NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Rheumatoid arthritis in over 16s (update)

Date of quality standards advisory committee post-consultation meeting:
3 October 2019.

1. Introduction

The draft quality standard for rheumatoid arthritis in over 16s (update) was made available on the NICE website for a 4-week public consultation period between 5 August and 3 September 2019. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 11 registered stakeholders, which included service providers, national organisations, professional bodies and others. Comments were also received from 1 individual.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 1: Is referral within 3 days of presentation achievable? Is there an alternative timescale that should be used?

5. For draft quality statement 2: Which of the two areas covered in the statement do you consider to be the priority area for quality improvement? Early commencement of treatment with cDMARDs, or regular monitoring of treatment until treatment target achieved?

6. For draft quality statement 2: Is the target of starting treatment within 6 weeks of referral achievable?

7. For draft quality statement 3: Are the timeframes for offering educational activities within 1 month and annually used in the process measures for this statement achievable?

8. For draft quality statement 3: Should offering educational activities annually happen as part of the annual review (draft quality statement 5)?

9. For draft quality statement 4: Is the timeframe of receiving advice within 1 working day of contacting the rheumatology services achievable?

10. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please provide details on the comment form.

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* The draft quality standard largely reflects the key areas for quality improvement in an important area.
* Stakeholders stated that primary care plays a significant part in the care of rheumatoid arthritis, not just for diagnosis but throughout the disease, and that this is not reflected in the quality standard.
* Stakeholders queried the loss of statement 2 from the current quality standard which recommended assessment in a rheumatology clinic within 3 weeks of referral. They commented that this would mean loss of a powerful lever for commissioning and could potentially lead to cutting of rheumatology clinics and an increase in patient waiting times. Patients want to be seen quickly as they are anxious and in pain and potentially unable to carry out activities of daily living. Stakeholders suggested that time to being seen is a key indicator of performance of a rheumatology department, the loss of this statement and the new statement 2 may mean people with suspected rheumatoid arthritis are seen within 6 weeks rather than 3 weeks.
* Concerns were raised about the measurability of some of the statements as some do not have defined timeframes.
* Stakeholders noted misalignment with alternative metrics such as the Best Practice Tariff (BPT) and the National Early Inflammatory Arthritis Audit (NEIAA).
* One stakeholder signposted NICE accredited guidance from the College of Occupational Therapists on use of orthoses for activity and rest.

### Consultation comments on data collection

* Stakeholders noted that some of the measures in this quality standard form part of the NEIAA but participation in this audit is variable throughout the UK. However, it was also noted that participation in the NEIAA is improving and shows that local data collection from clinical records is possible.
* The NEIAA only collects data on early disease.

### Consultation comments on resource impact

* Stakeholders suggested that with adequate staffing, units should be able to deliver quality improvement.
1. Summary of consultation feedback by draft statement
	1. Draft statement 1

Adults with suspected persistent synovitis affecting more than1 joint, or the small joints of the hands and feet, are referred to rheumatology services within 3 days of presenting in primary care.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

#### General

* Referral to rheumatology services for x-rays and blood tests is not required. GPs can arrange these tests alongside the referral so that they are available for the first appointment in secondary care and treatment can commence sooner than 6 weeks (draft quality statement 2). Early diagnosis clinic referral pathways are in place in many trusts.

#### Statement

* The timeframe for referral has been reduced from 3 working days in the current quality standard to 3 days in the update. This statement should be redrafted to reflect what is achievable in primary care, for example within 3 working days – weekends and bank holidays should not be counted.
* It can be difficult to measure the time period between GP presentation to referral.

#### Definitions

* The statement needs to include definitions to improve clarity. For example, the timeframe for ‘persistent’ synovitis should be defined. Clarification of assessment of affected joints is also required, for example “1 large joint or the small joints of the hands and feet”. The statement could result in referral of people with other conditions who have swollen joints of any cause if reviewed by a non-specialist.

### Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

Is referral within 3 days of presentation achievable? Is there an alternative timescale that should be used?

* This statement is achievable, and the timescale is appropriate. One stakeholder commented that the key point in the process is the skills of the health care professional who may be a GP but also a nurse, physician assistant or physiotherapist.
	1. Draft statement 2

Adults with active rheumatoid arthritis start conventional disease-modifying anti-rheumatic drug (cDMARD) monotherapy within 6 weeks of referral, with monthly monitoring until their treatment target is met.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

#### Statement

* A timeline for treatment is valuable for measurement of quality of care. Stakeholders suggested that timelines should align with the NEIAA and BPT.
* As there is no longer a quality statement on time to being seen by a specialist department, people with suspected rheumatoid arthritis may only have their first appointment within 6 weeks and treatment may be delayed. The statement could be reworded to avoid this.
* Monthly monitoring may not improve outcomes unless treatment is modified in response. Stakeholders suggested this should be included in the statement measures.
* The quality statements could be split to cover newly diagnosed and established disease. They noted that long term monitoring is important to assess for the need to continue treatment and to assist in drug tapering or step-down strategy.

