National Institute for Health and Clinical Excellence

Rheumatoid arthritis
Quality Standard Consultation Comments Table
21st January – 18th February 2013

ID	SH ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.	Responses
001	003	Society and College of Radiographers	Additional statement	Patients with RA are at a much higher risk of sustaining a fracture in the future and therefore bone health surveillance with DXA is appropriate and necessary to prevent fragility fractures such as hip and vertebral wedge fractures.	Thank you. The TEG considered assessment of fracture risk to be covered as part of the annual review (please see statement 7 in the final quality standard).
002	006	British Nuclear Medicine Society	Additional statement	A combination of anatomical and functional imaging techniques could enhance diagnostic accuracy in Rheumatoid Arthritis. Therefore, the following nuclear medicine techniques could be considered in patients with suspected synovial inflammation. Bone Scintigraphy: Tc99m MDP study shows abnormal increase in tracer uptake in the involved joints. Synovial inflammation can cause underlying cartilage destruction, bone erosions and joint deformities. Since bone scinitgraphy is very sensitive but less specific, it cannot differentiate active synovial inflammation from cartilaginous disease or underlying bone destruction as all of these conditions can cause abnormal increase in tracer uptake. However, 3 phase bone study could show features in keeping with active synovial inflammation. This technique can be applied for single joint involvement is suspected as it is impossible to perform whole body dynamic views when multiple joints are involved. Bone scan could also be used in monitoring treatment efficacy by doing baseline and follow-up scans after treatment. Tc99m HIG: This is a polyclonal human immunoglobulin, more specific than bone Scintigraphy, and shows abnormally increased accumulation of tracer in the inflamed joints. Unlike 3 phase bone study, Tc99m HIG can be used when multiple joints need assessment.	Thank you. The TEG felt that this suggestion was too specialised to be included in the quality standard, and was not underpinned by a recommendation from the key development source (NICE clinical guideline 79). NICE quality standards do not seek to reassess or redefine the evidence base.

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				References: 1. Comparison of Tc-99m HIG and three-phase Tc-99m MDP bone scintigraphy for evaluating the efficacy of Yttrium-90 silicate radionuclide synovectomy. Arzu Gencoglu E, Aras G, Kucuk O, Atay G, Tutak I, Ataman S, Soylu A, Ibis E. Clin Nucl Med. 2003 Apr;28(4):277-85 2. Measurement of synovial inflammation in rheumatoid arthritis with technetium 99m labeled human polyclonal immunoglobulin. Van der Lubbe PA, Amdt JW, Calame W, C, Pawels EK, Breedveld FC. G. Eur J Nucl Med. 1991; 18: 119-123. 3. 99mTc-human immunoglobulin (HIG)-first results of a new agent for the localization of infection and inflammation. Buscombe JR, Lui D, Ensing G, de Jong R, Ell PJ. Eur J Nucl Med. 1990; 16: 649-655. 4. Value of inflammation and bone scintigraphy in differential diagnosis of painful affections of small joints. Warchol O, Kφnig B, Dworak E, Kφhn H, Dunky A, Mostbeck A. Acta Med Austriaca. 1998; 25: 7-12.	
003	006	British Nuclear Medicine Society	Additional statement	The use of Beta emitting colloids such as Y90, Re186 and Er169 is a well established method of treating patients with chronic recurrent synovitis despite the use of pain killers (NSAIDs), Disease modifying anti-rheumatic drugs (DMARDs) and intra-articular steroids. References: 1. The indication for radiosynoviorthesis. From the perspective of the nuclear medicine expert, rheumatic orthopedist and internist. Linke R, Gelse K, Schuch F. Z Rheumatol. 2011 Jan; 70 (1):34-44. 2. Effectiveness of radiation synovectomy with Yttrium-90 and Samarium-153 particulate hydroxyapatite in rheumatoid arthritis patients with knee synovitis: a controlled, randomized, double-blinded trial. Dos Santos MF, Furtado RN, Konai MS, Castiglioni ML, Marchetti RR, Silva CP, Natour J. Clin Rheumatol. 2011 Jan;30 (1):77-85. 3. Radiation synovectomy with (90)Yttrium, (186)Rhenium and (169)Erbium: a systematic literature review with meta-analyses. van der Zant FM, Boer RO, Moolenburgh JD, Jahangier ZN, Bijlsma JW, Jacobs JW. Clin Exp Rheumatol.	Thank you. The TEG felt that this suggestion was too specialised to be included in the quality standard, and was not underpinned by a recommendation from the key development source (NICE clinical guideline 79). NICE quality standards do not seek to reassess or redefine the evidence base.

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				2009 Jan-Feb;27 (1):130-9. 4. Radiation synovectomy with 90Y colloid in the therapy of recurrent knee joint effusions in patients with inflammatory joint diseases. Chrapko B, Zwolak R, Nocuń A, Gołebiewska R, Majdan M. Rheumatol Int. 2007 Jun;27(8):729-34 5. Radiation synovectomy using 188Re-tin colloid improves knee synovitis as shown by MRI in refractory rheumatoid arthritis. Shin K, Lee JC, Choi HJ, Jeong JM, Son M, Lee YJ, Lee EB, Hong SH, Song YW. Nucl Med Commun. 2007 Apr;28(4):239-44. 6. 188Re-tin-colloid as a new therapeutic agent for rheumatoid arthritis. Lee EB, Shin KC, Lee YJ, Lee YJ, Cheon GJ, Jeong JM, Son MW, Song YW. Nucl Med Commun. 2003 Jun;24(6):689-96 7. Radiation Synovectomy: an effective alternative treatment for inflamed small joints. Karavida N, Notopoulos A. Hippokratia. 2010 Jan;14(1):22-7. 8. Is radiation synovectomy for arthritis of the knee more effective than intraarticular treatment with glucocorticoids? Results of an eighteen-month, randomized, double-blind, placebo-controlled, crossover trial. Jahangier ZN, Jacobs JW, Lafeber FP, Moolenburgh JD, Swen WA, Bruyn GA, Griep EN, ter Borg EJ, Bijlsma JW. Arthritis Rheum. 2005 Nov;52(11):3391-402. 9. EANM procedure guidelines for Radiosynovectomy. Eur J Nucl Med (2003) 30: BP12-BP16 Vol. 30, No. 3, March 2003.	
004	007	National Osteoporosis Society	Additional statement	Furthermore, CG146 (on use of fracture risk assessment) recommends use of a fracture risk assessment in people with RA and additionally those using glucocorticoid steroids. We would recommend that fracture risk assessment is included in this QS.	Thank you. The TEG considered assessment of fracture risk to be covered as part of the annual review (please see statement 7 in the final quality standard).
005	010	British Medical Association	Additional statement	Rheumatoid arthritis is usually dealt with under shared care arrangements, and these have considerable local variation. Local commissioners need to ensure that these shared care arrangements: 1. are negotiated with the LMC, 2. are clear regarding the separate responsibilities for GPs and secondary	Thank you. The TEG considered shared care arrangements throughout the development of the quality standard and in particular during the development of statement 3 in the final quality standard. Please see the definitions section of the statement for reference to shared care

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				care, both in the initiation and maintenance periods, 3. are appropriately resourced through enhanced services mechanisms, 4. contain effective pathways for GPs to access promptly specialist advise where required. All patients with a diagnosis of rheumatoid arthritis should have a named responsible consultant, and remain under their care unless this becomes inappropriate due to serious co-morbidities.	arrangements.
006	012	UCB Pharma Ltd	Additional statement	In line with this we propose that it is important patients with active rheumatoid arthritis have an agreed, comprehensive, personalised written care plan, reviewed annually with a specialist in the management of rheumatoid arthritis.	Thank you. The TEG considered care planning to be covered as part of the annual review (please see statement 7 in the final quality standard).
007	025	Arthritis Care	Additional statement	We recommend a QS for persons with RA who are admitted to a hospital: due account should be taken of any symptoms or disabilities that are due to rheumatoid arthritis.	Thank you. The TEG considered that a statement on people with RA who are admitted to hospital would be too generic, and was not underpinned by a recommendation from the key development source (NICE clinical guideline 79).
008	001	Bristol-Myers Squibb (BMS)	General	BMS welcomes the development of a Quality Standard for rheumatoid arthritis.	Thank you.
009	001	Bristol-Myers Squibb (BMS)	General	States that this quality standard covers the diagnosis and management of rheumatoid arthritis in adults (16 years and older). However, most NICE guidelines state adult RA as 18 years or older.	The TEG considered that the quality standard should cover adults aged 16 years and older.
010	007	National Osteoporosis Society	General	Indicators on Rheumatoid Arthritis for the Quality and Outcomes Framework (QOF) have been piloted and approved. They will be considered for inclusion in QOF from April 2013. The QOF indicators include risk assessments for fracture (people with RA are at increased risk of osteoporosis and subsequent fractures) and cardiovascular disease. However, these assessments are not included in the QS. It is inconsistent and confusing.	Thank you. The TEG considered assessment of fracture risk to be covered as part of the annual review (please see statement 7 in the final quality standard). We have now included reference to the QOF measures in this statement.
011	011	The Work Foundation	General	These comments are submitted on behalf of Fit for Work UK, a campaigning coalition established in 2011 with the aim of promoting the awareness and treatment of musculoskeletal disorders (MSDs) so that they are treated and understood as manageable conditions – not disabling conditions. The Coalition brings together healthcare professionals, policy makers, employers, and patient representatives. Dame Carol Black's review of the health of Britain's working age population,	Thank you. We believe the quality standard for rheumatoid arthritis contributes to improving the functional ability of people with rheumatoid arthritis and therefore contributes to optimising their employment outcomes. Please see statement 7 in the final quality standard, where employment status is explicitly referenced (in the definitions section)

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				Working for a healthier tomorrow, in March 2008 recognised the risks to long-term health arising from the lack of early support for staying and returning to work and recommended that management of employment outcomes begins in the clinical settings, rather than at the time when individual drops out of the labour market and is supported through the welfare system. FFW UK's original study of 809 people diagnosed with an MSD, published in December 2012 shows that maintaining work is a significant problem for people with MSDs, particularly as their condition exacerbates, and one that can have profound effects on their wellbeing and that of their families. Three quarters of respondents to the survey who were retired said their condition had influenced their decision to leave the labour market, with the majority retiring before reaching the age of fifty-five. Within three years of diagnosis, half of people with rheumatoid arthritis are registered as work disabled. Inability to stay in work may have a further spillover effect into the wellbeing and financial stability of entire households. In the FfW UK study 57.4 per cent of respondents who were not in work had been primary income earners before leaving their job. Despite the Government's commitment to optimise employment outcomes of individuals with long-term conditions, and the consecutive inclusion of 'Employment of people with long-term conditions' as an indicator in the NHS Outcomes Framework, there is a concern that the regulations have not yet transpired into clinicians' day-to-day practice. For example, the FfW survey above found that only half of respondents had discussed employment or return-to-work with health care professionals. It is therefore more crucial that work is reiterated in this draft quality standard of Rheumatoid Arthritis care.	as part of the annual review discussion with the patient about how the disease is affecting their life.
012	016	Arthritis research UK	General	We are pleased to see this activity moving forward and are supportive of the overall approach. Arthritis Research UK is committed to reducing the pain of arthritis, and enabling people to continue to do the things they love. As part of this, we passionately believe in the power of better data to improve services for people living with arthritis and other musculoskeletal disorders. One of the major projects we have therefore embarked on is the development of a generic musculoskeletal patient	Thank you. We welcome the development of a musculoskeletal patient reported outcome measure and its potential to support achievement of the quality standard.

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				reported outcome measure (M-PROM) which can be used to assess the health of people with a wide range of arthritis and musculoskeletal conditions at every step of their clinical journey, regardless of the health or social care professional who they are seeing for their care. The tool will be brief and multidimensional, including components of physical and mental health, as well as self-efficacy. We believe that a generic tool – used alongside other condition-specific tools where clinically indicated – has the potential to transform the way care is delivered for people with arthritis and musculoskeletal conditions. Since the project's inception, we have worked closely with the PROMs team at DH, and have regularly updated NICE about progress. We are working with the musculoskeletal community and recently held a stakeholder workshop at which there were representatives from patient-charities including Arthritis Care and NRAS, as well as professional societies representing general practice (RCGP), physiotherapy (CSP), orthopaedics (BOA) and rheumatology (BSR). We will shortly be issuing a research call for the next stage of this work, and we anticipate a usable instrument in late 2014. Although this instrument is not yet available, we would be keen to create a placeholder for this at this stage, and to remain in contact to see how the Arthritis Research UK M-PROM can support the desire of the quality standard in achieving its aims. There is more information about this on our website: http://www.arthritisresearchuk.org/policy-and-public-affairs/policy-priorities-and-projects/musculosketal-health-services/patient-reported-outcome-measures.aspx	
013	017	National Rheumatoid Arthritis Society	General	The quality standard states that total costs of rheumatoid arthritis in the UK, including indirect costs and work-related disability, have been estimated to be at around £2.4bn per year. This figure is derived from National Audit Office analysis produced in 2009 and is therefore out of date. NRAS believes the figure should be revised upwards to £2.5bn, as more recent research suggests that direct NHS costs may be as high as £700m. Indeed, further analysis of indirect costs suggests the total impact on the economy may be far greater than even the £2.5bn figure we have suggested here, which we believe represents a conservative estimate (Economic Burden of RA report, 2010).	Thank you. We have used the figures from the underpinning NICE clinical guideline as these have been quality assured through NICE processes.
014	022	Pfizer Ltd	General	Proposed response:	Thank you. NICE has produced a support document to help commissioners and others

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				Pfizer would like to thank NICE for the opportunity to respond to the draft quality standard for rheumatoid arthritis, which we believe to be an excellent start and we very much support its development. This is an important document to help ensure that any potential inappropriate variance in managing patients with rheumatoid arthritis is mitigated. In order for the quality standard to realise the aspirations it will be essential that providers plan and have the capacity and resource to deliver the quality measures. Additionally, it is important that the quality standard is future proofed, such that it is aligned to the health technology appraisal process to minimise the need for updating.	consider the commissioning implications and potential resource impact of this quality standard, available from www.nice.org.uk. NICE quality standards will be reviewed every 5 years.
015	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	General	The ABPI PRI welcomes the development of a Quality Standard for rheumatoid arthritis. The ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI) was set up in 2012 to enable member companies to work collectively with stakeholders from the rheumatology community and policy makers to raise awareness and improve quality of care for people with inflammatory arthritis. By ensuring individuals can be diagnosed quickly and are able to access timely and effective treatment, clinical outcomes can be improved and the wider impact on the health system and disease-related productivity losses can be reduced. The group therefore particularly welcomes the emphasis on early diagnosis, referral and initiation of treatment in the draft Quality Standard. As is recognised, early inflammatory arthritis is a critical period of the disease where a brief “window of opportunity” exists when effective treatment can radically improve long term outcomes. Early treatment can minimise joint damage helping people maintain their mobility and independence and reduce work related disability. The Quality Standard covers the diagnosis and management of rheumatoid arthritis in adults which it defines as 16 and over, however, most NICE guidelines state adult RA as 18 years or older.	Thank you. We believe the quality standard for rheumatoid arthritis will contribute to improving outcomes for these patients. The TEG considered that the quality standard should cover adults aged 16 years and older.
016	027	Royal College of Nursing	General	We welcome the mention of nurse specialists in the standards; it should also include nurse consultants, extended roles consultants and physiotherapists. The recognition of these roles in achieving quality standards might be considered useful to and particularly with the extended roles and responsibilities. This might be something that commissioners briefing should include.	Thank you. The definition of the rheumatology service (see statements 1, 2, 3, 6 and 7 in the final quality standard) has been extended to reflect this. The support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard (available from

