population at risk of rapid progression.	prognosis differs from the general RA population – see question 4.6.
Roche Products	4	104	In order for the different treatment approaches used in clinical practice to be fully incorporated into the cost-effectiveness evaluation of corticosteroids, we recommend including an investigation of dose and dose titration, as well as considering the consequences of sub-therapeutic dosing.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the GC when setting the protocols, including more specific details such as how dose will be considered.
Roche Products	4	110	For the different treatment approaches used in clinical practice to be fully incorporated into the cost-effectiveness evaluation of conventional DMARDs, we recommend including an investigation of dose and dose titration as well as considering the consequences of sub-therapeutic dosing.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the GC when setting the protocols, including more specific details such as how dose will be considered.
Roche Products	5	123	We recommend the cost-effectiveness comparison between standard care and a 'treat-to-target' approach considers clinical best practice for maintaining long-term outcomes for RA patients, as well as treatment adherence.	Thank you for your comment. There are existing NICE guidelines on Medicines adherence (CG76) therefore this topic has not been prioritised within this guideline scope. The scope sets out the key areas for review and draft review questions, including a review question on treat to target. These review questions will be further refined with the guideline committee, including defining appropriate interventions, comparators and outcomes.

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				As per the NICE reference case all relevant comparators will be included in any original cost-effectiveness analysis conducted. NICE guideline development methods can be found in the relevant manual (NICE 2014)
Roche Products	5	127	In order to fully evaluate the burden of illness and the treatment benefits, we suggest including additional clinically appropriate outcomes, such as psychological factors of sub-optimal RA treatment and caregiver quality of life. Additionally, as a scenario analysis to the Reference Case, we believe there would be benefit in considering a broader perspective to the analysis. This would take into account costs falling outside of the health & social care system, i.e. informal caregiver burden and quality of life, plus productivity loss from the patient and caregivers. This could give a wider evaluation of costs and cost-effectiveness for the analysis of clinical benefits.	Thank you for your comment. The outcomes included in the protocol are based on the OMERACT Core Set of outcomes, as the main outcomes that are likely to be relevant to the majority of review questions. These will be further refined with the guideline committee for each review question, and the specific outcomes relevant to the particular question will be agreed. As per the NICE reference case the perspective of the base-case analysis will be that of the NHS and Personal Social Services. Additional scenarios will be discussed and agreed with the guideline committee.
Roche Products	5	143	We recommend including reference to NICE's 'Into practice guide' [NICE article pg1] https://www.nice.org.uk/article/pg1/chapter/1%20introduction%20and%20background	Thank you for your comment. The scope lists only 'closely related guidance'. This has not been added because it applies to all NICE guidance and not specifically to rheumatoid arthritis.
Royal College of General	General	General	The RCGP welcomes the opportunity to comment on this draft scope on the management of adults with rheumatoid arthritis. It is clearly focused	Thank you for your comment. The areas in the scope of this update are those that have been identified as

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Practitioners			on pharmaceutical treatment and could benefit from widening the scope to include • Lifestyle changes particularly smoking cessation • Screen and treatment for depression and other common mental health co-morbidities • Vaccinations • Considering rheumatoid arthritis in the context of multi-morbidities • Deprescribing and other considerations for end of life care of people with rheumatoid arthritis	having new evidence that will change the original recommendations. The final guideline will still include all areas from CG79 that are not being updated (including non-pharmacological treatment) and therefore the full guideline will not be focused on pharmacological treatment. The guideline will cross-refer to existing NICE guidance where appropriate, which will include many of the topics you raise. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and what should be monitored. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions. Providing guidance on vaccinations is beyond the remit of NICE guidelines. Please see relevant guidance from the Joint Committee on Vaccination and Immunisation.
Royal College of Nursing	General	General	The Royal College of Nursing welcomes proposals to update the clinical guidelines for rheumatoid arthritis in adults.	Thank you for the comments you've provided.