#### Quality measures

* The statement measures should align with NICE NG100 which defines treat-to-target as “target of remission or low disease activity if remission cannot be achieved”.
* Consideration should be given to the use of disease activity score (DAS) and patient reported outcomes (PRO) as a measure of the treat-to target approach to care. This would align with the BPT of measurement of DAS and PRO within 3 months of specialist care and as part of the annual review.
* One stakeholder commented that not all centres measure C-reactive protein (CRP). Erythrocyte sedimentation rate (ESR) and plasma viscosity (PV) can also be used to assess disease activity.

### Consultation question 5

Stakeholders made the following comments in relation to consultation question 5:

Which of the two areas covered in the statement do you consider to be the priority area for quality improvement? Early commencement of treatment with cDMARDs, or regular monitoring of treatment until treatment target achieved?

* Treatment and monthly monitoring should be separate quality statements that align to the BPT. These areas are both associated with improving outcomes and so quality care involves delivering both. They are separate clinical processes and are often provided by different areas of the service and therefore need distinct quality improvement efforts.

### Consultation question 6

Stakeholders made the following comments in relation to consultation question 6:

Is the target of starting treatment within 6 weeks of referral achievable?

* The target of starting treatment within 6 weeks of referral is achievable.
	1. Draft statement 3

Adults with rheumatoid arthritis are given opportunities to take part in educational activities that support self-management throughout the course of their disease.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

#### Statement

* The draft statement should be modified, or an additional statement written, to include specific educational materials for women of childbearing age as this group have unique family planning and pregnancy related challenges. There should be additional measures on this to check for adherence.
* The statement should be reworded to encompass the principles of shared decision making.

#### Quality measures

* The statement is difficult to measure due to lack of a time bound component. Timelines for newly diagnosed people are important as a marker of quality of care and would align with NEIAA and BPT.

#### Definitions

* The draft statement requires a definition of educational activities. There is discrepancy in what is considered an educational activity by clinicians and by people with rheumatoid arthritis. NICE NG100 is clear on what are educational activities and the quality statement should reflect this.

### Consultation question 7

Stakeholders made the following comments in relation to consultation question 7:

Are the timeframes for offering educational activities within 1 month and annually used in the process measures for this statement achievable?

* The rationale for early educational activities seems clear but is difficult to see why this should be repeated annually. It seems good practice to be offered at each appointment.

### Consultation question 8

Stakeholders made the following comments in relation to consultation question 8:

Should offering educational activities annually happen as part of the annual review (draft quality statement 5)?

* Incorporating educational activities into the annual review may not work in every centre. The principle of giving education is more important than how or when it is delivered.
* One stakeholder agreed that educational activities should be offered at annual review.
	1. Draft statement 4

Adults with rheumatoid arthritis and disease flares or possible treatment-related side effects receive advice within 1 working day of contacting rheumatology services.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

* Disease flares and side-effects are potentially serious and very distressing for patients and so access should be within 24 hours not 1 working day. This could be achieved by a telephone service on non-working days.

### Consultation question 9

Stakeholders made the following comments in relation to consultation question 9:

Is the timeframe of receiving advice within 1 working day of contacting the rheumatology services achievable?

* Few departments are able to offer this in practice. Some rheumatology services have the view that urgent care should take place through primary care or emergency departments. Stakeholders acknowledged that this statement could help with commissioning of such rheumatology services and the need to increase in capacity.
* This statement is achievable but some smaller units or those on multiple sites may struggle. Some units currently use a target of 2 working days which is more achievable.
	1. Draft statement 5

Adults with rheumatoid arthritis have a comprehensive annual review that is coordinated by rheumatology services.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

#### Statement

* This statement could include annual review in primary care as well as in secondary care, especially for those with chronic and stable disease.

#### Quality measures

* Annual review should include a requirement for advice on family planning for women of childbearing age and there should be additional quality measures in the statement to reflect this.