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					www.nice.org.uk) considers the different roles and responsibilities of those professionals working in the rheumatology service.
017	027	Royal College of Nursing	General	We welcome these standards and hope that the commissioners can have sufficient frameworks to aid the management of increased activity in the short term.	Thank you. A support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard is available from www.nice.org.uk.
018	028	AbbVie Ltd	General	AbbVie welcomes the development of this quality standard for rheumatoid arthritis (RA) and the opportunity to comment on this draft via the consultation process. AbbVie believes that quality standards have the potential to drive positive change in clinical standards if constructed correctly and are adopted by clinical practitioners and commissioners across the NHS. AbbVie believes RA is an area of clinical practice where improved outcomes are possible for patients. As the consultation notes, the cost to the economy of RA is significant, and the cost to patients can be greater still, with the National Audit Office (NAO) Report into RA services[1] indicating that one third of patients cease to work within two years of symptom onset. AbbVie therefore strongly welcomes any policy development that improves both the speed and accuracy of diagnosis for RA; that encourages treatment targets and regular disease monitoring; and that enables patients to access the most appropriate and beneficial interventions as determined by their clinicians.	Thank you. We believe the quality standard for rheumatoid arthritis will contribute to improving outcomes for these patients.
019	029	Royal College of General Practitioners	General	The rest of the Draft Quality Statements are reasonable but perhaps a little unrealistic because so many patients cannot be diagnosed instantly, even by a skilled team, and overenthusiastic labelling leads to overdiagnosis, overtreatment and unacceptable treatment risk. There is an unstated undercurrent in the whole document that diagnosis is simple and quick. Often it isn't even in the hands of senior and experienced specialists.	Thank you. The TEG acknowledged this point but considered that early diagnosis and rapid initiation of treatment are the key quality improvement areas that will have the biggest impact on outcomes for people with rheumatoid arthritis.
020	030	AstraZeneca UK	General	AstraZeneca UK welcome the opportunity to comment on the draft quality standard for rheumatoid arthritis (RA). AstraZeneca agrees that RA is a chronic, progressive and disabling disease that affects more than 690,000 people in the UK. Over the next 10 years, with the aging population, it is expected that the number of people affected with RA will increase by 15% adding additional pressure to the health care system.	Thank you. We believe the quality standard for rheumatoid arthritis will contribute to improving outcomes for these patients.

[1] http://www.nao.org.uk/publications/0809/services_for_people_with_rheum.aspx

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Please insert each new comment in a new row.</th><th>Responses</th></tr>
<tr><td></td><td></td><td></td><td></td><td>The quality standards that NICE are developing will play a critical role in addressing the treatment pathway for RA patients and increasing the health outcomes for patients, reducing the burden on the health system and improving productivity.</td><td></td></tr>
<tr><td>021</td><td>017</td><td>National Rheumatoid Arthritis Society</td><td>Outcomes frameworks</td><td>The draft quality standard states it could contribute to certain outcomes, overarching indicators and improvement areas outlined in the Adult Social Care Outcomes Framework 2013-14, the NHS Outcomes Framework 2013-14 and the Public Health Outcomes Framework 2013-14.

NRAS believes the current draft significantly underestimates the number of areas that it can help to deliver against. The following framework domains should therefore also be highlighted in the document to ensure commissioners and service providers clearly understand the wider range of benefits:

NHS Outcomes Framework 2013-14
<table><tr><th>Domain</th><th>Overarching Indicator</th><th>Improvement Area</th></tr><tr><td>1: Preventing people from dying prematurely</td><td>1a. Mortality from causes considered amenable to healthcare

1b. Life expectancy at 75 i Males ii Females</td><td>Reducing premature mortality from the major causes of death

1.1 Under 75 mortality rate from cardiovascular disease* (PHOF 4.4)

1.4 Under 75 mortality rate from cancer* (PHOF 4.5)

i One-and ii Five-year survival from all cancers</td></tr><tr><td>2: Enhancing quality of life for people with long-term conditions</td><td>2 Health-related quality of life for people with long-term conditions**</td><td>Reducing time spent in hospital by people with long-term</td></tr></table></td><td>Thank you. The outcomes, overarching indicators and improvement areas referenced from the frameworks are those which we believe the quality standard could contribute towards achieving. Whilst we acknowledge that some studies suggest that people with rheumatoid arthritis may be at greater risk of other conditions, we are unable to propose that achieving the quality standard will directly impact upon those indicators, for example the quality standard does not contain actions or interventions that would directly impact upon mortality. It is considered however that achieving the quality standard will lead to improvements in quality of life as measured across the three frameworks, as statement 7 in the final quality standard for example refers to functional ability and the impact of the disease on a person’s life. We acknowledge that there are many other areas that care will impact upon, and we are currently in the process of assuring our methods of linking quality standards to the outcomes framework with NHS England’s domain directors.</td></tr>
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					(ASCOF 1A)	*conditions* 2.3 i Unplanned hospitalisation for chronic ambulatory care sensitive conditions (adults) *Enhancing quality of life for carers* 2.4Health-related quality of life for carers** (ASCOF 1D)	
				4: Ensuring that people have a positive experience of care	4a Patient experience of primary care i GP services ii GP Out of Hours services 4b Patient experience of hospital care 4c Friends and family test	*Improving hospitals' responsiveness to personal needs* 4.2 Responsiveness to in-patients' personal needs *Improving people's experience of integrated care* 4.9 An indicator is under development***(ASCOF 3E)	
				Adult Social Care Outcomes Framework 2013-14			
				Domain	**Overarching Indicator**	**Outcome Measures**	
				1: Enhancing quality of life with care and support needs	1A. Social care-related quality of life	*Carers can balance their caring roles and maintain their desired quality of life*	

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						1D Carer-reported quality of life	
				Public Health Outcomes Framework 2013-14			
				Domain	**Objective**	**Indicators**	
				1: Improving the wider determinants of health	Improvements against wider factors that affect health and wellbeing and health inequalities	1.5 16-18 year-olds not education, employment or training 1.9 Sickness absence rate	
				2: Health improvement	People are helped to live healthy lives , making healthy choices and reduce health inequalities	2.23 Self-reported wellbeing	
				4: Healthcare public health and preventing premature mortality	Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities	4.4 Mortality from all cardiovascular diseases (including heart disease and stroke) 4.5 Mortality from cancer 4.12 Preventable sight loss 4.11 Emergency readmissions within 30 days of discharge from hospital (placeholder)	

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				4.13 Health-related quality of life for older people (placeholder) Medical evidence illustrates that the risk of heart attack is doubled for rheumatoid arthritis patients. The risk of atrial fibrillation is also around 40 per cent higher than those without the disease. Likewise, the risk of stroke is 30 per cent higher compared to the general population (Lindhardsen J et al, 'Risk of atrial fibrillation and stroke in rheumatoid arthritis: Danish nationwide cohort study', British Medical Journal, 2012; 344). It is currently not well understood why those with rheumatoid arthritis have a greater risk of heart attack, although it is thought the disease may cause higher levels of inflammation in the body generally which can trigger plaque in the arteries to form blood clots (Web MD, Heart Disease and Rheumatoid Arthritis). Meanwhile, leukaemia, lung cancer, lymphoma and multiple myeloma are all more common in people with rheumatoid arthritis (CKS Clinical Knowledge Summaries, Rheumatoid Arthritis – management), brought on as a result of chronic stimulation of the immune system or excess antibody-related proteins in the blood (Worth T, '8 Types Of Cancer Linked To Rheumatoid Arthritis', Huffington Post). About a quarter of patients also have manifestations of rheumatoid arthritis in the eyes. This can be inflammation of the interior of the eye (uveitis), which can (in the most severe cases), reduce vision (NRAS, Ocular manifestations of rheumatoid arthritis, 2010). The quality statements contained in the document, with the exception of statement 8 (People with rheumatoid arthritis offered referral for a specialist surgical opinion if surgery may be indicated), should lead to a reduction in the degree of inflammatory processes detected in patients with rheumatoid arthritis. We would therefore expect to see a decline over time in mortality from cardiovascular disease and the cancers outlined above if the quality statements are widely enacted, contributing to the achievement of objectives set out in the NHS Outcomes Framework and the Public Health Outcomes Framework 2013-14. Preventable sight loss is also an outcome set out in the Public Health Outcomes Framework which better treatment of rheumatoid arthritis can contribute towards.	

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				These quality statements should also have a similar impact on reducing disability and improving quality of life, leading to detectable improvements in self-reported wellbeing and the quality of life of carers for people with this disease, which are additional objectives set out in the Adult Social Care Outcomes Framework 2013-14 and the Public Health Outcomes Framework 2013-14.	
022	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Outcomes frameworks	The NHS Outcomes Framework 2013-14 in the RA quality standards demonstrates it could contribute to overarching indicators and improvement areas. ARMA feel an important issue to note here is that RA patients have an elevated risk of a variety of health problems including cardiovascular disease, stroke and atrial fibrillation when compared to the general population. This is an issue we believe should be substantially highlighted to ensure commissioners and service providers completely understand the wider benefits, which we feel have not been sufficiently stressed in this report.	Thank you. The outcomes, overarching indicators and improvement areas referenced from the frameworks are those which we believe the quality standard could contribute towards achieving. Whilst we acknowledge that some studies suggest that people with rheumatoid arthritis may be at greater risk of other conditions, we are unable to propose that achieving the quality standard will directly impact upon those indicators, for example the quality standard does not contain actions or interventions that would directly impact upon mortality. It is considered however that achieving the quality standard will lead to improvements in quality of life as measured across the three frameworks, as statement 7 in the final quality standard for example refers to functional ability and the impact of the disease on a person's life. We acknowledge that there are many other areas that care will impact upon, and we are currently in the process of assuring our methods of linking quality standards to the outcomes framework with NHS England's domain directors.
023	020	MSD Ltd	Outcomes frameworks	The text on page 2 states that "The table below shows the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving" However, the aforementioned table discusses outcome measures around employment and health-related quality of life which MSD feels are not addressed in the draft quality statements. The draft quality statements appear related to the	Thank you. The TEG sought to strengthen the link to employment and health-related quality of life outcomes by extending the definitions of some statements, for example in statement 7 in the final quality standard, specifically referencing employment status as part of the annual review discussion with the patient

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				specifications of Domain 4 (NHS outcomes framework 2013-14) around patient experience and GP services etc., however, their relationship to the other domains in the table is less clear	about how the disease is affecting their life. Please also see the 'rationale' sections for each statement that have been included in the final quality standard to set out why the statement is important in terms of quality and outcomes, which describes the link to quality of life (see statements 1-4 and 7 for example).
024	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Outcomes frameworks	In addition, e note that on page 2 the table considers the outcome measures on quality of life and employment – however, these appear not to have been referenced in the quality statements…	Thank you. The TEG sought to strengthen the link to employment and health-related quality of life outcomes by extending the definitions of some statements, for example in statement 7 in the final quality standard, specifically referencing employment status as part of the annual review discussion with the patient about how the disease is affecting their life. Please also see the 'rationale' sections for each statement that have been included in the final quality standard to set out why the statement is important in terms of quality and outcomes, which describes the link to quality of life (see statements 1-4 and 7 for example).
025	001	Bristol-Myers Squibb (BMS)	Question 1	Question 1; Regarding quality statements 3 & 5, a clinical response is to be determined by a change in DAS28 by 1.2 within 4-6 months.	Thank you. The TEG considered it could not be this prescriptive about determining clinical response.
026	014	Royal college of pathologists	Question 1	The outcomes of quality statements 1-4 can be determined by clinical audits. The outcome for statement 5 can be induction of clinical remission, or achievement of alternative treatment goals where remission cannot be achieved, for example as sustained low disease activity. If neither is achieved then evidence of frequent monitoring and treatment escalation needs to be provided. A number of validated questioners can be used to assess functional outcomes: • Health Assessment Questionnaire (HAQ) • Health-related Quality of life: EQ-5D • RAQoL Work disability could (should) be included – but at present this is not formally validated as outcome measure. However working towards this would be important in assessing wider impact on health/economic and benefits of treatment.	Thank you. An outcome measure of disease activity is included in statement 5 in the final quality standard. Please see statement 7 in the final quality standard for reference to the Health Assessment Questionnaire.

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027	017	National Rheumatoid Arthritis Society	Question 1	We are unclear what is meant by this consultation question, as we believe the expectation should be that all the quality statements will be implemented by service providers, primary care professionals, commissioners and people with rheumatoid arthritis. Where it has not been possible to achieve these healthcare outcomes universally then we would expect each audience to strive for continuous improvement. A number of the quality statements are process driven targets and should be readily achievable if services are suitably financed and resourced. For example, it should be possible for all GPs to refer patients with suspected inflammatory arthritis on to a rheumatology service within 1 working day, as indeed it should be for providers to undertake assessments, initiate treatment and provide rapid access within the specified timings.	Thank you. Outcome measures are stated where the TEG felt these were appropriate, measureable and specifically attributable to the action described by the statement.
028	022	Pfizer Ltd	Question 1	Proposed response: In reference to all the draft quality statements, the health outcomes should be 'treat to remission'.	Thank you. An outcome measure of disease activity is included in statement 5 in the final quality standard, although the TEG considered that it was important to agree a target of low disease activity with the patient rather than treating to remission in all cases.
029	024	Chartered Society of Physiotherapy	Question 1	No, these healthcare outcome seem appropriate	Thank you.
030	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Question 1	In relation to quality statements 3 and 5 a clinical response is to be determined by a change in DAS28 by 1.2 within 4-6 months.	Thank you. The TEG considered it could not be this prescriptive about determining clinical response.
031	029	Royal College of General Practitioners	Question 1	No further suggestions	Thank you.
032	001	Bristol-Myers Squibb (BMS)	Question 2	Question 2; Measures of quality of life - HAQ-DI. Other PROs - fatigue, sleep deprivation, pain.	The TEG consider the quality standard to broadly contribute to quality of life measures, and these are explicitly referenced where appropriate (see statement 7 in the final quality standard for example).
033	004	NHS Direct	Question 2	What important areas of care, if any, are not covered by the quality standard? The QS talks about DMARDS as treatment for Rheumatoid Arthritis. It is a known	Thank you. Reference has been included to the importance of regular monitoring for people receiving DMARD treatment in statement 3 in