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			The RCN invited members caring for people with rheumatoid arthritis to review and comment on the draft document on its behalf. The comments below include the views of our reviewers.	
Royal College of Nursing	General	General	The draft scope seems comprehensive.	Thank you for your comment.
Royal College of Nursing	3	63	It is not clear why the scope is excluding evidence on support services for people with RA from this update. Guideline around this area will help to improve quality of service delivery for people with RA.	Thank you for your comment. All areas of CG79 were considered in the surveillance review to identify whether there was any new evidence. Only areas with new evidence likely to have an impact on the current guideline recommendations are prioritised to be updated. This process did not identify any new evidence in this area that would impact upon current recommendations. The existing recommendations on this topic from CG79 will be retained.
Royal College of Psychiatrists	4	96	Explicitly include reference to psycho-social factors which frequently get overlooked and have a significant impact on long term physical health outcomes in RhA. I.e. change to '*Identifying the prognostic factors (including psycho-social) that indicate which people are at greatest risk of disease progression'*	Thank you for your comment. This guideline update will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and whether they should be managed differently. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.
Royal College of Psychiatrists	4	98	Change to *2.1' In adults with RhA, which features (including psycho-social) help to identify the prognosis of the disease?'*	Thank you for your comment. This guideline update will include identifying the

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				prognostic factors that indicate which people are at greatest risk of disease progression and whether they should be managed differently. The list of factors that will be considered will be determined by the guideline committee when developing the protocol for these review questions.
Royal College of Psychiatrists	4	99	Add a line '*In adults with RhA what screening and assessment (including psycho-social) should be done at initial presentation?'*	Thank you for your comment There is existing NICE guidance in this area, for example 'Depression in adults with a chronic physical health problem: recognition and management'. The guideline will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and what and when to monitor. The committee will consider which factors to review when developing the protocol for this review question. The factors identified by the committee may include psycho-social factors.
Royal College of Psychiatrists	5	117	In an earlier version there was a section 'non-pharmacological treatments relevant to RhA'…this is not present in the latest version. We are presuming as there is no new evidence (if we have understood the Scoping procedure properly). Whilst there is growing evidence that incorporating a system of collaborative and stepped care of depression in patients with physical illness is effective I don't think there is anything new particularly relevant to RhA.…and think this aspect is already	Thank you for your comment. Your understanding is correct. All areas of the current guideline were reviewed in the surveillance review to identify whether there was any new evidence. Only areas with new evidence likely to have an impact on the current guideline recommendations are updated. This process did not identify any new evidence on

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			covered in the below cited closely related guidance 'depression in adults with a chronic physical health problem CG91…so perhaps that is why there is nothing regarding this?	non-pharmaceutical treatments that would impact upon current recommendations. The existing recommendations from CG79 will be retained in this area and relevant existing NICE guidance will be cross-referenced as appropriate.
Royal College of Psychiatrists	5	126	We would strongly recommend that an assessment of mood is included in the main outcomes. Mood disorders are important predictors of prognosis and are closely linked to quality of life measure. We estimate that about one third of those suffering with Rheumatoid arthritis also suffer with co-morbid clinical depression.	Thank you for your comment. The outcomes included in the protocol are based on the OMERACT Core Set of outcomes, as the main outcomes that are likely to be relevant to the majority of review questions. These will be further refined with the guideline committee for each review question, and the specific outcomes relevant to the particular question will be agreed. The guideline will include identifying the prognostic factors that indicate which people are at greatest risk of disease progression and whether they should be managed differently. The committee will consider which prognostic factors to review when developing the protocol for this review question which may include mood disorders.
UCB Pharma	4	101	We suggest clarifying in the scope how will the clinical and cost-effectiveness be assessed for analgesics and what will be the standard of care used to compare with.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the guideline committee when established, including

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				what comparators and outcomes are appropriate. Clinical effectiveness will be considered based on whether the intervention results in a clinically important improvement of the key outcomes identified for the review (for example, pain, quality of life). As per the NICE reference case all relevant comparators will be included in any original cost-effectiveness analysis conducted. NICE guideline development methods can be found in the relevant manual (NICE 2014).
UCB Pharma	4	104	As per the previous comment, we suggest clarifying what will be the standard of care corticosteroids will be compared with.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the GC when setting the protocols, including what comparators are appropriate. As per the NICE reference case all relevant comparators will be included in any original cost-effectiveness analysis conducted. NICE guideline development methods can be found in the relevant manual (NICE 2014)
UCB Pharma	4	107	We would suggest clarifying in the scope what is meant by "early introduction" of conventional DMARDs, compared to the current clinical	Thank you for your comment. The scope sets out the key areas for review and draft review questions.