#### Definitions

* Orthotists should be included in the makeup of a multidisciplinary team (MDT). Orthotists are embedded in rheumatology services and are required to prescribe biomechanical treatment plans including footwear solutions as well as devices for joints of the lower limb, upper limb and spine. By failing to list as part of an MDT, patients may have disjointed service provision and the need to see an orthotist separately for upper limb / spine and feet.
* The term ‘comprehensive’ needs defining. There were suggestions to include offer of referral to allied health professionals, record of cardiovascular risk score and FRAX score, measure of function (health assessment questionnaire) and measure of work in the definition.
1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

* Stakeholders suggested an additional statement on the treatment step-down strategy used when the disease is under control. It was noted that this would have a potential cost saving but would need initial investment in outpatient capacity and in health literacy.
* An additional statement on increasing public awareness of rheumatoid arthritis would help to reduce the delay in diagnosis caused by people with symptoms not seeking early medical advice.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

|  | **Stakeholder** | **Statement number** | **Comments[[1]](#footnote-1)** |
| --- | --- | --- | --- |
|  | British Society for Rheumatology | General | In general – a common issue with the new statements is that some are difficult to measure, and are not time bound. I would be very keen to see all statements align to the SMART objective’s principle, in line with National QI recommendations. In addition, it would make sense to ensure that the QS aligns to other metrics currently out there, namely BPT. Otherwise we will have trusts unsure which targets / metrics to chase. |
|  | British Society for Rheumatology | General | Losing the old QS 2 results in loss of any easy to measure and validated clinical standard. This statement has proved a powerful lever in negotiations with managers and commissioners and losing this component, and measure of care, removes this powerful lever. This measure is used currently to identify outlier performance in the National Early Inflammatory Arthritis Audit (NEIAA). |
|  | British Society for Rheumatology | General | Merging the old QS 2,3 and 5 will make it much more difficult to identify where there are problems in the patient pathway. Trusts may be able to meet one component (e.g.: initiation of treatment) but unable to meet another (e.g. treat to target) and by combining these QS we do not get the level of detail about where the issues are for that individual trust.Keeping these as separate QS will help trusts understand where problems are arising. These separate QS have been reported within the NEIAA |
|  | British Society for Rheumatology | General | This proposal does not align with the recently launched BPT or the ongoing HQIP funded National Early Inflammatory Arthritis Audit and it is unclear that the significant implications of this have been considered |
|  | GlaxoSmithKline | General | The draft quality standard on rheumatoid arthritis largely reflects the key areas for quality improvement in assessing, diagnosing and managing rheumatoid arthritis. |
|  | Royal College of General Practitioners | General | Primary care plays a significant part in the care of this chronic illness, in managing the long term effects of this disease, performing annual reviews, dealing with acute flare ups, managing chronic and stable patients with RA (or in those whom the disease has burnt out), in addition to the holistic treatment of the patient and their family/ carers from diagnosis to death. This is not reflected in the current quality standards.The committee should consider adding a further quality standard or adapting one of the current ones to reflect the primary care involvement |
|  | Royal College of General Practitioners | General | The committee should justify the removal of the QS from the 2013 version “Patients … are assessed in a rheumatology clinic within 3 weeks”. Whilst not all trusts may have achieved this, it is a very valuable access clinic for primary care for patients who would otherwise have to be admitted on the same day via an ambulatory care ward or alternatively wait for several weeks, or months for a routine rheumatology review. The removal of this statement will potentially increase time to treatment, if hospital trusts remove the clinics based on the omission of the quality standard in this version. |
|  | Royal College of Nursing (RCN) | General | No comments. |
|  | Royal College of Occupational Therapists | General | Please note the following publication (which is a NICE accredited guideline) in particular recommendations 1-3 on RA - orthoses for activity and rest.College of Occupational Therapists (2015) *Hand and wrist orthoses for adults with rheumatological conditions: practice guideline.* London: COT. Available at: <https://www.rcot.co.uk/node/394> |
|  | The Royal College of Physicians (RCP) | General | The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our experts and would be happy to support this draft quality standard. |
|  | The Royal College of Physicians and Surgeons of Glasgow | General | The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments.The College welcomes this Quality Standard in an important area. It does however recognise some of the standards are ambitious and may be hard to achieve reflecting differing expertise especially in primary care, differing commissioning practices throughout the UK and varying resources |
|  | British Society for Rheumatology | Question 1 | *Does this draft quality standard accurately reflect the key areas for quality improvement*?Only in part. The loss of the time to first appointment target is a major deficit. The previous standard (of three weeks – though two weeks was considered in the original draft some years ago, to be analogous to cancer waits) was important as (a) patients with suspected early inflammatory arthritis want to be seen quickly as they are in pain and anxious and potentially unable to work and carry out activities of daily living, (b) it provided an unequivocal, measurable target that appears in administrative datasets that does not rely on self-reporting (as does treatment initiation) and cannot be gamed or selectively reported, and (c) when trying to implement quality improvement activities, achieving time to first appointment is a critical step in ensuring that there is sufficient capacity in the local system to see new referrals (of all suspected early inflammatory arthritis) and so administrative processes such as triage and booking are aligned to achieve this; there can be discussions about the right length of time that people should have to wait for that first appointment, but I think it will be an error to lose that target entirely in favour of only having a composite referral to treatment quality standard. |