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				fact that the side effects of these drugs can cause very serious complications (liver kidneys and blood disorders), with this in mind should there be mention or regular blood tests and the importance of the same to the patients/GP services to ensure early detection and prevention	the final quality standard.
034	011	The Work Foundation	Question 2	More importance needs to be placed on providing patient with early support to remain in work, and these services should be included in the assessment of individuals with suspected inflammatory arthritis. Employment of individuals with long-term conditions is one of the indicators of the NHS Outcomes Framework; however, clear targets should be set for health care professionals to manage that outcome. We therefore propose to enhance the service standards for diagnosis and management of rheumatoid arthritis by including a standard an measure of employment outcomes of individuals with rheumatoid arthritis, expressed as change in the proportion of people with rheumatoid arthritis in paid and unpaid work year on year. Numerator – proportion of individuals with RA in paid and unpaid work in the current year. Denominator – proportion of individuals with RA in paid and unpaid work in the previous year.	Thank you. Outcome measures are stated where the TEG felt these were appropriate, measureable and specifically attributable to the action described by the statement. Although no one statement was considered to directly contribute to the outcome you suggest, the quality standard is considered to more broadly contribute to quality of life measures, of which employment would be an aspect (please see statement 7 in the final quality standard).
035	014	Royal college of pathologists	Question 2	The quality standards are in line with recently proposed recommendations for treating RA to target, which were developed by European League Against Rheumatism (EULAR) and American College of rheumatology (ACR) (Smolen et al. ARD 2010;69:631-637).	Thank you.
036	015	Roche products Ltd	Question 2	We agree that the proposed quality statements reflect key requirements, across the patient pathway, for high-quality care and service provision.	Thank you.
037	017	National Rheumatoid Arthritis Society	Question 2	In simple terms, the wording of the quality statements fail to link to work-related objectives set out in the NHS Outcome Framework 2013-14, the Adult Social Care Outcomes Framework 2013-14 and the Public Health Outcome Framework 2013-14. This is a significant failing and needs to be addressed (see our comments above in relation to quality statements 4 and 9 for practical solutions).	Thank you. The TEG sought to strengthen the link to employment and health-related quality of life outcomes by extending the definitions of some statements, for example in statement 7 in the final quality standard, specifically referencing employment status as part of the annual review discussion with the patient about how the disease is affecting their life.
038	021	Napp Pharmaceuticals Limited	Question 2	The RA QS briefing paper in section 9 highlights the importance of symptom control & the introduction to the review quotes that “pain relief is the priority for people with RA”. However, pain relief has not been included as a proposed QS statement; therefore we believe an important area of care has not been covered	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by

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				and that should be included within Quality Statement 3. The information which should be included is: • Measuring and recording of pain scales: It would be useful to highlight specific scales such as VAS or BS-11 pain scales with alternatives for specific patients who these may not be suitable for e.g. those suffering from dementia. • Pain relief: In addition to other drugs such as DMARDs it would be useful to cover other pharmacological and non-pharmacological options such as paracetamol, NSAIDS and opioids such as codeine, buprenorphine low dose patches, tramadol etc. Consideration should also be given to defining when additional pain medication is appropriate e.g. breakthrough pain CG 79 quote: 1.4.4.1 Offer analgesics (for example, paracetamol, codeine or compound analgesics) to people with RA whose pain control is not adequate, to potentially reduce their need for long-term treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or cyclo-oxygenase-2 (COX-2) inhibitors.	cross-cutting quality standard topics that have been referred to NICE, such as pain management and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
039	021	Napp Pharmaceuticals Limited	Question 2	The RA QS briefing paper in section 9 highlights the importance of symptom control & the introduction to the review quotes that “as pain relief is the priority for people with RA”. Symptom control is not included as a proposed QS standard; therefore we believe an important area of care has not been covered. Pain should be considered as a condition in its own right. We suggest including more information on the pharmacological and non-pharmacological options for pain relief in patients with RA in conjunction with RA specific treatments, such as DMARDs. This could cover the information from CG79 where it states the following: CG 79 quote: 1.4.4.1 Offer analgesics (for example, paracetamol, codeine or compound analgesics) to people with RA whose pain control is not adequate, to potentially reduce their need for long-term treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or cyclo-oxygenase-2 (COX-2) inhibitors. It may also be useful to outline guidance on when additional pain medication may be appropriate e.g. breakthrough pain.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
040	022	Pfizer Ltd	Question 2	Proposed response: Pfizer believes the following are currently omissions within the draft quality standard:	Thank you. The TEG prioritised the areas of care (derived from the evidence source listed) where practice is variable, or where implementation could have a significant impact

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				• Access to good quality local data and epidemiological evidence; • The work needed to be undertaken by CCGs who are seeking to raise public awareness of the symptoms of rheumatoid arthritis, in order for appropriate public presentation to GP; • The support and information required by people with an RA diagnosis to support them with employment issues; and • In specific reference to QS 9, the question of who will provide the annual yearly update and if this remains in primary care, how QOF will be aligned to the draft quality standard. • Patients with RA should have the opportunity to have their treatment reviewed between fixed appointments should the need arise	on patient care and improved outcomes, and where there is potential to generate measurable indicators. Please see statement 7 in the final quality standard, where the definitions section has been extended to provide further information about the annual review process. NICE quality standards have a broader scope than the QOF and in future will be feeder products for QOF indicators. We believe statement 6 in the final quality standard covers the concept of review in between fixed appointments.
041	025	Arthritis Care	Question 2	We note that currently there is no standard for pain management in the rheumatoid arthritis (RA) QS, no general QS for such, and as yet no plans to develop one. We recommend a QS on pain management, either specific ones for each condition, or a general one, which includes the following: o assessment of benefits and side effects of analgesic and anti-inflammatory drugs o offer of resources to self-manage pain, including referral to third sector organisations such as Arthritis Care.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
042	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Question 2	If the initiation of biologic treatments cannot be adequately covered in the quality statement on disease control then the ABPI PRI believes that, for the reasons stated above, it should be directly addressed in a quality statement on the appropriate usage of biologic treatments. Whilst the ABPI PRI recognises the need to avoid over-complicating the Quality Standard in the interests of encouraging widespread compliance, it believes consideration should be given to encouraging the recording of the relevant clinical data on the response and side effects of patients receiving biologic treatments with appropriate national databases. The Quality Standard necessarily takes people presenting with symptoms of	Thank you. Statement 5 in the final quality standard refers to the use of biologic drugs to control disease. The detail around their use is considered to be covered by the NICE technology appraisals (as compliance is mandatory there is considered to be 'another lever in the system' to address this issue). The TEG consider the quality standard to broadly contribute to quality of life measures, and these are explicitly referenced where appropriate (see statement 7 in the final quality standard for example).

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				inflammatory arthritis as its starting point before focusing on rheumatoid arthritis. Given the prevalence and highly debilitating nature of other forms of inflammatory arthritis, Quality Statement 2 needs to ensure that these patients are not disadvantaged. Measures of quality of life - HAQ-DI. Other PROs - fatigue, sleep deprivation, pain are not covered within the Quality Standard	
043	027	Royal College of Nursing	Question 2	We think the important areas have been covered by these quality statements	Thank you.
044	029	Royal College of General Practitioners	Question 2	Information sources for patients. Withdrawing drugs Drug safety considerations. Occupational advice – both in relation to job and also daily living. Preventing/treating osteoporosis.	Thank you. We consider these concepts to be covered by the NICE quality standard on 'patient experience in adult NHS services' (which is cross-cutting and referenced in this quality standard), the NICE technology appraisals, and statement 7 in the final quality standard.
045	030	AstraZeneca UK	Question 2	Although implicit in quality standards 5, 6 and 9 we think there should be more focus on ensuring patients quality of life is maintained through monitoring the impact of disease on work, home and social life.	Thank you. Please see statement 7 in the final quality standard, where the definitions section has been extended to more explicitly reference these aspects.
046	001	Bristol-Myers Squibb (BMS)	Question 3	Question 3; Quality statements 1 & 3 are most important (early recognition and diagnosis of patients). It has been shown that the early use of therapy increases the outcomes of the patient with less radiographic progression over time.	Thank you. Please see statements 1 and 3 in the final quality standard.
047	004	NHS Direct	Question 3	What, in your opinion, are the most important quality statements and why? In my opinion all of the quality statements are very important for the management of this condition	Thank you.
048	012	UCB Pharma Ltd	Question 3	UCB Pharma Ltd welcomes the emphasis on early diagnosis, referral and initiation of treatment in the draft Quality Standard. Early effective treatment can significantly improve long term outcomes & minimise joint damage helping people maintain their mobility and independence and reduce work related disability.	Thank you.
049	014	Royal college of pathologists	Question 3	It is now well established that early diagnosis with immediate commencement of disease modifying anti-rheumatic drugs (DMARDs) prevents joint erosions and improves functional and structural outcomes. The achieve this, the aims outlined in statements 1-3 and 5, which deal with early referral, specialist review,	Thank you.

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				immediate treatment and agreed treatment goals such as induction of remission or low disease activity, need to be met.	
050	015	Roche products Ltd	Question 3	As a leading manufacturer of innovative medicines, including in the field of rheumatology, Roche believes quality statements 3, 5 and 8—through setting aspirations to ensure rapid access to the most effective treatment(s)—will significantly improve health outcomes. Quality statement 5 clearly establishes that an appropriate target for treatment should be agreed by each individual patient and their specialist. The importance of treating to target has been recognised internationally reflecting the potential to improve outcomes and reduce the costs of care when the target agreed is remission or low disease activity [1,2,3]. The British Society for Rheumatology 2012; http://www.rheumatology.org.uk/includes/documents/cm_docs/2012/t/top_10_quality_standards_for_ra.pdf Smolen *et al*., *Ann Rheum Dis* 2010; **69**:964-975 Singh JA, *et al. Arthritis Care Res 2012;* ***64****:625-639*	Thank you.
051	017	National Rheumatoid Arthritis Society	Question 3	All of the quality statements are important as they are based on comprehensive evidence derived from NICE Clinical Guideline 79 on Rheumatoid Arthritis. It is not possible for us to differentiate their importance as there are significant problems with the care offered to rheumatoid arthritis patients all along the pathway from diagnosis right through to ongoing management. If adopted and enacted together, we believe the proposed quality statements will lead to significant improvements across the care pathway with the potential for rheumatoid arthritis to become an exemplar of how to effectively treat and manage a long-term condition.	Thank you.
052	022	Pfizer Ltd	Question 3	Proposed response: In our opinion, the following quality statements as the most important: QS 5 QS 1, 2 and 3 Timely access to effective treatment in order to give the best chance to control disease progression is crucial and therefore Pfizer believe that the quality standards relating to access to timely treatment are the most important quality statements.	Thank you. Please see statements 1, 2, 3 and 5 in the final quality standard.
053	024	Chartered Society of Physiotherapy	Question 3	Quality statement 1, 2, 5, 6. 1 = Quick access to accurate diagnosis is important for those with suspected RA; 2 = rapid diagnosis and initial advice is important to establish an understanding	Thank you. Please see statements 1, 2 and 5 in the final quality standard. Statement 6 was not progressed to the final quality standard as

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				and relationship with their ongoing service and to reduce anxiety; 5 = early stabilisation on medication important; 6 = early access to a MDT important to provide advice and preventative behaviours We are not entirely convinced that this question is best answered in this fashion; we wondered if NICE could use a more robust method for prioritising its quality standards	the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
054	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Question 3	The ABPI PRI believes the emphasis on fast referral, initiation of treatment and intensive treatment strategies are particularly important. . As is recognised, early inflammatory arthritis is a critical period of the disease where a brief "window of opportunity" exists when effective treatment can radically improve long term outcomes. Early treatment can minimise joint damage helping people maintain their mobility and independence and reduce work related disability. Quality Statements 1,2,3,5 and 9 address this most directly and are therefore likely to have the biggest impact.	Thank you. Please see statements 1, 2, 3, 5 and 7 in the final quality standard.
055	027	Royal College of Nursing	Question 3	The most important standards are 1, 2 and 3 – referral, assessment and treatment	Thank you. Please see statements 1, 2 and 3 in the final quality standard.
056	028	AbbVie Ltd	Question 3	AbbVie believes that all of the Quality Statements within this draft quality standard are appropriate. However AbbVie would like to stress the particular importance of quality statements 1, 2, 3, 5 and 9. Early referral and treatment institution - where appropriate - for RA patients, and rapid treatment alteration in any RA patient with uncontrolled disease is vital in order to improve outcomes in RA and there is a large evidence base to support best patient outcomes with this approach. Regular review of disease activity is also critical in order to ensure patient's disease activity is controlled and disease progression is limited.	Thank you. Please see statements 1, 2, 3, 5 and 7 in the final quality standard.
057	029	Royal College of General Practitioners	Question 3	They are all important, but the overarching assumption is that the natural history of inflammatory arthritis can be improved by prompt treatment… and this is not stated.	Thank you. There is evidence that rapid initiation of treatment can improve clinical outcomes such as symptoms, joint damage, function and quality of life, which is covered by the underpinning clinical guideline (NICE CG79).
058	030	AstraZeneca UK	Question 3	AstraZeneca believe that all quality measures included in the draft document are important to deliver high quality care to adults with RA. Within these we believe the key quality statements are 2, 3, 4 and 5 as they address the central elements of care - rapid referral, appropriate treatment and access to educational tools and self management activities	Thank you. Please see statements 2, 3, 4 and 5 in the final quality standard.
059	014	Royal college of	Question 4	No	Thank you.

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		pathologists			
060	017	National Rheumatoid Arthritis Society	Question 4	As outlined in NRAS's more detailed response to quality statements 2 and 3 above, the chosen timeframes for assessment by a specialist team from point of referral and initiation of disease modifying anti-rheumatic drugs both need to align with proposals set out in the Best Practice Tariff. Quality statement 4 must also incorporate explicit reference to sign-posting and involvement of third sector organisations in relation to the delivery of education and self-management support. It is not acceptable for newly diagnosed patients, many of whom will be vulnerable and actively seeking emotional support, to be unsupported during this early phase. Quality statement 7 must also be amended so that patients can expect their rheumatology service to respond within 48 hours of first contact. The present wording of rapid access is too vague and in its current form it will become too difficult to measure implementation. Finally, we have made a number of suggestions in relation to how the accompanying guidance for quality statements 1, 5, 6 and 9 can be improved to add clarity to the quality and method of delivery.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement; following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard. Please see statement 4 in the final quality standard where the definitions section has been extended to take account of the role of third sector organisations. Please see revised statement 6 in the final quality standard where rapid access has been defined as within 1 working day.
061	022	Pfizer Ltd	Question 4	Proposed response: Pfizer agrees with all the draft quality measures, they are all appropriate.	Thank you.
062	027	Royal College of Nursing	Question 4	Comments and suggestions made as above re inappropriate quality measures & reasonable time frame for diagnosis to being offered education and self-management	Thank you.
063	029	Royal College of General Practitioners	Question 4	See above	Thank you.
064	005	Primary Care Rheumatology Society	Statement 1	Our society is formed from primary care clinicians, mainly GPs with a special interest in rheumatology. While we broadly welcome these standards we do have concerns over the details in Quality Measure 1. There is a drive across all CCGs for referrals to be as appropriate as possible. It is our members experience that this often involves non specialist GPs asking patients to see GPs with a special interest either within their practice or in a local triage service. This quality standard seems to prevent such local arrangements. Also many patients have very subtle	Thank you. It was considered important that a person with suspected persistent synovitis was referred to a member of a rheumatology service that is led by a consultant rheumatologist. It may be that GPs with a special interest are considered part of the rheumatology service (in that the consultant

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				or transient symptoms and signs and this QS may lead to many inappropriate referrals. There is also a group of patients where blood tests can be very helpful if deciding on the need to refer. We feel the 1 day limit is too short and should be extended to 3 days, also seeking opinion and advice from GP with a special interest or other local triage service is in patients interests. We believe this delay would not cause any adverse outcome for patients	rheumatologist still takes responsibility for diagnoses), but NICE quality standards do not aim to be prescriptive about local service delivery arrangements. The TEG acknowledged the points raised and further defined the set of symptoms that would indicate urgent referral, as well as revising the timeframe for referral. Please see revised statement 1 in the final quality standard.
065	009	The Royal College of Radiologists	Statement 1	Please note that a radiologist with an MSK MRI & ultrasound interest should be a "core member" of the rheumatology team. Simply access to radiology is insufficient.	Thank you. Please see revised definition wording in statements 1, 2, 3, 6 and 7.
066	009	The Royal College of Radiologists	Statement 1	I agree that the radiology reference should refer to Musculoskeletal Radiologist with experience of rheumatological Ultrasound and MR. I'm not sure about the definition of core team though or whether it is simply enough to state 'access to'.	Thank you. Please see revised definition wording in statements 1, 2, 3, 6 and 7.
067	010	British Medical Association	Statement 1	Subject to the caveats in our next comment, the quality statements all cover important areas and we approve of the themes underlying them, but we have concerns that targets for referral times do not reflect the difficulties in dealing with early, mild, or atypical disease within the general practice population, and cannot support standard 1 as it is currently written.	Thank you. Please see revised statement 1 in the final quality standard.
068	010	British Medical Association	Statement 1	Although we agree that referral to specialist care should take place at the earliest opportunity and agree a quality standard should be included to cover this, this standard is inappropriate. There is no evidence that failure to refer within 24 hours of presentation (as opposed to two or three days) will have any bearing on the clinical outcome. This is tacitly admitted in the consultation, as quality statement two allows for people with suspected inflammatory arthritis to wait up to two weeks for assessment following a referral. To include a quantitative standard with no evidence base for the timescale proposed cannot be justified. While we recognise the total time should be within the NICE proposal, it is wrong for the primary care section of the patient's journey to be so extremely compressed for this reason. The NICE guideline refers to urgent referral of ¬'persistent' synovitis and makes no comment about a one working-day deadline for referral. In primary care many patients present very early in their disease process and it is	Thank you. The TEG acknowledged the points raised and revised the statement accordingly, in terms of the set of symptoms that would indicate urgent referral as well as the timeframe for referral. Please see statement 1 in the final quality standard.