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			practice or existing clinical guidelines (eg British Society of Rheumatology (BSR)).	These review questions will be further refined with the guideline committee when established, including what interventions/lines of treatment are of interest and all definitions of terms used will be agreed with the guideline committee.
UCB Pharma	4	109	We suggest clarifying in the scope how will the clinical and cost-effectiveness be assessed for single or combination conventional DMARDs and what will be the standard of care used to compare with.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the guideline committee when setting the protocols, including what comparators will be included and which outcomes will be assessed to determine clinical effectiveness. As per the NICE reference case all relevant comparators will be included in any original cost-effectiveness analysis conducted. NICE guideline development methods can be found in the relevant manual (NICE 2014)
UCB Pharma	4	110	We suggest clarifying in the scope whether this point will focus solely on the decrease/withdrawal of conventional DMARDs as the sole medication, or their decrease/withdrawn as a background medication to a biologic treatment.	Thank you for your comment. This question has now been removed from the scope as no evidence was identified in the surveillance review that would change the recommendations for the interventions that will be included within the update. At the time the surveillance review was conducted,

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				the recent MTA on biologics had not been published. The evidence on this question identified by the surveillance review related solely to biologics, and so the question is no longer a priority for update. The existing recommendations from CG79 will be retained in this area.
UCB Pharma	4	113	We suggest clarifying in the scope whether this point will focus solely on the administration of non-biologics only, or the administration of the later as a background medication to a biologic treatment.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the guideline committee when the protocols are developed. Biological DMARDs will not be included within this guideline as guidance on their use is already covered by existing NICE technology appraisals. Please note that we have clarified the wording of this question in the revised scope.
UCB Pharma	5	124	We suggest clarifying in the scope the definition of the "treat-to-target" management strategy and alignment with the 2014 treat to target recommendations and the 2016 draft EULAR recommendations.	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the guideline committee when setting the review protocols where more specific detail will be agreed.

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UCB Pharma	5	125	Clarification should be made in the draft scope with respect to the definition of the "standard of care",	Thank you for your comment. The scope sets out the key areas for review and draft review questions. These review questions will be further refined with the guideline committee, including definitions of terms used.
UCB Pharma	5	128	We ask that the outcomes to be considered for the pharmacological treatments considered should also capture adverse effects. Furthermore, other outcomes relevant to patients for the condition in scope, such workplace/household productivity should also be considered, as these are not captured through health related quality of life measures.	Thank you for your comment. The outcomes included in the protocol are based on the OMERACT Core Set of outcomes, as the main outcomes that are likely to be relevant to the majority of review questions. These will be further refined with the guideline committee for each review question, and the specific outcomes relevant to the particular question will be agreed. We will record health related quality of life for all questions, where reported, and will include activities of daily living within this.
UCB Pharma	5	126	Given the complexities and significant burden of co-morbidities in the RA patient we strongly suggest that scoping should be broadened to include co-morbidity management.	Thank you for your comment. NICE is developing a guideline on multimorbidity, which will be cross referred to in this guidance as appropriate.
UCB Pharma	3	64	We propose that 'self-management' be considered for updating in this clinical guideline and be expanded to consider sleep and mindfulness as self-management techniques	Thank you for your comment. All areas of CG79 were considered in the surveillance review to identify whether there was any new evidence. Only areas with new evidence likely to have an impact on the current guideline recommendations are prioritised to be updated. This process did not identify any new evidence in this area that would impact upon current

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				recommendations. The existing recommendations on this topic from CG79 will be retained.
UCB Pharma	General	General	We propose that consideration be given to reviewing the evidence of good management of pregnant women with rheumatoid arthritis	Thank you for your comment. We are aware that pregnant women are a distinct group in this area. This is stated within the equalities considerations within the scope and the equalities impact assessment to note that this is a subgroup that will be considered when drafting recommendations for pharmacological management.