|  | The Royal College of Physicians and Surgeons of Glasgow | Question 1 | *Does this draft quality standard accurately reflect the key areas for quality improvement*?Yes There is however a need for a standard to address drug therapy in patients once stable. Good practice would suggest that dose tapering should be considered when disease has been controlled.  |
|  | British Society for Rheumatology | Question 2 | *Are local systems and structures in place to collect data for the proposed quality measures? If not how feasible would it be for these to be put in place?* It is extremely difficult to determine from routinely available data whether time from GP presentation to referral is within three days; the only way this can be done at present is to ask patients to try to recall the dates when they first presented to their GP and then look at the date of the referral – patients are rarely able to do recall this information. Statements 2-5 require dedicated collection and reporting by local units, for the duration of the HQIP National Early Inflammatory Arthritis Audit (NEIAA) (which is due to run for a further two years before needing to be recommissioned) these data will be manually extracted and entered by local clinical teams, sometimes with administrative support. The required information should all be available through local clinical records; strong and improving participation in NEIAA demonstrates that people are able to collect these data at the time of consultation or retrospectively from records.  |
|  | The Royal College of Physicians and Surgeons of Glasgow | Question 2 | *Are local systems and structures in place to collect data for the proposed quality measures? If not how feasible would it be for these to be put in place?* Routine collection of this data will be highly variable throughout the UK. Some of the outcomes form part of the HQIP/BSR funded National Clinical Audit of Rheumatoid Arthritis and early inflammatory arthritis in England and Wales, and will be recorded as part of the audit. This does not apply in all 4 nations of the UK. There is no equivalent in Scotland or Northern Ireland so data collection in these areas is likely to be difficult. The currently collected audit data pertains to early disease only. Recording outcomes in patients with established disease is likely to be difficult. In Scotland a pilot disease registry is being tested and funding for roll out of this would facilitate data collection. |
|  | British Society for Rheumatology | Question 3 | *Do you think each of the statements in the draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.*Statement 1 is out of the control of rheumatology services as it sits entirely in primary care. Prompt referral should not take any additional resource from primary care, though it may appropriately increase referrals to secondary care. For Statements 2-5, NEIAA already demonstrates huge variation in attainment, with some units achieving these very well while others struggle. This suggests that net resources are adequate, but there may be local decisions about resource allocation that mean some units are inadequately staffed to deliver these. With adequate staffing, sustained quality improvement efforts should be able to deliver against these quality statements. |
|  | The Royal College of Physicians and Surgeons of Glasgow | Question 3 | *Do you think each of the statements in the draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.*See responses to individual quality statements. In Scotland, funding of the Rheumatology quality registry would facilitate this type of quality measurement and patient engagement. Highlighting and facilitating drug tapering could be both a quality indicator (harm reduction) and a source of potential cost saving but would need initial investment in return outpatient capacity and a programme of health literacy. This would be in line with the Scottish “Realistic Medicine” agenda.  |
|  | The Royal College of Physicians and Surgeons of Glasgow | Question 10 | *Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please provide details on the comments form.*No |
|  | AbbVie Ltd  | 1 | The time to referral from primary care has been reduced from ‘3 working days’ in the current quality standards to ‘3 days’ in the draft quality standards. It is unclear if this is intentional or achievable. |
|  | British Society for Rheumatology | 1 | This is fine. |
|  | British Society for Rheumatology | 1 | This should be achievable, and the timescale is appropriate. |
|  | GlaxoSmithKline | 1 | Currently Statement 1 covers referral times to specialist services by primary care but does not address the delay in diagnosis caused by people with RA not seeking early medical advice. A public awareness programme within primary care would be beneficial in addressing this issue. |
|  | Royal College of General Practitioners | 1 | The committee should consider defining what ‘persistent’ means in this statement? 1 week, 1 month or longer? |
|  | Royal College of General Practitioners | 1 | The committee should consider redrafting this statement to reflect what is possible in primary care appropriately.Can the committee consider changing the wording to “as soon as possible, and ideally within 3 working days” rather than “within 3 days”? • Many GPs will complete their referral letter on the day the patient is seen but due to workload issues this is not always possible. There is then a delay whilst the secretaries write the letter. Weekends and bank holidays should not be counted, hence the need to add “working days” as in statement 4. |