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				rare to see patients at these early presentations with classical symptoms and signs. The symptoms and signs mentioned are not often all present, and in isolation can occur in many other illnesses which are self-limiting. If patients are to be referred at first presentation there will be a very large number presenting at the clinics with non-rheumatoid disease and this is not only bad for the individuals concerned but will also harm the care of those with rheumatoid arthritis by diluting the resources available to care for them. The suggestion that referral should take place at first presentation also does not allow time for basic investigations to take place in primary care, which will not only lead to over-referral but also may mean that patients arrive at their specialist consultation without investigations in place, which may delay and not improve the patient's overall care. Referral without investigation will make it very difficult for secondary care to prioritise urgent over non-urgent cases. We do not agree that the examples cited in the document of multiple primary care attendances in themselves are indicators of poor care, particularly when the number of visits is set at three or below. It is worth noting that a patient journey consisting of an initial consultation, a visit for phlebotomy, and a consultation to be informed of the results and to have the proposed referral discussed, represents three consultations. The fact that rheumatoid arthritis can present in patients with pre-existing musculoskeletal difficulties further clouds the issue, particularly when patients' comments about 'waiting a long time' are considered. These criticisms are not meant to detract from the importance of early referral, but it might be that it is not possible to refine a quality standard that both allows for the vagaries of general practice and permits easy analysis of compliance. We would suggest rewording to 'People with suspected synovitis affecting the small joints of the hands or feet or more than one joint are promptly investigated and referred for specialist opinion.'	
069	012	UCB Pharma Ltd	Statement 1	As stated in the London School of Economics report (June 2012) ,'Given the incidence of RA, first contact with the health service may lead to slow diagnosis or even misdiagnosis and given that a range of conditions can resemble RA symptoms. It would seem appropriate then, given the high burden imposed on individuals, for clear diagnostic information to be made widely available to non-specialists We therefore suggest the quality statement be amended to include a more specific	Thank you. The TEG acknowledged this point and revised the statement to more specifically define the symptoms and signs indicating urgent referral. Please see statement 1 in the final quality standard.

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				and diagnostic description of the signs or symptoms of inflammatory arthritis. We believe this would be more informative to primary care physicians and as such would result in a more appropriate population being referred to secondary care.	
070	013	University Hospitals Birmingham NHS FT	Statement 1	'Inflammatory arthritis' covers a whole range of clinical problems many of which are self-limiting. For example inflammatory flares of osteoarthritis are common or occasionally a viral arthritis such as parvovirus or an allergic reaction to a drug can present with an inflammatory arthritis. GPs should be permitted the flexibility of exercising their own judgment about whether to refer or not and certainly patients should have a say.	Thank you. The TEG acknowledged this point and revised the statement to more specifically define the symptoms and signs indicating urgent referral. Please see statement 1 in the final quality standard. All statements are underpinned by patient choice and involvement in the decision-making process.
071	017	National Rheumatoid Arthritis Society	Statement 1	NRAS supports the wording of the quality statement to encourage GPs to refer people with signs or symptoms of inflammatory arthritis to a rheumatology service within 1 working day of presentation. We believe this offers the best opportunity to improve the likelihood of rheumatoid arthritis patients being treated within the twelve weeks 'window of opportunity'. Patients stand a much better chance of achieving remission if they are started on optimal treatment within twelve weeks of symptom onset. To ensure this statement is adhered to properly we suggest the text within 'Description of what the quality statement means for each audience - Primary care professionals' guidance on page 6 is strengthened to say that GPs should refer immediately if they suspect inflammatory arthritis and need not conduct blood tests. The National Audit Office report on Services for People with Rheumatoid Arthritis (2009) makes it clear that: "Rheumatoid arthritis is difficult to diagnose and there is no single diagnostic test that can differentiate it from other types of arthritis. Early diagnosis relies on specialist knowledge, with blood and imaging tests sometimes helping to confirm the diagnosis". In light of the fact that blood tests are often inconclusive, add further time delays, GPs can misinterpret the results, and that specialists will usually repeat the blood test results when seeking to diagnose a patient with rheumatoid arthritis, we believe it is appropriate to include this additional guidance. We do not believe the addition of this guidance to quality statement 1 will lead to a	Thank you. The TEG considered early referral to be a key area for quality improvement and progressed this statement to the final quality standard, whilst revising it to take account of stakeholder feedback about what timeframe would be realistic and prevent any unintended consequences. The definitions section has also been extended to acknowledge that blood tests can be inconclusive. Data sources are included that will support commissioners and providers to audit achievement of the statement. While the QOF indicator is relevant, it is not considered a means of measuring the statement.

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				dramatic increase in inappropriate referrals because only 10% of people with rheumatoid arthritis are treated within 12 week window of opportunity and that this figure has not improved in recent years, staying constant at around nine months since 2003 (National Audit Office, 2009). The issue is therefore still very much one of outcomes being too far skewed in the other direction at the moment. Indeed, people with rheumatoid arthritis visit a GP on average four times before being referred to a specialist for diagnosis, and 18 per cent of patients visit more than eight times. Surveys also show that a half of patients believe GPs are responsible for delays in diagnosing their disease and 25% of the GPs themselves feel they have inadequate access to support and advice to help them identify new cases when it is needed (National Audit Office, 2009). An online NRAS poll conducted of people with rheumatoid arthritis also verifies these concerns. 46 per cent (of those who responded said they were not confident their GP would spot the early signs and symptoms of the disease (NRAS HealthUnlocked Forum, 2012). To ensure baseline information around the draft quality measure process is adequately captured, we also recommend the 'Data Source' text is amended to include specific reference to Quality and Outcomes Framework data on the number of rheumatoid arthritis patients registered at GP practices.	
072	018	British Society for Rheumatology	Statement 1	BSR suggests that a one day timescale is unrealistic and does not allow clinicians to use time as a diagnostic tool; time may exclude certain conditions such as self-limiting viral arthritis. We also are concerned that the proposed standard is not sufficiently specific, given it relates to inflammatory arthritis as a whole. We believe this, coupled with a one day timescale, would result in a high volume of inappropriate referrals to rheumatology services and would cause undue patient distress. We suggest rewording as follows: "People presenting to a GP with suspected, persistent synovitis, particularly affecting hands and feet, suspicious of early rheumatoid arthritis, should be referred urgently to a rheumatology service."	Thank you. The TEG acknowledged the points raised and revised the statement accordingly, in terms of the set of symptoms that would indicate urgent referral as well as the timeframe for referral. Please see statement 1 in the final quality standard.
073	019	The Arthritis and Musculoskeletal	Statement 1	ARMA supports this statement.	Thank you.

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		Alliance (ARMA)			
074	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Statement 1	The ABPI PRI recommends the quality statement be amended be include a brief description of the signs or symptoms of inflammatory arthritis. It is understood and accepted that to achieve maximum impact quality standards should be constructed with both brevity and clarity and that the signs and symptoms of inflammatory arthritis are explained in the definition. However, as identified by the NICE briefing paper, current practice is that people with rheumatoid arthritis visit a GP on average four times before being referred to a specialist for diagnosis, and 18 per cent of patients visit more than eight times. As also noted, the 10th report of the Public Accounts Committee on services for people with rheumatoid arthritis in 2010 concluded that GPs often fail to recognise the symptoms of rheumatoid arthritis, causing delay in referring to a specialist for a diagnosis. Given this, and other supporting evidence, a minor amendment to the quality statement which briefly and clearly outlined the signs and symptoms of inflammatory arthritis would support the quality statement's overall aim of faster referral for patients with suspected inflammatory arthritis by ensuring that the symptoms demonstrated are clearly highlighted. The ABPI PRI therefore suggests the following statement, "People presenting to a GP with symptoms or signs of inflammatory arthritis, such as persistent pain, swelling, heat, early morning stiffness lasting more than 30 minutes and loss of function of the affected joint, are referred to a rheumatology service within 1 working day of presentation."	Thank you. The TEG acknowledged the points raised and further defined the set of symptoms that would indicate urgent referral, as well as revising the timeframe for referral. Please see revised statement 1 in the final quality standard.
075	027	Royal College of Nursing	Statement 1	Draft Quality Statement 1 **Referral**. **… quality measure**… We applaud this statement; however, consider that GP referring patient within one day seems strict and probably unrealistic. We suppose it depends how one defines the 'act' of referral and when that will be measured. This needs to be considered carefully – for example administrative factors such as typing letters, or GP trainees etc seeking a 'specialist musculoskeletal GP' within their practices might reduce a large and difficult to manage burden to specialist teams based on inappropriate referrals. We would have thought referral within 5 to 7 working days would be more realistic.	Thank you. The TEG acknowledged this point and revised the timeframe, as well as the set of symptoms that would indicate urgent referral. Please see revised statement 1 in the final quality standard.
076	027	Royal College of	Statement	**Definition** - the definition of signs and symptoms stated in this standard seems	Thank you. The TEG acknowledged this point

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		Nursing	1	too broad. It presumes that the standards would advocate being supported by robust referral guidelines on presenting symptoms etc to ensure within regions that referrals are appropriate. We would suggest evidence based referral criteria such as the EULAR (Emery & Smollen) criteria which includes - "metacarpophalangeal or metatarsophalangeal" a positive squeeze test **Or** as in the NICE Rheumatology Arthritis Clinical Guideline (CG 79) as follows: " Suspected persistent synovitis of unknown cause, plus any of the following: _ small joints of hands or feet affected _ more than one joint affected _ symptoms were present for 3 months or longer before presentation."	and further defined the set of symptoms that would indicate urgent referral to ensure consistency with the underpinning NICE Guideline. Please see revised statement 1 in the final quality standard.
077	028	AbbVie Ltd	Statement 1	AbbVie welcomes the emphasis placed on early referral to a rheumatology service for individuals with the signs and symptoms of inflammatory arthritis. AbbVie believe that referral within 1 working day is an appropriate measure as in general there should not be any mitigating circumstances justifying a delay in referral. However, AbbVie would suggest a minor addition to this quality statement to briefly describe what the key signs and symptoms of inflammatory arthritis are. The NAO Report that considered rheumatology services and the subsequent Public Accounts Committee[2] scrutiny of the NAO report highlighted how infrequently GPs are trained on inflammatory arthritis and infrequently GPs may typically see cases of RA in a given year. The key "SSS" signs and symptoms – stiffness, swelling and pain on joint squeezing – could be incorporated into this quality statement to provide more overt guidance to those healthcare professionals and commissioners utilising this quality standard. AbbVie would therefore suggest: "*People presenting to a GP with symptoms or signs of inflammatory arthritis – such as* *persistent pain, swelling, stiffness lasting more than 30 minutes loss of function of*	Thank you. The TEG acknowledged the points raised and further defined the set of symptoms that would indicate urgent referral, as well as revising the timeframe for referral. Please see revised statement 1 in the final quality standard.

[2] http://www.publications.parliament.uk/pa/cm200910/cmselect/cmpubacc/46/46.pdf

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				the affected joint are referred to a rheumatology service within 1 working day of presentation. "	
078	029	Royal College of General Practitioners	Statement 1	This statement is unrealistic, un-evidenced and inappropriate. It will also be counterproductive and self-defeating for reasons explained below: 1. Most presentations of inflammatory joint symptoms in general practice (other than gout, on which more later) are vague and subtle. It is very uncommon for patients to present with a clear picture of inflammatory polyarthropathy. 2. Of those who do present, a majority settle down without a clear diagnosis. This is not a reflection on the poor diagnostic skills of GPs. It is about the process of becoming ill being gradual and the fact that most presentations are self-limiting. Is there any data on the frequency of presentation of apparent inflamed joints in general practice? A rough estimate would be 1 per GP per week, or an annual rate of 1 per 40 patients. It is often difficult at first presentation to separate out such entities as PMR, tendinitis around the shoulder/ankle, frozen shoulder, arthralgia of viral illness, all of which are conditions far commoner than inflammatory joint disease proper, and all entirely diagnosable and manageable in Primary Care. 3. If all these patients in a city the size of Leeds were to present in Rheumatology the number of referrals per annum would approach 20000, far in excess of the capacity of an (even modestly expanded) rheumatology service. 4. Furthermore, instant, same day referral would preclude preliminary investigation, further burdening the secondary care service. 5. Gout is the commonest diagnosable inflammatory joint disease. It is generally diagnosable and easily manageable in primary care, and indeed it usually is. 6. A significant proportion of such presentations are self-limiting (including palindromic and reactive arthropathy and also a mixed bag of undiagnosable aches and pains). 7. Same-day referral from general practice is generally reserved for emergencies and suspected cancer. Even in this situation, patients are often disadvantaged by such rapid referral because the GP does not have time to give a holistic appraisal of his patient, and referral forms are often terse tick box forms. Similarly, the receiving clinic is often very process-oriented, with the patient as a human being getting little opportunity to express his/her narrative. This may be appropriate in an emergency, but	Thank you. The TEG acknowledged the points raised and revised the statement accordingly, in terms of the set of symptoms that would indicate urgent referral as well as the timeframe for referral. Please see statement 1 in the final quality standard.