|  | Royal College of General Practitioners | 1 | There is no need to refer to rheumatology for x-rays and blood tests. GPs can order appropriate tests in primary care alongside the referral to rheumatology. By doing so, the information will be available on arrival at the rheumatology department and treatment can commence at first appointment, rather than patient requiring 2 secondary care appointments, benefiting the patient, and will be a potential cost saving to the NHS |
|  | The Royal College of Physicians and Surgeons of Glasgow | 1 | *Is referral within 3 days of presentation achievable? Is there an alternative timescale that should be used?*Referral within 3 days is aspirational but achievable. The key point in the process is making the decision that referral is indicated. This depends on the knowledge and skills of the health professional involved. Although the referrer will usually be the general practitioner, the patient may be seen by a nurse, physician assistant or physiotherapist.As the standard is currently worded, many patients with conditions other than new onset inflammatory arthritis may be referred eg Osteoarthritis. While rheumatologists and their staff recognise synovitis. Many non-specialists could refer anyone with a swollen joint from any cause.The document cites “*suspected persistent synovitis of more than 1 joint, or the small joints of the hands and feet”.* Since this is a clinical diagnosis, there is no delay for investigations. “Persistent” should be defined.The second clause requires clarification. “*affecting more than 1 joint, or the small joints of the hands and feet*,”– either delete “or the small joints of the hands and feet” or qualify: “1 large joint or the small joints of the hands and feet”.  |
|  | AbbVie Ltd  | 2 | Monthly monitoring may not improve outcomes per se unless treatments are modified accordingly in response, which is not currently captured as a quality measure. An additional quality measure could be included to align with EULAR guidelines which state that if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted.  |
|  | AbbVie Ltd  | 2 | The rationale and quality measures for QS2 describe the treatment target as remission or low disease activity. This is not aligned with NICE guideline NG100 which defines treat-to-target as the aim of achieving a target of remission or **low disease activity if remission cannot be achieved**. |
|  | British Society for Rheumatology | 2 | This is not easily measurable. The time to DMARD component is currently QS3. Research has shown that QS3 corresponds to clinical outcome (DAS remission) using the HQIP data. It therefore makes sense to keep this. We would suggest removing the second component (treat to target) and including this in a separate statement. Ideally the additional statement would align to the BPT standard (otherwise our clinical colleagues will think no one in the NHS teams talk to each other?). Perhaps:“Adults with newly diagnosed rheumatoid arthritis have at least one follow up DAS28 and a patient reported outcome (e.g. MSK-HQ / HAQ) within three months of diagnosis.” |
|  | British Society for Rheumatology | 2 and 3 | Consideration may be needed of splitting the new quality statements to cover newly diagnosed vs established disease?As a minimum, timelines for providing treatment and education for newly diagnosed patients is valuable as a measurable marker for quality of care and to align with the national audit data collection and with the BPT. |
|  | British Society for Rheumatology | 2 and 5 | To align with BPT, has consideration been given to specifying the value of DAS and PRO assessment as a “measure” of the treat to target” approach to care - as a minimum within the first 3 months of specialist care and as part of an annual review process? |
|  | British Society for Rheumatology | 2 | Combining these two elements is a mistake. There is evidence that both early treatment and a treat to target approach are associated with improved outcomes, and it’s a false dichotomy to try to choose between these – high quality care involves delivering both, and it could create perverse incentives with unintended consequences to select one of these only. The larger point is that these are separate clinical processes – often initiation is by the medical doctor at the point of diagnosis, after which monthly review and titration is by a nurse specialist – and therefore need distinct quality improvement efforts locally to implement. Keeping these distinct and reported separately flags to services where their problems are; given that none of these items are included in routine datasets, if they were lost as separate items from the Quality Standard, then these will no longer be collected and the opportunity for services to understand the performance of their systems and processes will be lost. |
|  | British Society for Rheumatology | 2 | Yes, this should be achievable, and many services are able to achieve this for a large majority of their patients. |
|  | GlaxoSmithKline | 2 | Given the long-term benefits of starting treatment early and the importance of monitoring patients for efficacy and side-effects of cDMARDs, both early commencement of treatment, and regular monitoring until treatment target is achieved, are high priority areas for quality improvement. |
|  | National Rheumatoid Arthritis Society | 2 | There is a sticking point around QS 2 as it now combines being seen by specialist care with getting started on treatment.This caused some concern recently at the national audit committee meeting as the CQC is looking at time to being seen as a key indicator of performance of a rheumatology department, however with this change to QS almost giving a further 3 weeks to being seen is this is now changing the goal posts. Our concern would be that if the patient is not say seen until week 6 but for some reason is unable to start on treatment immediately (i.e. more tests required, patient needs to come to terms with diagnosis before starting medication etc.) However, when the QS2 was to be seen within 3 weeks then start treatment within 6 then that made that far more achievable.Our concern would be that the wording of the proposed QS2 may need to be clearer along the lines of**Adults with active RA to have been examined and diagnosed by a specialist in ample time to have had all appropriate tests and consultations to then start conventional DMARDs therapy within 6 weeks of referral, with monthly monitoring until their treatment target is met.** |
|  | Royal College of General Practitioners | 2 | Can the committee consider adding that patients should be referred by a GP to a specialist along with all the relevant blood tests and investigations as part of a referral pathway?The committee should note that many trusts now have an “emergency, early diagnosis clinic referral pathway with patients seen within 2-3 weeks following the QS in 2013. If, as part of the referral process, primary care performed all of the relevant blood tests required by the rheumatologists and this early diagnosis clinic were maintained, then DMARD therapy could be commenced at the first appointment and much sooner than 6 weeks, reducing the time to treatment and benefiting patients with potential cost savings for the NHS. |
|  | The Royal College of Physicians and Surgeons of Glasgow | 2 | *Which of the two areas covered in the statement to you consider to be the priority area for quality improvement? Early commencement with cDMARDs, or regular monitoring of treatment until treatment target achieved?*Both are important but starting treatment is the greater priority if regular monitoring for some patients could only be achieved by delaying starting treatment in others.  In the sections that deal with monitoring, the guidance stipulates measurement of CRP and disease activity. Not all centres routinely measure CRP. ESR or PV (plasma viscosity) can also be used to assess disease activity. Is the mandating of CRP measurement deliberate?Long term monitoring is also important for consideration of continuing need for the drugs and possible step down in dosage and or drugs |
|  | The Royal College of Physicians and Surgeons of Glasgow | 2 | *Is the target of starting treatment within 6 weeks of referral achievable?*Yes |
|  | British Society for Rheumatology | 3 | The old QS was easier to measure. The suggested new version lacks any time bound component. We think it is crucial that the statement has clarity and is measurable. |
|  | British Society for Rheumatology | 3 | As a minimum, timelines for providing treatment and education for newly diagnosed patients is valuable as a measurable marker for quality of care and this would maintain alignment with the national audit data collection and with the BPT. |
|  | British Society for Rheumatology | 3 | It’s not clear why these timeframes have been selected, or what ‘educational activities’ means in this context (see below). Does a one-hour appointment with a nurse specialist within a month of diagnosis count as an educational activity? The rationale for early educational activities seems clear, but for yearly seems less clear. The 2018 NICE CG100 is much clearer, more pragmatic and helpful, and the Quality Statement should reflect this and it’s very difficult to see why the Quality Statement is different: (1) Offer verbal and written information to adults with RA to improve their understanding of the condition and its management, and counter any misconceptions they may have and (2) Adults with RA who wish to know more about their disease and its management should be offered the opportunity to take part in existing educational activities, including self-management programmes. |
|  | British Society for Rheumatology | 3 | It’s unclear what is actually meant here by ‘educational activities’ (unlike the CG100 which is much clearer – see above), and there is evidence from the NEIAA that there’s discrepancy between what clinicians-report as educational activities, and what patients report as educational activities. The scope of what this might be is huge from one on one discussions with nurses, signposting to electronic resources via patient-held record, group education sessions (which very few units still run, in part as experience is that uptake of these is poor) to peer led support through a local charity such as NRAS (does this count as offering?). It’s difficult to see why the offer of ‘educational activities’ should be repeated as such at the annual review in particular (and indeed this is not included in NICE CG100), but it seems good practice that at every appointment people are given the change to explore the understanding of their condition and are offered written information and oral discussion/explanation of their condition.  |
|  | GlaxoSmithKline | 3 and 5 | Educational materials and activities should be offered annually as part of the annual review. A patient’s circumstances can change during a year e.g. the development of co-morbidities, changes in treatment adherence etc, and hence additional more specific educational support may be required.  |
|  | The Royal College of Physicians and Surgeons of Glasgow | 3 | *Are the timeframes for offering educational opportunities within 1 month and annually used in the process measures for this statement appropriate?*YesRewording the statement to encompass the principles of shared decision making would be preferable. The current statement implies stand-alone educational “events” rather than building patient empowerment into the essence of the consultation and engendering a culture of active listening so that the patients’ preferences, priorities and values are central to every consultation. |
|  | The Royal College of Physicians and Surgeons of Glasgow | 3 | *Should offering educational activities annually happen as part of the annual review?*This may be acceptable in some areas. Another method could be for a less didactic approach as the model of incorporating it into annual review may not work in every centre. The principle of giving education is more important than how or when it is delivered.  |
|  | UCB Pharma Ltd | 3 | UCB requests that NICE considers adding a further statement (or that Statement 3 is modified) to include a specific requirement to provide educational materials to women of childbearing age. Women of childbearing age who have RA experience unique family planning and pregnancy related challenges, for instance:* Only 1/3 of RA patients with high disease activity will achieve pregnancy within a year of trying, compared to 2/3 of patients in remission[[2]](#footnote-2)
* More than half of women diagnosed with RA prior to the completion of childbearing had fewer children than they hoped for[[3]](#footnote-3)
* Among women with RA, the rate of infertility was higher among women diagnosed during childbearing than those diagnosed once childbearing was complete. Women who had fewer children than desired had a high rate of infertility (42%)[[4]](#footnote-4)