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				not in this situation, where the environmental, social and psychological dimensions of the problem are often of great relevance. 8. There is a need to start DMARDs (and if appropriate biologicals) promptly to minimise joint damage, but it is part of the GP role to protect patients from over-enthusiastic specialists who sometimes have an uncritical belief in the efficacy and safety of their treatments. If all self-limiting arthropathies (or pseudoarthropathies) treated with methotrexate, it will certainly boost cure rate, but will also boost adverse effect rate Physicians must always have a healthy scepticism about their treatments. 9. There is no evidence that adopting a same-day referral strategy will affect outcomes. 10. If this Quality Statement were to be introduced as written, the workload of rheumatology services would be rendered unfeasible and the rest of the Quality Standards would not be deliverable. 11. A suggestion is that the Draft Quality Statement be amended to read: 'People presenting to a GP with polyarthalgia with either signs of symmetrical inflammatory arthropathy or raised inflammatory markers or persistence of symptoms for over 2 weeks should normally be referred to a rheumatology service without delay.' Healthcare Outcomes: 1. Patients with rheumatoid arthritis would be treated with disease modifying drugs sufficiently early to prevent joint damage. 2. Patients with other progressive inflammatory polyarthropathies are diagnosed and treated promptly and appropriately. 3. Patients in whom a clear diagnosis has not been made are not exposed to the risks of disease-modifying treatments unless they are likely to have progressive disease.	
079	012	UCB Pharma Ltd	Statement 2	Strongly support statement 2 and while brevity is important much more information is required as variation in practice remains. We would suggest to include a comment on imaging and specific assessment examples such as DAS 28, HAQ, SF-36 within the statement to define the assessment requirement. This would enable healthcare professionals to more ably quantify: - inflammation, - disease progression to inform on disease status - and response to therapy	Thank you. Please see statements 5 and 7 in the final quality standard, which refer to specific assessment tools such as DAS28 and HAQ.

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080	013	University Hospitals Birmingham NHS FT	Statement 2	Again the term 'suspected inflammatory arthritis' is insufficiently precise. Our service receives a large number of referrals which could be categorised as 'suspected inflammatory arthritis'. Such patients commonly have aches and pains and joint stiffness that may be prolonged in the morning. Relatively few of these patients have rheumatoid arthritis or a serious inflammatory condition. Morning stiffness is a poor discriminatory of serious disease. A majority have age related aches and pains. The key to sound referral is to have good clinical judgment backed up by appropriate testing in primary care if necessary. Entirely deskilling and removing experience from primary practitioners by mandating referral is unwise.	Thank you. Please see statements 1 and 2 in the final quality standard which have been revised to refer to people with suspected persistent synovitis.
081	015	Roche products Ltd	Statement 2	People with suspected inflammatory arthritis are assessed by a rheumatology service within 2 weeks of referral. To be consistent with the proposed terminology in QS 1 and the recommendations of the TEG, the following is suggested: People with suspected symptoms or signs of inflammatory arthritis are assessed by a rheumatology service within 2 weeks of referral.	Thank you. Please see statements 1 and 2 in the final quality standard which have been revised to refer to people with suspected persistent synovitis.
082	015	Roche products Ltd	Statement 2	We welcome the recognition of Commissioning for Quality in Rheumatoid Arthritis (CQRA) patient metric data collection forms as appropriate tools to support local data collection. To be consistent with the proposed terminology in QS 1 the term "suspected" should be replaced with "signs and symptoms of".	Thank you. Please see statements 1 and 2 in the final quality standard which have been revised to refer to people with suspected persistent synovitis.
083	015	Roche products Ltd	Statement 2	To be consistent with the proposed terminology in QS 1 the term "suspected" should be replaced with "signs and symptoms of".	Thank you. Please see statements 1 and 2 in the final quality standard which have been revised to refer to people with suspected persistent synovitis.
084	015	Roche products Ltd	Statement 2	To be consistent with the proposed terminology in QS 1 the term "suspected" should be replaced with "signs and symptoms of". According to the minutes of the NICE TEG meeting held on 5th November, it was suggested that appropriate investigations at assessment should be included in the definitions section of QS 2. We agree with the TEG that the QS will be enhanced by this definition and suggest defining assessment as including joint assessment, serology, acute phase reactants and the duration of symptoms in line with the 2010 ACR/EULAR RA Classification Criteria (4). Procedurally, we believe the QS consultation process would be improved if the actions taken following a TEG meeting were transparent—actions recommended by the TEG may have been discussed further, addressed differently or rejected but this is not clear to consultees. (4) Aletaha D et al., Arthritis & Rheumatism 2010; 62; 2569–2581	Thank you. Please see statements 1 and 2 in the final quality standard which have been revised to refer to people with suspected persistent synovitis. The development of statements is an iterative process and therefore some work continues with the TEG Chair and TEG members outside of the meeting. The TEG did not consider it necessary to be prescriptive about what should be included in the assessment as there are a number of validated instruments that are able to provide an objective measure for disease activity, and the area for quality improvement

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					is the speed of assessment rather than the content of the assessment.
085	017	National Rheumatoid Arthritis Society	Statement 2	We agree with the principles set out in this statement. However, in light of the proposed introduction of a new Best Practice Tariff for Inflammatory Arthritis in April 2013 we believe it is sensible to align the measures set out in both these documents and therefore recommend assessment by a rheumatology service should take place within 3 weeks of referral.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
086	018	British Society for Rheumatology	Statement 2	BSR welcomes this statement but believes the timescale should align with the Best Practice Tarrif, which commences in April 2013. As such we suggest assessment by a rheumatology service within 3 weeks of referral.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
087	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 2	Timescales should align with the Best Practice Tariff (commencing April 2013). Therefore, people with suspected inflammatory arthritis should be assessed by a rheumatologist within three weeks of referral.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate,

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					timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
088	021	Napp Pharmaceuticals Limited	Statement 2	There are a number of quality statements where it would be useful to include pain assessment (other than indirectly within DAS28). We suggest adding this as a specific quality measure within the initial assessment (statement 2), initiating treatment (statement 3), disease control (statement 5) and in the annual review (statement 9). Recording of pain scores and sharing information on pain levels between HCPs should take place. It may also be useful to provide information on when appropriate referrals should be made to the pain team, either via the RhA team or directly by the GP. Controlling the disease may be the mainstay of the RhA teams, whilst controlling the pain is as important to the patient as the disease itself. Therefore, involvement with the pain team as early as possibly in conjunction with the RhA team could be recommended. The mandate from the DOH to the NHS Commissioning board identifies that improving quality of life for patients with long term conditions is a key objective. Ensuring that pain is controlled in parallel with improving disease state in RA is a way of improving QOL for this LTC.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management, and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
089	022	Pfizer Ltd	Statement 2	It is important that other relevant commissioning and provider metrics, and other NICE implementation tools are aligned to the Quality Standard. Statement 2 of the Quality Standards states People with suspected inflammatory arthritis are assessed by a rheumatology service within 2 weeks of referral, however the proposed best practice tariff for early inflammatory arthritis is paid for those patients with suspected early inflammatory arthritis who are seen within three weeks of referral,. .	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
090	026	ABPI Pharmaceutical	Statement 2	The ABPI PRI strongly supports the proposed timescale for assessment by a rheumatology service (within two weeks of referral) and the supporting quality	Thank you. The QS is based upon the clinical guideline and the timescales are either derived

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		Rheumatology Initiative (ABPI PRI)		statement 2 which proposes initiation of treatment within four weeks of assessment by a rheumatology service if diagnosed with active rheumatoid arthritis.	directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG considered that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
091	027	Royal College of Nursing	Statement 2	Draft quality statement 2 **.. Assessment** We agree and support this statement in principle as the key to effective use of resources and better outcomes for patient care rests with starting this pathway in the right way. However, we are not sure how 'patient exceptions' would be measured against the service – for example there are a proportion of patients who will not wish to start treatment despite all the right support and information. So a service could be trying very hard to achieve best outcomes but the decision rests with the patient. In clinical practice, we have seen quite a few challenges in achieving this particularly with some ethnic minority groups who may have a different cultural view about receiving drug therapies etc. Also the statement asks for a proportion of people to be referred within 2 weeks. What is an acceptable target? …is a 100% target acceptable or 90% or 50% etc?	Thank you. Quality measures should form the basis for audit criteria developed and used locally to improve the quality of health and social care. As part of developing these audit criteria the audit standards or levels of expected achievement should, unless otherwise stated, be decided locally. Reference is made to national standards where these exist. While typical aspirational achievement is likely to be 100% or 0%, realistic standards should take account of patient safety, patient choice and clinical judgment. Patient choice and shared decision-making are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
092	027	Royal College of Nursing	Statement 2	With regards to these definitions: We are mindful that some rheumatology services/areas/centres may not be able to deliver this, but is an acceptable standard and should be included.	Thank you.
093	027	Royal College of Nursing	Statement 2	In order to obtain an accurate measure and understanding of the findings of any respective audit for this assessment standard, it would be helpful and useful that a parallel local/national survey be undertaken, as this will help identify what specialist services (at that time), are available, and help the analysts compare	Thank you. It is anticipated that a baseline assessment will need to be conducted locally in order to identify improvements required to meet the quality statement.

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				these findings against national recommendations for this. This information should be included in the audit's final analysis process, so as to ensure that the conclusions drawn are accurate, objective (i.e. true reflection of the what and why), and purposeful - for both patients and service providers (i.e. it will help to identify where care standards and service provisions are good or lacking and help inform and support the development of improved future care and services, standards and outcomes per se.	
094	028	AbbVie Ltd	Statement 2	AbbVie supports this quality statement. Because RA is progressive, chronic condition early referral and assessment for patients suspected as having RA is critical. The abovementioned NAO report noted that "the likelihood of people with rheumatoid arthritis being diagnosed and treated within the clinically recommended period of three months from the onset of symptoms has not improved in recent years." In order to make progress against this it is therefore critical that a rapid referral target is proscribed clearly.	Thank you.
095	013	University Hospitals Birmingham NHS FT	Statement 3	Comments about two key elements of this statement: 1. Universal combination therapy: a. We disagree with current NICE RA guidance in this respect as there is sufficient robust evidence to indicate that monotherapy with a disease modifying drug can be similarly effective provided a target of low disease or remission is kept in mind – see http://www.ncbi.nlm.nih.gov/pubmed/22508468 or http://www.ncbi.nlm.nih.gov/pubmed/21415052 . b. Our view is supported by European guidance on rheumatoid arthritis (which includes UK rheumatologists on the author list. See http://ard.bmj.com/content/early/2010/05/04/ard.2009.126532.full.pdf c. American guidance on RA treatment recommend monotherapy or combination therapy depending on presence of prognostic markers. See http://www.rheumatology.org/practice/clinical/guidelines/Singh%20et%20al-ACR%20RA%20GL-May%202012%20AC&R.PDF 2. Start treatment within 4 weeks of assessment by a rheumatology service: a. Most trials of early RA include patients with disease duration of 1	Thank you. The quality standard is underpinned by recommendations from the key development source (NICE clinical guideline 79). NICE quality standards do not seek to reassess or redefine the evidence base. Quality measures should form the basis for audit criteria developed and used locally to improve the quality of health and social care. As part of developing these audit criteria the audit standards or levels of expected achievement should, unless otherwise stated, be decided locally. Reference is made to national standards where these exist. While typical aspirational achievement is likely to be 100% or 0%, realistic standards should take account of patient safety, patient choice and clinical judgment. Patient choice and shared decision-making are important themes for all NHS care. The NICE quality standard on 'patient experience in adult

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				to 2 years. We accept that early treatment gives better outcomes however some patients need time to accept their disease and the fact that they may need long term treatment with an immune suppressing drug such as methotrexate. Some may chose not to take these drugs and often do so early in disease until they have gained trust in their specialist and have understood all the implications. It is therefore better to take a measured approach to treatment. Creating a therapeutic imperative by demanding treatments are given within 4 weeks is unwise.	NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
096	017	National Rheumatoid Arthritis Society	Statement 3	We also agree with the principles set out in this statement. However, because of the planned introduction of a Best Practice Tariff for Inflammatory Arthritis in April 2013 we believe that people with newly diagnosed active rheumatoid arthritis should be offered a combination of disease-modifying anti-rheumatic drugs and short-term glucocorticoids within 3 weeks of assessment by a rheumatology service. This would align proposals in both documents with the effect that patients are still assessed and initiated on appropriate treatment within 6 weeks of referral from a GP.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
097	018	British Society for Rheumatology	Statement 3	BSR welcomes this statement but believes the timescale should align with the Best Practice Tarrif, which commences in April 2013. As such we suggest people with newly diagnosed active rheumatoid arthritis are offered a combination of disease-modifying antirheumatic drugs and short-term glucocorticoids within 3 weeks of assessment by a rheumatology service.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
098	019	The Arthritis and Musculoskeletal	Statement 3	When newly diagnosed, patients should be offered a combination of disease-modifying anti-rheumatic drugs and short-term glucocorticoids in alignment with	Thank you. The QS is based upon the clinical guideline and the timescales are either derived

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		Alliance (ARMA)		the Best Practice Tariff, which is three weeks.	directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The TEG agreed that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
099	021	Napp Pharmaceuticals Limited	Statement 3	There are a number of quality statements where it would be useful to include pain assessment (other than indirectly within DAS28). We suggest adding this as a specific quality measure within the initial assessment (statement 2), initiating treatment (statement 3), disease control (statement 5) and in the annual review (statement 9). Recording of pain scores and sharing information on pain levels between HCPs should take place. It may also be useful to provide information on when appropriate referrals should be made to the pain team, either via the RhA team or directly by the GP. Controlling the disease may be the mainstay of the RhA teams, whilst controlling the pain is as important to the patient as the disease itself. Therefore, involvement with the pain team as early as possibly in conjunction with the RhA team could be recommended. The mandate from the DOH to the NHS Commissioning board identifies that improving quality of life for patients with long term conditions is a key objective. Ensuring that pain is controlled in parallel with improving disease state in RA is a way of improving QOL for this LTC.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management, and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
100	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Statement 3	The ABPI PRI strongly supports the proposed timescale for assessment by a rheumatology service (within two weeks of referral) and the supporting quality statement 2 which proposes initiation of treatment within four weeks of assessment by a rheumatology service if diagnosed with active rheumatoid arthritis.	Thank you. The QS is based upon the clinical guideline and the timescales are either derived directly from the guideline or where this is not possible from the expert opinion of the committee. The QS describes areas for quality improvement, following publication it is envisaged that these will then be used by the NHS to commission high quality services. The

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					TEG considered that where appropriate, timescales included in the quality standard should align to those in the best practice tariff. Please see revised statements 2 and 3 in the final quality standard.
101	027	Royal College of Nursing	Statement 3	Draft quality standard 3 **Initiating treatment** ... We support this statement in principle. However, as in statement 2 what proportion should achieve this standard 100% 90% %50 % etc? Is this quality standard also considering informed/shared decision making in relation to the initiation of treatment? It certainly needs to be encompassed to ensure that the effective and safe use of drug therapies is taken into account.	Quality measures should form the basis for audit criteria developed and used locally to improve the quality of health and social care. As part of developing these audit criteria the audit standards or levels of expected achievement should, unless otherwise stated, be decided locally. Reference is made to national standards where these exist. While typical aspirational achievement is likely to be 100% or 0%, realistic standards should take account of patient safety, patient choice and clinical judgment. Patient choice and shared decision-making are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
102	027	Royal College of Nursing	Statement 3	**Draft quality statement 3 – Definitions** - We would have thought a DAS score of 3.2 or above would constitute active RA not a DAS score of greater than 2.6. If 3 tender swollen joints is going to be one of the criteria for referral we consider 2.6 is acceptable as someone with 3 tender swollen joints, a normal ESR and low Global VAS can achieve this and we should be initiating treatment promptly and Inflammatory markers do not always reflect disease activity. However, what is also important is that some units may prefer an alternative composite disease activity scores, for example the CDAI or SDAI. It is very important that recommendations should be made and a standard set to identify what "DAS" scoring system is to used, to define active disease. The DAS scoring system is known to be subjective and possesses some interpretive flaws; however it remains to be the most widely used composite score.	Thank you. The quality standard refers to the DAS scoring system as this is the system recommended in NICE Clinical Guideline 79, which considers this a well validated composite score of disease activity, and is the evidence-based guidance underpinning this quality standard. The guideline also recommends CRP as a laboratory measure of disease activity.

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				We would very much welcome clarity as to whether both an ESR and or CRPDAS score and or both, should be used (and or at the very least, the one that most accurately reflects the patients disease activity).	
103	028	AbbVie Ltd	Statement 3	AbbVie supports this quality statement for the reasons outlined in our comment pertaining to Quality Statement 2. To make progress against the clinically recommended period of three months for diagnosis and treatment commencement, swift progression onto first line medications for those patients diagnosed with active RA is essential in order to increase the probability of improved healthcare outcomes for patients. To reflect the fact that some patients may be contraindicated to combination therapy AbbVie would suggest a minor amendment to this quality statement along the following lines: *"People with newly diagnosed active rheumatoid arthritis are offered disease-modifying anti-rheumatic drugs in combination with short-term glucocorticoids, if not contra-indicated, within 4 weeks of assessment by a rheumatology service."*	Thank you. Please see revised statement 3 in the final quality standard, where we have extended the definitions section to include reference to when combination therapy is contraindicated.
104	001	Bristol-Myers Squibb (BMS)	Statement 4	Question 5; Yes, a reasonable timeframe from diagnosis within which people with rheumatoid arthritis are offered educational and self-management activities is within 1 month of diagnosis.	Thank you. Please see revised statement 4 in the final quality standard.
105	002	Gloucestershire Hospitals NHS Foundation Trust	Statement 4	Regarding the timeframe in which people with RA are offered educational and self management activities. I believe this should be offered at the time of diagnosis by the consultant. Some people may accept this offer and be ready to take on board the advice and make lifestyle changes; others may need time to come to terms with the diagnosis. The offer should be made within 3 months of diagnosis.	Thank you. Please see revised statement 4 in the final quality standard.
106	004	NHS Direct	Statement 4	What do you consider to be a reasonable timeframe from diagnosis within which people with rheumatoid arthritis are offered educational and self-management activities, for example within 1 month of diagnosis? In my opinion patients require information about the disease on diagnosis both verbal and written. They will normally be commenced on treatment on diagnosis and the patients must be informed of the side effects of their treatment in writing and the importance of monitoring of the same. Engaging with the patient at this initial stage encourages compliance with their treatment. Self-management of their disease should come later possibly after a couple of months of treatment as most patients are in a great deal of discomfort and require treatment before they can start to self-manage.	Thank you. Please see revised statement 4 in the final quality standard. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
107	010	British Medical	Statement	This should usually happen at the consultation at which the specialist confirms the	Thank you. The TEG considered the feedback

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		Association	4	diagnosis, so the audit standard ought to be 'by the second specialist consultation' to allow for reasonable exceptional circumstances.	from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities.
108	011	The Work Foundation	Statement 4	Patients play a crucial part in managing their continuous employment activity and return to work. Therefore, interventions that aim to educate individuals on the course of their disease, and support self-management should include a module on planning and managing work outcomes. This could include both educating patients on the implications of their physical and psychological symptoms on their ability to stay in and return to work, advice on discussing their condition in workplace settings, and – very importantly – aim to counteract self-stigma about individual's own ability to live a productive life, rather than focusing on incapacity.* To monitor referral to self-management a measure of effectiveness should include the timing of such referral, in addition to the number of people being referred. *Rahman A, Reed E, Underwood M, Shipley ME, et al. (2008). Factors affecting self-efficacy and pain intensity in patients with chronic musculoskeletal pain seen in a specialist rheumatology pain clinic. Rheumatology 47(12):1803-1808.	Thank you. We believe statement 4 in the final quality standard supports this.
109	011	The Work Foundation	Statement 4	The consultation includes a question on what would be a reasonable timeframe between diagnosis and offering the individual self-management and educational activities (Statement 4). While, clearly, this depends upon how severe the condition is and which parts of the body are affected, evidence suggests that early self-management interventions help improve compliance rates, and therefore support the clinical treatment plan**, and help prepare for the long-term impact of the condition on quality of life and productivity. Work outcomes of individuals with chronic disease are best addressed in the primary care settings, with a routine conversation about work status and aspirations of a patient with their GP and secondary care professionals. We would therefore recommend that GPs discuss the impact of symptoms on work ability of the patients in the first instance, with Specialist clinicians, such as rheumatologists, referring individuals to existing tools for self-management of RA at the time diagnosis. **Cedraschi C, Desmeules J, Rapiti E, Baumgartner E, Cohen P, Finckh A, Allaz AF, Vischer TL. Fibromyalgia: a randomised, controlled trial of a treatment	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities. It is acknowledged that care of patients with rheumatoid arthritis tends to be shared between primary and secondary care, but NICE quality standards do not aim to be prescriptive about local service delivery arrangements.

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				programme based on self management. Ann Rheum Dis. 2004 Mar;63(3):290-296.	
110	012	UCB Pharma Ltd	Statement 4	UCB Pharma Ltd strongly supports the offering of patients educational and self-management activities and believes this offering should be re-visited annually, beyond time of diagnosis. It is recognised that patients' needs and disease severity will change over time and regular support of this kind could further improve patient experiences, concordance and outcomes.	Thank you. Please see revised statement 7 in the final quality standard, which refers to annual review. The offer of educational and self-management activities is included in the definitions section as being part of a comprehensive annual review.
111	014	Royal college of pathologists	Statement 4	Although a holistic and patient-centered approach to health care is important, the early goals of therapy should be focused on establishing the diagnosis and commencing the treatment, since any delay here is associated with subsequent poorer treatment responses and structural joint damage. Once the patient is established on a treatment then involvement of physiotherapists, occupational therapies and other members of a multi-disciplinary team should be initiated within few weeks.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities, and that at diagnosis the first priority is initiation of treatment.
112	015	Roche products Ltd	Statement 4	People with rheumatoid arthritis are offered educational and self-management activities starting around the time of diagnosis. We support the inclusion of patient information in the QS and believe health outcomes would be improved further if the content of educational activities was defined, reflecting NICE clinical guideline 79, as well as the way in which information should be delivered. The following text is suggested: People with rheumatoid arthritis are offered educational and self-management activities starting around the time of diagnosis, which includes the risks and benefits of treatment options, improves understanding of the condition and its management and counters misconceptions.	Thank you. Please see the definitions section in statement 4 which sets out what educational and self-management activities might include, reflecting NICE clinical guideline 79 and the expert opinion of the group. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
113	015	Roche products Ltd	Statement 4	CQRA have developed a Patient Reported Experience Measures (PREMs) questionnaire which is currently being piloted. Once it has been established how well the questionnaire captures the patient experience of RA services at participating study sites, the questionnaire could be considered as a recommended data source.	Thank you. NICE welcomes the development of tools to support measuring achievement of quality standards.
114	015	Roche products Ltd	Statement 4	We feel there is a benefit in defining the content as well as format of educational activities and self-management programmes as per NICE clinical guideline 79: the risks and benefits of treatment options; improving understanding of the condition and its management; and countering misconceptions. To take an active part in	Thank you. Please see the definitions section in statement 4 which sets out what educational and self-management activities might include, reflecting NICE clinical guideline 79 and the

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				treatment decisions and the management of their condition, patients need to understand the meaning of composite scores of disease activity, the signs and actions to take when disease flare occurs, how to self-refer to members of the multidisciplinary team and the importance of concordance with prescribed medication. The National Rheumatoid Arthritis Society self-management course (5) aims to help patients: get the best from their medication; communicate more effectively with the healthcare team; learn how to better manage disease flares, pain and fatigue; understand the benefits of pacing, set meaningful, achievable goals and action plans; manage anxiety and depression. Suggested definition: Educational and self-management activities should aim to help patients: get the best from their medication; communicate more effectively with the healthcare team; learn how to better manage disease flares, pain and fatigue; understand the benefits of setting meaningful, achievable goals and action plans including the meaning of composite scores of disease activity; and managing anxiety and depression. (5) National Rheumatoid Arthritis Society. http://www.nras.org.uk/help_for_you/ra_self_management_programme/default.aspx	expert opinion of the group. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
115	015	Roche products Ltd	Statement 4	If treatment is to be initiated within 6 weeks of referral, patients must receive sufficient information to support choices about management within 4 weeks of assessment. Therefore, educational and self-management activities should begin as early as possible after diagnosis, and no later than 4 weeks after diagnosis.	Thank you. Please see revised statement 4 in the final quality standard.
116	017	National Rheumatoid Arthritis Society	Statement 4	Greater provision of education and self-management support is vital. An online poll by NRAS of people with rheumatoid arthritis discovered that 57 per cent of respondents felt their hospital did not do enough to help them understand their disease (NRAS HealthUnlocked Forum, 2011). In responses to these sorts of concerns, NRAS developed a RA Self-Management Programme (in partnership with the Expert Patients Programme CIC). This has been fully piloted and evaluated across three sites at Woking, Stoke and Middlesex and delivered at Queen Alexandra Hospital, Portsmouth. We are one of a number of third sector organisations offering this sort of valuable support to patients alongside comprehensive booklets and information through our website and peer-to-peer support, which is not being routinely or adequately delivered by providers. To ensure patients are able to benefit from this range of support as much as	Thank you. The definitions section has been amended to include reference to third sector organisations in terms of the support they can provide for education and self-management. Please see revised statement 4 in the final quality standard. Please see the definitions section in statement 4 which sets out what educational and self-management activities might include, reflecting NICE clinical guideline 79 and the expert opinion of the group. The TEG did not feel they could be too prescriptive about educational and self-management activities given the lack of supporting evidence in the underpinning clinical guideline.

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				possible, we therefore believe the quality statement should be strengthened by ensuring there is an enhanced duty on healthcare professionals to sign-post to third sector organisations for support with education and self-management. We would like to see sections on the 'Draft quality measure' and the 'Description of what the quality statement means for each audience' strengthened to make specific reference to sign-posting to third sector support. This could include the introduction of 'process' measures to record the proportion of people with rheumatoid arthritis that are sign-posted to third sector organisations for education and self-management support. We therefore suggest paragraph 1 should also be amended in the 'Definitions' guidance on page 11 to say that education and self-management also means sign-posting patients to relevant support services provided by the third sector. To ensure more consistent coverage in the provision of education and self-management materials, a new paragraph should be added to the 'Definitions' guidance on page 11 stipulating what topics should be covered. We would suggest this includes a reference to the expectation that all newly diagnosed patients will be given an information pack that describes what all the available local and relevant national services are, and gives advice on medicines adherence and when it is appropriate to contact the rheumatology service for rapid access, as well as and advice on staying in work. In the case of the latter, ensuring that education and self-management materials include coverage of work issues will ensure the quality standard contributes to employment objectives specified in Domain 1 of the Adult Social Care Outcomes Framework 2013-14 and Domain 2 of the NHS Outcomes Framework 2013-14.	Please see statement 7 in the final quality standard, where employment status is explicitly referenced (in the definitions section) as part of the annual review discussion with the patient about how the disease is affecting their life, which strengthens the link to employment outcomes in the outcomes frameworks.
117	017	National Rheumatoid Arthritis Society	Statement 4	If rheumatoid arthritis is diagnosed, NRAS would recommend that educational and self-management activities are offered on the same day as assessment by the specialist. People will often be in a state of shock and will be looking for emotional support, which can be obtained through these activities. It also makes sense that if a patient is to be offered disease-modifying anti-rheumatic drugs 3 weeks after being assessed by their rheumatology service that they will want to understand what treatments they are going to receive and do their own appropriate research in advance. Failure to give appropriate information may reduce adherence or cause patients to refuse treatments altogether.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE

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				From the point of view of work outcomes, we also believe it is important that patients are given information and support about their rights and the reasonable help they can expect to receive from their employer as soon as possible to ensure they stand a realistic chance of remaining in work, or making a swift return to employment.	quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail. Please see the definitions section in statement 4 which sets out what educational and self-management activities might include, reflecting NICE clinical guideline 79 and the expert opinion of the group. The TEG did not feel they could be too prescriptive about educational and self-management activities given the lack of supporting evidence in the underpinning clinical guideline.
118	018	British Society for Rheumatology	Statement 4	BSR believes that the timing of educational and self-management activities varies by patient, in terms of what they need and what they want. We suggest such activities should form part of a process of on-going support, according to individual needs, and as such a timescale should not be specified. The Institute of Healthcare Improvement in Boston has recently identified patients' needs and emotional states change with time, requiring an individualised approach to information-giving and support. We suggest rewording as follows: "People with rheumatoid arthritis are offered **appropriate** educational and self-management activities **at appropriate times for each individual patient along the pathway.**"	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities. Please also see revised statement 7 in the final quality standard, which refers to annual review. The offer of educational and self-management activities is included in the definitions section as being part of a comprehensive annual review, reflecting the fact that as emotional states change with time, the opportunity for further support should be offered throughout the course of their disease on an ongoing basis.
119	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 4	Patient requirements and needs vary greatly, therefore the timing of educational and self-management activities will be dependent upon these. Activities should form part of on-going support, which is individually tailored and thereby resulting in no specified timescale.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities.

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					Please also see revised statement 7 in the final quality standard, which refers to annual review. The offer of educational and self-management activities is included in the definitions section as being part of a comprehensive annual review, reflecting the fact that as emotional states change with time, the opportunity for further support should be offered throughout the course of their disease on an ongoing basis.
120	020	MSD Ltd	Statement 4	In answer to Question 5, MSD feels that offering advice on educational and self-management activities within 4 weeks of diagnosis would be optimal, and further suggests that the quality statement should specify how frequently this advice should be updated and re-discussed with patients throughout the course of their treatment MSD feels that the annual review (as discussed in Quality Statement 9) is a useful opportunity to include continuing and updated advice on educational and self-management activities, in order to accurately reflect the changing nature of the disease with progression. However, as stated in later comments, MSD believes that annually is too infrequent and would advocate a more frequent patient review in which the provision of this advice could be incorporated MSD further suggests that the advice on educational and self-management activities should specifically include guidance around the merits of hospital- versus home-based care from the patient perspective, in order to adequately prepare and empower patients for later decisions regarding treatment options following disease progression	Thank you. Please see revised statement 4 in the final quality standard. The definitions section has been extended to state that the opportunity to take part in existing educational activities and self-management programmes should be offered to people with rheumatoid arthritis throughout the course of their disease on an ongoing basis. Please also see revised statement 7 in the final quality standard, where the offer of educational and self-management activities is included in the definitions section as being part of a comprehensive annual review.
121	021	Napp Pharmaceuticals Limited	Statement 4	We believe that it would be helpful to define who are members of the Multi Disciplinary Team (MDT): BSR & NRAS Recommendations are: Consultant (who leads the team) Nurse specialist Physiotherapist Occupational Therapist Podiatrist	Thank you. Please see the definitions section in statements 1, 2, 3, 6 and 7 in the final quality standard, which sets out the members of the multidisciplinary team that comprises the rheumatology service.