Women of childbearing age should be empowered to focus on optimal care of their disease and have the freedom to choose the best treatment with their doctor. However, research suggests a large majority of HCPs do not proactively the raise topic of family planning; 69% of patients with CRD, and 77% of women with PSO, who visited an HCP before pregnancy had to initiate discussions with their HCPs[[5]](#footnote-5),[[6]](#footnote-6)The European League Against Rheumatism (EULAR)[[7]](#footnote-7) has highlighted the overarching points to consider for use of antirheumatic drugs before and during pregnancy, and lactation, as:1. Family planning should be addressed in each patient of reproductive age and adjustment of therapy considered before a planned pregnancy.
2. Treatment of patients with rheumatic disease before/during pregnancy and lactation should aim to prevent or suppress disease activity in the mother and expose the foetus/ child to no harm.
3. The risk of drug therapy for the child should be weighed against the risk that untreated maternal disease represents for the patient and the foetus or child.
4. The decision on drug therapy during pregnancy and lactation should be based on agreement between the internist/rheumatologist, gynaecologist/obstetrician and the patient, and including other healthcare providers when appropriate. The risk of drug therapy for the child should be weighed against the risk that untreated maternal disease represents for the patient and the foetus or child.
5. The decision on drug therapy during pregnancy and lactation should be based on agreement between the internist/rheumatologist, gynaecologist/obstetrician and the patient, and including other healthcare providers when appropriate.
 |
|  | UCB Pharma Ltd | 3 | UCB requests that NICE considers adding another measure to evaluate adherence, with a requirement to provide educational materials to women of childbearing age.**Proposed Additional Quality measure**Structure Evidence of availability of relevant educational activities before and during pregnancy, and lactation **for women of childbearing age** Data source: Local data collection, for example, service protocols and treatment plans, or evidence of referral to patient organisations documented in patient record. Process a) Proportion of **women of childbearing age** offered relevant educational activities before pregnancy (within 1 month of diagnosis) and during pregnancy, and lactation Numerator – the number in the denominator with a record of an offer of educational activities within 1 month of diagnosis and during pregnancy, and lactation. Denominator – the number **women of childbearing age** with rheumatoid arthritis. |
|  | British Society for Rheumatology | 4 | This is essentially saying departments need emergency access to advice within 1 working day. We do not feel the new wording is an improvement and it feels a little like change for change sake. |
|  | British Society for Rheumatology | 4 | In practice probably not –very few departments are able to offer this in practice with current resource, and the additional resource from Best Practice Tariff would not meet this. Some services would like to discontinue this aspect of their service, taking the view that urgent care should be provided through patients’ GPs or the local Emergency Department. This Quality Statement could feel on the front line like setting up the overwhelming majority of services to fail; conversely it could provide services with the argument they need to request an increase in their capacity to be able to deliver this. |
|  | GlaxoSmithKline | 4 | Given the seriousness and potential distress to patients of disease flare or treatment side-effects, Statement 4 and the measure, should relate to access to rheumatology services within 24 hours rather than 1 working day. On non-working days this could potentially be achieved by a telephone advice service. This approach would potentially reduce the use of non-specialist resources and provide better outcomes for patients. |
|  | The Royal College of Physicians and Surgeons of Glasgow | 4 | *Is the timeframe of receiving advice within 1 working day of contacting rheumatology services achievable?*YesIt will however be challenging especially in smaller units or those who do clinics on multiple sites. Many units currently work to a target of 2 working days which is more realistic. |
|  | The British Association of Prosthetists & Orthotists (BAPO) | Statement 5(Definitions)Page 19 | It is disappointing that orthotists are not listed as members of the MDT. Orthotists are embedded with Rheumatology services through the country. With reference to NG100 there is recommendation that (1.8.6 Functional insoles and therapeutic footwear should be available for all adults with RA if indicated). NG100 is flawed in that this role is listed solely under podiatry. Orthotists are HCPC registered AHPs who work autonomously to prescribe biomechanical treatment plans – these include insoles and footwear solutions. There is a crossover here in terms of the scope of practice between podiatrists and orthotists as both professions can prescribe insoles and footwear. The orthotist also can prescribe the RA patient supportive devices for joints of the lower limb, upper limb and spine – where as podiatrists will only consider feet and legs. Failure to list the orthotist as a member of the MDT may create barriers where patients are directed solely into podiatry and may have disjointed service provision if they then need to see orthotists separately for upper limb/spine. |
|  | British Society for Rheumatology | 5 | ‘Comprehensive’ needs defining. We would suggest that it should include: Referral to AHPs offered, record of CV risk, FRAX, measure of function (HAQ), and measure of work. Would be good if this could be made explicit in this QS. |
|  | Royal College of General Practitioners | 5 | Can the committee consider the GP annual review in this statement in addition to, or instead of a secondary care lead annual review? This is especially important for those with chronic and stable disease, or those who opt not to be seen in secondary care. |
|  | UCB Pharma Ltd | 5 | UCB requests that NICE considers adding a further statement (or that Statement 5 is modified) to include a specific requirement that discussions about family planning are part of the annual review for women of child bearing age. As noted by EULAR and The British Society of Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), there are considerations when managing RA in women who are pregnant or planning to become pregnant. The annual review, for those women with RA who have achieved the treatment target and who are of child bearing age should include discussions about:• whether they are considering starting a family in the coming year• whether they have any concerns about continuing treatment while pregnant the safety of women/infants breastfeeding while on treatment |
|  | UCB Pharma Ltd | 5 | **Proposed Additional Quality measure**StructureEvidence of arrangements to ensure that **women of childbearing age** with rheumatoid arthritis received a comprehensive annual review by rheumatology services, **including discussions about family planning.**Data source: local data collection, for example, service specificationsProcessa) Proportion of **women of childbearing age** with rheumatoid arthritis diagnosed more than 12 months ago who had a comprehensive review within the past 12 months by rheumatology services, **including discussions about family planning**.Numerator – the number in the denominator who had a comprehensive review within the past 12 months.Denominator – the number of **women of childbearing age** with rheumatoid arthritis diagnosed more than 12 months ago.Data source: Local data collection, for example, audit of patient record. Data on provision of an annual review by rheumatology services is collected as part of the National Clinical Audit for Rheumatoid and Early Inflammatory Arthritis. |

## Registered stakeholders who submitted comments at consultation

* Abbvie Ltd.
* The British Association of Prosthetists and Orthotists (BAPO)
* British Society for Rheumatology
* GlaxoSmithKline
* National Rheumatoid Arthritis Society (NRAS)
* Royal College of General Practitioners
* Royal College of Nursing (RCN)
* Royal College of Occupational Therapists (RCOT)
* The Royal College of Physicians (RCP)
* The Royal College of Physicians and Surgeons of Glasgow
* UCB Pharma Ltd.
1. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-1)
2. Brouwer J et al. Ann Rheum Dis. 2015; 74:1836-1841 [↑](#footnote-ref-2)
3. Clowse MEB et al. Arthritis Care Res. 2012;64(5):668–674. [↑](#footnote-ref-3)
4. Clowse MEB et al. Arthritis Care Res. 2012;64(5):668–674. [↑](#footnote-ref-4)
5. Tincani A et al. EULAR 2018. Abstract 2063. [↑](#footnote-ref-5)
6. Murase J et al. AAD 2019. Poster 8060. [↑](#footnote-ref-6)
7. Götestam Skorpen, C. et. al. (2016). The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. Ann Rheum Dis. 75(5):795-810. [↑](#footnote-ref-7)