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				Some form of Psychological support service representative Primary care pick up once diagnosis and stability of disease achieved Additionally inclusion of Pain Specialists should be considered.	
122	022	Pfizer Ltd	Statement 4	Proposed response: Pfizer agrees with the proposed time frame – within 1 month of diagnosis.	Thank you.
123	024	Chartered Society of Physiotherapy	Statement 4	Consultation question 5: What do you consider to be a reasonable timeframe from diagnosis within which people with rheumatoid arthritis are offered educational and self-management activities, for example within 1 month of diagnosis? One month.	Thank you.
124	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Statement 4	The ABPI PRI strongly supports the offering of patients educational and self-management activities and understands the rationale for these being offered from the point of diagnosis. However, in some cases patients derive greater benefit from such activities when they have been diagnosed for long enough to have come to terms to some degree with their diagnosis. It is also important to recognise that the level of support needed can depend on the severity of the condition. The ABPI PRI therefore believes that whilst educational and self-management programmes should be offered within one month of diagnosis this should be the start of the process and the quality statement and measure should display a greater recognition of their continuing need. Indeed, the Quality Statement in full goes some way to address this point, as it is stated that offering educational and self-management programmes should form part of the annual review, but the quality statement 4 could be interpreted to suggest the offering should be a “one off”. The ABPI PRI therefore believes the section on self-management would be strengthened if the references to education and self-management starting around the time of diagnosis were amended to state, “initially offered within one month of diagnosis and thereafter at the annual review”. This would allow for more flexibility of services to support varying and changing patient needs.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities. The definitions section has been extended to state that the opportunity to take part in existing educational activities and self-management programmes should be offered to people with rheumatoid arthritis throughout the course of their disease on an ongoing basis.
125	027	Royal College of Nursing	Statement 4	Draft quality statement 4 - **Education & self management.** A reasonable time frame from diagnosis within which people are offered education depends on the type of education. For example, there should be documented evidence of education before patients commence on DMARD’. Written information should be given on the day of diagnosis	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in

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				However for formal programmes, patients should be able to choose when to take up, as a number of patients decline formal programmes until later in their disease course, hence needs to be available when patient are ready to access. This is always a difficult aspect of care to get right as each patient's educational needs and learning abilities vary i.e. research has indicated that some patients prefer and do well from attending group educational sessions, whilst others prefer and do better with the more personal one-to-one approach. However, patient education has been identified and is known to be a key component of RA patient care and has a positive effect on patient outcomes i.e. knowledge, decision making, self-efficacy/self-management etc. Individual patient needs and readiness for education is going to vary considerably. It is, therefore, important that the method of education and timing are tailored to the individual patient needs. There may be many reasons why patients are unable to attend formal programmes such as work, social issues, and distance from programme. It is important to document what education has been given / offered and that patients are made aware of the different sources of education – one-to-one, programmes at the Rheumatology centre and patient groups, internet and telephone based programmes so in conjunction with the patient the most appropriate method can be used. We would reiterate that if and where such educational group sessions are available, these should be offered to patients within the first six months of diagnosis, and that if patients decline this offer (which should be documented), that this service be offered again to patients, in case the patient has changed his/her mind.	terms of how soon they may wish to be offered these activities. The definitions section has been extended to state that the opportunity to take part in existing educational activities and self-management programmes should be offered to people with rheumatoid arthritis throughout the course of their disease on an ongoing basis. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail. All statements are underpinned by patient choice and involvement in the decision-making process.
126	028	AbbVie Ltd	Statement 4	AbbVie is supportive of the principle behind this quality statement. However, AbbVie believes that true patient–centred care should enable patients have the ability to access education, support and self-management activities throughout the course of their condition. This quality statement could be amended to reflect this and to avoid it being interpreted as an initial activity at diagnosis that ceases to be relevant thereafter. AbbVie therefore suggests: "*People with rheumatoid arthritis are offered educational and self-management activities starting around the time of diagnosis and access to this when required thereafter, including at the annual review.*"	Thank you. The definitions section has been extended to state that the opportunity to take part in existing educational activities and self-management programmes should be offered to people with rheumatoid arthritis throughout the course of their disease on an ongoing basis. Please also see revised statement 7 in the final quality standard, where the offer of educational and self-management activities is included in the definitions section as being part

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					of a comprehensive annual review.
127	029	Royal College of General Practitioners	Statement 4	It is important to cover these issues from the beginning. Patients need to be told what they are likely to have, what are the implications and where to find information.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities. Patient information about their condition and the risks and benefits of treatment options are important themes for all NHS care. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail.
128	030	AstraZeneca UK	Statement 4	To optimise treatment and outcomes educational and self management activities should be offered at diagnosis and if accepting patients should be able to access them within a month of diagnosis.	Thank you. The TEG considered the feedback from stakeholders and agreed that the offer of educational and self-management activities should start within a month of diagnosis, to acknowledge a range of patient preferences in terms of how soon they may wish to be offered these activities.
129	010	British Medical Association	Statement 5	There are occasions where there is demonstrated clinical improvement after the initiation of a DMARD, but the disease will not have reached an acceptable final level of control. However as the direction of travel is positive, and as escalation of treatment is not without risks or unwanted effects, the correct clinical decision after one month's treatment is to continue and review. The standard has to allow for such periods of observation.	Thank you. The definitions section has been extended to clarify that treatment escalation relates to the use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs to control the disease (in accordance with relevant NICE technology appraisals), and a review of the treatment in terms of disease response and patient safety.
130	012	UCB Pharma Ltd	Statement 5	UCB Pharma Ltd believes that this statement could be strengthened to support the measure in the British Society for Rheumatology's top ten quality standards for treatment of RA to state "people with uncontrolled active rheumatoid arthritis receive monthly reviews for a decision on treatment escalation or change of therapy until treatment has induced remission, or minimal disease activity where this is not achievable.	Thank you. Please see revised statement 5 in the final quality standard, which has been strengthened to refer specifically to low disease activity. The definitions section has been extended to clarify that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability

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				In addition and to further emphasise our comment for draft statement 2, some reference to imaging requirements could significantly improve RA patient data and provide a stronger baseline from which to evaluate current service provision and outcomes. Such an emphasis would seem particularly desirable given the increasing evidence (as noted in the NICE briefing document, such as the 2 RCT studies of recent-onset RA) that intensive treatment strategies aimed at keeping the DAS to low levels resulted in substantially better outcomes.	that is agreed with each person as their goal for ongoing management of the disease.
131	012	UCB Pharma Ltd	Statement 5	In support of the belief that intensive treatment strategies result in better outcomes UCB Pharma Ltd believes the current proposed quality measure should be expanded to include the following: Structure: Evidence of local arrangements to ensure that people with uncontrolled active rheumatoid arthritis receive monthly treatment escalation and that people receive biologic treatment as soon as possible after their condition fulfils NICE technology appraisal criteria with a view to achieving disease control as specified in QS 5. Process: c) Proportion of people with uncontrolled active rheumatoid arthritis who receive biologic treatment as soon as possible after their condition fulfils NICE technology appraisal criteria. Numerator – the number of people in the denominator who receive biologic treatment.	Thank you. The measures included are designed to measure the statement. The definitions section refers to the use of biological drugs as a means of achieving low disease activity.
132	013	University Hospitals Birmingham NHS FT	Statement 5	Monitoring this quality standard will pose substantial challenges. We have a shared care agreement, under a local enhanced scheme, with our primary colleagues whereby drug and disease monitoring are done in primary with less frequent review in hospital. This permits the delivery of care closer to a patient's home and also maximises use of hospital resources. Measurement of disease activity scores monthly in many cases is unnecessary, for example because parenteral corticosteroids such as intra-muscular methylprednisolone can provide good relief from symptoms for up to 12 weeks. We allow GPs and practice nurses, under our guidance, to make judgements about treatment escalation based on initial recommendations by consultants. Thus face to face consultations monthly within rheumatology are unnecessary, may be burdensome to patients who struggle to travel to hospital and would demand considerably more resources	Thank you. Please see revised statement 5 in the final quality standard. The definitions section no longer refers to a face-to-face consultation with a member of the rheumatology service. The TEG recognise that a target of disease activity should be agreed with the patient, as per the underpinning NICE guideline recommendation, and this is set out explicitly in the definitions section, which states that an agreed low disease activity target is a level of low disease activity, ideally remission, or

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				than we have. In addition such an approach would exclude primary care providers from an important role in patients who commonly have multiple morbidities. Individual disease activity measures are also not always reliable – some distressed patients with high tender joint counts do not necessarily require escalation of therapy – such patients are not uncommon. Agreeing a target for disease activity is best done directly with patients and should not be based on numerical criteria alone – for example a DAS28 of 3.2 or less has no meaning for most patients. HAQ is not a measure of joint function. Repeatedly measuring HAQ in routine practice is unlikely in my view to contribute to better care and indeed may get in the way of doctors and health professionals listening to patients rather than focusing on imperfect numerical measures of health.	functional ability that is agreed with each person as their goal for ongoing management of the disease. HAQ is referenced as an available tool but use of it is not mandated by the quality statement.
133	015	Roche products Ltd	Statement 5	People who have uncontrolled active rheumatoid arthritis receive monthly treatment escalation until the disease is controlled to an agreed target. The term *treatment escalation* is commonly used to describe increasing the dose of a drug rather than changing: the dose-schedule (e.g. daily or weekly administration); the route of administration (e.g. oral or parenteral glucocorticoids); or changing to alternative agents (e.g. biologicals). Although monthly clinical *review* is appropriate in uncontrolled rheumatoid arthritis, for some treatments 4 weeks may be too short an interval to adequately assess response (e.g. rituximab). An international expert taskforce [(6)] have recommended that drug therapy be adjusted at least every 3 months. Treating to clinical remission is recognised as the ultimate aim of treatment by BSR[(1)], EULAR[(2)] and ACR[(3)]. Low disease activity may be an acceptable alternative therapeutic goal, particularly in established long-standing disease. Treating to remission or low disease activity has been: correlated with significantly reduced joint damage, pain and symptom relief; and is associated with improved patient quality of life, mental health and work productivity. Studies have indicated the financial benefits for Western healthcare systems in achieving remission or low disease activity [(7, 8, 9, 10)]. We believe this is important enough to be explicit in the quality statement and therefore suggest the following: ***People who have uncontrolled active rheumatoid arthritis ~~receive monthly treatment escalation until~~ have their treatment reviewed monthly and adjusted at least every three months until clinical remission or low disease activity is demonstrated or the disease is controlled to another agreed target.*** (1) The British Society for Rheumatology 2012;	Thank you. The definitions section has been extended to clarify that treatment escalation relates to the use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs to control the disease (in accordance with relevant NICE technology appraisals), and a review of the treatment in terms of disease response and patient safety. The statement has been strengthened to refer specifically to low disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease.

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				http://www.rheumatology.org.uk/includes/documents/cm_docs/2012/t/top_10_quality_standards_for_ra.pdf (2) Smolen *et al*., *Ann Rheum Dis* 2010; **69**:964-975 (3) Singh JA, *et al. Arthritis Care Res* 2012; **64**:625-639 (6) Smolen *et al., Ann Rheum Dis* 2010; **69**:631-637 (7) Barnabe *et al., Ann Rheum Dis* published online November 1, 2012 [doi: 10.1136] (8) Miranda *et al., Acta Reumatol Port.* 2012; **37**:40-48 (9) Beresniak *et al.,* Rheumatol 2011; **38:**439-445 (10) Hallert *et al., Rheumatology* 2011; **50**:1259-1267	
134	015	Roche products Ltd	Statement 5	Process: we recommend the term 'optimisation' replaces 'escalation' in the proposed process measures (a) and (b). We also suggest two further process measures as defined by Commissioning for Quality in Rheumatoid Arthritis ((CQRA): (c) proportion of people with previously uncontrolled active rheumatoid arthritis who receive treatment optimisation in line with NICE clinical guidelines until EULAR DAS28 defined remission of DAS < 2.6 is achieved; (d) proportion of people with previously uncontrolled active rheumatoid arthritis who receive treatment optimisation in line with NICE clinical guidelines until EULAR DAS28 defined low disease activity of DAS ≥ 2.6 to ≤ 3.2 is achieved; and a third as recommended by Smolen et al (6) (e) proportion of people with previously uncontrolled active rheumatoid arthritis who have a composite measure of disease activity documented at least every 3 months. Outcome: early treatment to minimise damage to joints is desirable, as reflected in 2009 by The National Audit Office (11). The Genant modified Sharp method for scoring radiographs of hands and feet in rheumatoid arthritis, is now a reference method used in clinical trials; we suggest this as an additional health outcome measure to assess joint erosion (12). (6) Smolen et al., Ann Rheum Dis 2010; 69:631-637 (11) Report by the Comptroller and Auditor General 2009. National Audit Office. (12) Kremer JM et al., Arthritis & Rheumatism 2011; 63:609-621	Thank you. The measures included are designed to measure the statement. Outcome measures are stated where the TEG felt these were appropriate, and for this statement include a) controlled rheumatoid arthritis and b) functional ability.
135	015	Roche products Ltd	Statement 5	In light of our response to the statement and measure, the following definition is suggested: Treatment ~~escalation~~ optimisation relates to disease-modifying antirheumatic drugs, glucocorticoids or biological drugs, given in combination or as single agents, and includes: assessing response to and intolerance of existing treatment; increasing the dose of a drug currently being administered; substitution of one drug in a combination with an alternative drug; changing the route of	Thank you. Please see revised statement 5 in the final quality standard. The definitions section has been expanded to reflect the recommendations in the underpinning NICE clinical guideline (CG79) and the expert opinion of the group.

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				administration e.g. intramuscular or intra-articular steroids; switching to an alternative drug or therapy if the current combination has been optimised without effect. Treatment modification ~~and~~ is undertaken after a face-to-face consultation with a member of the rheumatology service. The intervals at which treatment response should be assessed should be agreed with each patient with reference to NICE technology appraisal guidance, clinical guidelines and Summaries of Product Characteristics. Disease activity is measured using a composite score such as DAS28. Active rheumatoid arthritis can be defined as a disease activity score (DAS28) of greater than 2.6, or disease that cannot be considered as being adequately controlled. An agreed target is a level of disease activity or functional ability that is agreed with each person as their goal for ongoing management of the disease; whenever possible the target should be to achieve remission (DAS28 < 2.6) or low disease activity (≥ 2.6 to ≤ 3.2) as quickly as possible. The agreed target of treatment should not be confused with interim targets agreed to assess adequate response to treatment (e.g. a reduction in DAS28 of ≥1.2 after 6 months of treatment). Controlled disease represents the agreed target being achieved and the person being satisfied with their functional ability and suppression of symptoms. Uncontrolled disease is any level of disease that doesn't meet the agreed target. Function of joints can be measured using the Health Assessment Questionnaire.	
136	017	National Rheumatoid Arthritis Society	Statement 5	We suggest paragraph 3 should be amended in the 'Definitions' guidance on page 14 to say the agreed target should be discussed and assessed using an independent measure of illness intrusiveness such as the Rheumatoid Arthritis Impact of Disease measure (RAID) as a way to effectively structure conversations between clinicians and patients. Of all of the outcome measures available this has had major input from patient partners and has been validated across 10 countries.	Thank you. Please see revised statement 5 in the final quality standard. The definitions section has been expanded to reflect the recommendations in the underpinning NICE clinical guideline (CG79) and the expert opinion of the group.
137	018	British Society for Rheumatology	Statement 5	BSR supports this statement.	Thank you.
138	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 5	ARMA supports this statement.	Thank you.
139	020	MSD Ltd	Statement 5	MSD is concerned that the reference to an "agreed target" for disease control is too vague and could encourage suboptimal clinical practice. The grounding for this concern is based around the EULAR treatment-to-target guidelines which indicate that remission should ideally be the goal for treatment ("The primary target for treatment of rheumatoid arthritis should be a state of clinical remission"; "While remission should be a clear target, based on available evidence low disease	Thank you. The statement has been strengthened to refer specifically to low disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each

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				activity may be an acceptable alternative therapeutic goal, particularly in established long-standing disease" - Smolen et al., Ann Rheum Dis. 2010; 69: 631-97) MSD believes that the use of vague terminology is not amenable to developing standards and/or metrics which aim to improve the quality of healthcare provision and would suggest incorporating specific guidance as to the level of disease control (i.e. DAS threshold score, HAQ score) that can be considered as having met the quality standard target	person as their goal for ongoing management of the disease. The level of disease control that is acceptable with therefore be specific to each patient.
140	021	Napp Pharmaceuticals Limited	Statement 5	There are a number of quality statements where it would be useful to include pain assessment (other than indirectly within DAS28). We suggest adding this as a specific quality measure within the initial assessment (statement 2), initiating treatment (statement 3), disease control (statement 5) and in the annual review (statement 9). Recording of pain scores and sharing information on pain levels between HCPs should take place. It may also be useful to provide information on when appropriate referrals should be made to the pain team, either via the RhA team or directly by the GP. Controlling the disease may be the mainstay of the RhA teams, whilst controlling the pain is as important to the patient as the disease itself. Therefore, involvement with the pain team as early as possibly in conjunction with the RhA team could be recommended. The mandate from the DOH to the NHS Commissioning board identifies that improving quality of life for patients with long term conditions is a key objective. Ensuring that pain is controlled in parallel with improving disease state in RA is a way of improving QOL for this LTC.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management, and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 8 in the final quality standard).
141	022	Pfizer Ltd	Statement 5	We believe that QS5 should be further strengthened to reflect the British Society for Rheumatology's top ten quality standards for treatment of RA "people with uncontrolled active rheumatoid arthritis receive monthly treatment escalation until treatment has induced remission, or minimal disease activity where this is not achievable".	Thank you. The statement has been strengthened to refer specifically to low disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease.
142	023	Novartis Pharmaceuticals	Statement 5	Novartis Pharmaceuticals UK considers this proposed Quality Statement as the most important, due to the urgent need to effectively control RA in order to prevent	Thank you. The statement has been strengthened to refer specifically to low

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		UK Ltd		long term morbidity and complications that can lead to a high burden on the health service. There are now a large number of effective interventions (both medical and surgical) that are available to treat RA so adopting a “treat to target” mentality is essential to ensure patients are effectively treated and to avoid clinical inertia that can occur. Treatment escalation may include drug dose optimisation, drug change, combination therapy or surgical interventions and this should be specified in the Quality Standard. Treatment targets need to consider both disease activity (DAS-28, ACR20 etc), functional measures and also patient-centric measures such as quality of life (RA specific QoL measures, societal measures such as work productivity etc) to ensure the target is of true benefit. These additional measures should be included in the Quality Standard. Disease severity needs to be measured consistently and frequently in order to allow for treatment escalation decisions to be made effectively. Therefore, the Quality Standard should include a measure of quantity and quality of disease severity, functional and QoL assessment. At times, patients need to be referred for supra-specialist care (e.g. patient has failed DMARDs, multiple biologics etc) and this is part of “treat to target”. Therefore, allowances and measures of appropriate tertiary referrals should be included in the Quality Standard.	disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease. The definitions section has been expanded to reflect the recommendations in the underpinning NICE clinical guideline (CG79) and the expert opinion of the group. The measures included are designed to measure the statement, and the focus of this statement is on suppressing inflammation.
143	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Statement 5	The draft quality statement is, “People who have uncontrolled active rheumatoid arthritis receive monthly treatment escalation until the disease is controlled to an agreed target”.. The ABPI PRI believes that given current advances in treatment this statement is too vague and could be open to misinterpretation. It could be strengthened considerably and as support the EULAR guidelines that state that remission should be the goal of treatment and reflect the measure in the British Society for Rheumatology’s top ten quality standards for treatment of RA which states “all patients under the care of a rheumatologist with uncontrolled active rheumatoid arthritis receive monthly treatment escalation until treatment has induced remission, or minimal disease activity where this is not achievable”. Such an emphasis would seem particularly desirable given the increasing evidence (as noted in the NICE briefing document, such as the 2 RCT studies of recent-onset RA) that intensive treatment strategies aimed at keeping the DAS to low levels resulted in substantially better outcomes.	Thank you. The statement has been strengthened to refer specifically to low disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease.
144	026	ABPI	Statement	The definition of treatment escalation states, “Treatment escalation relates to the	Thank you. The use of biologic drugs in

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		Pharmaceutical Rheumatology Initiative (ABPI PRI)	5	use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs, and is undertaken after a face-to-face consultation with a member of the rheumatology service". NICE Clinical Guideline 79 states that, biological drugs are recommended as options for the treatment of adults who have both of the following characteristics. • Active rheumatoid arthritis as measured by DAS 28 greater than 5.1 confirmed on at least two occasions, 1 month apart, • Have undergone trials of two DMARDs (a trial of a DMARD is defined as being normally of 6 months). As the NICE Commissioning Guide on biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology states, biologic drugs have emerged as an important advance in the treatment of inflammatory disease and where conventional treatments become ineffective for the treatment of rheumatoid arthritis, biologic drugs may slow the destruction of joints, reduce inflammation, slow disease progression or induce full remission. They are therefore a critical component of disease control. Given the importance of these treatments, and the fact that the NICE commissioning guide acknowledges evidence from bodies such as the National Audit Office that trusts are not able to provide biologic drugs to everyone who qualifies for them in accordance with NICE criteria, the exclusion of a direct statement as to when biologic treatment should be initiated is a significant omission. As the NICE commissioning guide states, "effective commissioning of biologic drugs has the potential to contribute to efficiency savings within the care pathway. For example, earlier initiation and better long-term care of patients may help to prevent or reduce costly exacerbations of the disease, hospital admissions and surgical interventions." The ABPI PRI therefore believes the current proposed quality measure should be expanded to include the following: Structure: Evidence of local arrangements to ensure that people with uncontrolled active rheumatoid arthritis receive monthly treatment escalation and that people receive biologic treatment as soon as possible after their condition fulfils NICE technology appraisal criteria with a view to achieving disease control as specified in QS 5.	accordance with NICE guidance is mandated by NICE technology appraisals so this area was not prioritised as an area for quality improvement to be addressed through the quality standard. The measures included are designed to measure the statement, and the focus of this statement is on suppressing inflammation to achieve disease control. The definitions section refers to the use of biological drugs as a means of achieving low disease activity.

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				Process: c) Proportion of people with uncontrolled active rheumatoid arthritis who receive biologic treatment as soon as possible after their condition fulfils NICE technology appraisal criteria. Numerator – the number of people in the denominator who receive biologic treatment.	
145	027	Royal College of Nursing	Statement 5	Draft quality statement 5 - **Disease control - definition** This draft definition suggests that consultations should be only face to face. This does not allow for remote monitoring with Tele-health, which in remote parts can be more convenient. Tele-health which includes rheumatology phone and email advice lines (which are non-face-to-face consultation) are and have become a vitally important and extremely useful and effective system of managing such patient care and picking up patients in trouble. We agree that treatment escalation is undertaken monthly, with a **qualified** member of the rheumatology service, until the agreed level of control reached i.e. DAS and HAQ. We would suggest deletion of “face to face “.	Thank you. Please see revised statement 5 in the final quality standard. The definitions section no longer refers to a face-to-face consultation with a member of the rheumatology service.
146	027	Royal College of Nursing	Statement 5	Also see comments in relation to disease escalation issues in draft quality statement 3. Although we note definitions outline agreed with each person on their goals. A similar statement in 5 might be helpful	Thank you. The definitions state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease. As stated earlier, all statements are underpinned by patient choice and involvement in the decision-making process, and realistic audit standards, developed locally, should take account of patient safety, patient choice and clinical judgment.
147	028	AbbVie Ltd	Statement 5	AbbVie is supportive of the principle this quality statement is predicated on but would note that it could have potential to be interpreted as focussing on newly diagnosed RA.	Thank you. Please see revised statement 5 in the final quality standard, which refers to people with *active* rheumatoid arthritis, which

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				AbbVie would suggest: "All people who have diagnosed, uncontrolled active rheumatoid arthritis receive monthly treatment escalation until the disease is controlled to an agreed target." This would hopefully ensure all patients – both new and with chronic disease - are included. AbbVie would also suggest modifying 'receive monthly treatment escalation' to 'receive monthly treatment escalation or alteration' to include patients where treatment escalation may not be feasible or may be contra-indicated. NICE describe quality standards as "central to the Government's vision for an NHS and social care system focused on delivering the best possible outcomes for people who use services"[3], AbbVie believes an ideal treatment target should be incorporated into this quality statement, and would suggest: *'until the disease is controlled to an agreed target, ideally aiming for minimal disease activity or remission where possible.'* Disease remission would constitute the best possible outcome for RA patients, the NHS and the wider economy and therefore AbbVie believes there is strong rationale for making this amendment given the raison d'etre of quality standards. AbbVie would make one final comment relating to this quality statement. NICE have previously noted that biologic medications may slow the destruction of joints, reduce inflammation, slow disease progression or induce full remission[4] and their utilisation in clinical practice has grown in recent years. Recent studies have shown that early access to anti-TNF therapy can reduce the severity, impact or progression of the disease and improve patients' capacity for work.[5] Biologic medications are therefore a critical component of disease control and improved health and functional outcomes for patients. AbbVie believe that there should ideally be a distinct quality statement relating to swift initiation of biologic medications in appropriate patients and in line with the most recent NICE guidelines. At a minimum AbbVie would suggest inclusion of a statement in the	includes those newly diagnosed and those with established disease which is active. The definitions section has also been extended to clarify that treatment escalation relates to the use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs to control the disease (in accordance with relevant NICE technology appraisals), and a review of the treatment in terms of disease response and patient safety. The statement has been strengthened to refer specifically to low disease activity, and the definitions also state that an agreed low disease activity target is a level of low disease activity, ideally remission, or functional ability that is agreed with each person as their goal for ongoing management of the disease. The use of biologic drugs in accordance with NICE guidance is mandated by NICE technology appraisals so this area was not prioritised as an area for quality improvement to be addressed through the quality standard. The measures included are designed to measure the statement, and the focus of this statement is on suppressing inflammation to achieve disease control. The definitions section refers to the use of biological drugs as a means of achieving low disease activity.

[3] http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp

[4] http://www.nice.org.uk/media/F95/42/UpdateTA247AndPsoriasisCG.pdf

[5] V Bejarano, *Effect of the early use of the anti-tumor necrosis factor adalimumab on the prevention of job loss in patients with early rheumatoid arthritis*, Arthritis & Rheumatism, 2008, 59(10):1467–1474, Available at: onlinelibrary.wiley.com/doi/10.1002/art.24106/full

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				"structure" of the quality standard such as: "biologics are initiated where appropriate as soon as possible after fulfilling NICE criteria, and usually in combination with methotrexate." This statement would be congruent with the British Society of Rheumatology (BSR) Top Ten Quality Standards document which states that "People with RA should be offered biologic therapy as soon as possible after their condition fulfils NICE Technology Appraisal criteria, and should have their relevant clinical data on response and side effects recorded and shared with appropriate national databases."[6]	
148	030	AstraZeneca UK	Statement 5	Under draft quality statement number 5: Disease control, AstraZeneca is in agreement with the statement but would offer the following comments on the definition: - In the treatment escalation definition, the document refers to the use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs. As the review date for this quality standard is likely to be 2018, this definition should be broadened to account for any future drugs that may not fit under these drug definitions but may be available and receive NICE approval. - Additionally, the definition speaks about treatment escalation review every month, which we support so that patients do not stay on therapies that are not working for too long. This quality measure provides an opportunity to more actively ensure the right patient is on the right therapy. - - We are also supportive of the DAS 28 measurement and inclusion of physician/patient agreed upon targets, including productivity and quality of life targets. Targets should include monitoring early response as well as identifying a class of drug which may not be working for a patient to facilitate switching to a more appropriate treatment. Cycling through treatments that have the same mechanism of action may be futile1 and not cost effective.2 (References: 1: Navarro-Sarabia, F et al. BMC Musculoskeletal Disorders 2009, 10(91), pp1-7 and	Thank you for your support. The definitions section has been extended to clarify that treatment escalation relates to the use of disease-modifying antirheumatic drugs, glucocorticoids or biological drugs to control the disease (*in accordance with relevant NICE technology appraisals*), which should address the point you raise about new treatments that do not fall into the categories listed in the underpinning NICE guideline.

[6] http://www.rheumatology.org.uk/includes/documents/cm_docs/2012/t/top_10_quality_standards_for_ra.pdf

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				2: Sullivan, SD, et al. J Medical Economics 2013, 16(3), pp1-6.)	
149	002	Gloucestershire Hospitals NHS Foundation Trust	Statement 6	What do you mean by a multidisciplinary team with “arthritis expertise”? Would you expect the OT to have had specific post graduate training and/or work solely in this area.	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service. Please see the definition of a rheumatology service in statements 1, 2, 3, 6 and 7 in the final quality standard, which describes the composition of the team.
150	008	Podiatry Rheumatic Care Association	Statement 6	A timeframe for accessing MDT post diagnosis would help promote early intervention from a foot health perspective	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
151	010	British Medical Association	Statement 6	GPs need rapid access for advice too.	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
152	015	Roche products Ltd	Statement 6	CQRA have developed a Patient Reported Experience Measures (PREMs) questionnaire which is currently being piloted. Once it has been established how well the questionnaire captures the patient experience of RA services at participating study sites, the questionnaire could be considered as a recommended data source.	Thank you. NICE welcomes the development of tools to support measuring achievement of quality standards.
153	017	National Rheumatoid Arthritis Society	Statement 6	We suggest the text in paragraph 2 of the ‘Definitions’ guidance on page 15 should be strengthened to say that ‘patients with rheumatoid arthritis should be given a single point of contact responsible for co-ordinating their care’ as a means to promoting continuity. This is in line with the recommendations of an extensive multi-stakeholder exercise on the proposed rheumatoid arthritis quality standard which was conducted by the British Society for Rheumatology (Top Ten Quality Standards for RA, 2012).	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
154	018	British Society for Rheumatology	Statement 6	BSR supports this statement.	Thank you. This statement was not progressed to the final quality standard as the concept of

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					access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
155	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 6	ARMA suggest that the 'Definitions' guidance (page 15) for this statement could be strengthened by ensuring that people with RA receive care by multi-disciplinary team, and are provided a single-point of contact who is responsible for co-ordinating their care (i.e. a specialist nurse). This reflects recommendations from the British Society for Rheumatology's Top Ten Quality Standards for RA, 2012.	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
156	025	Arthritis Care	Statement 6	We welcome a QS on access to a MTD. We suggest the definition of a MTD also include the following medical professionals: o general practitioner o consultant orthopaedic surgeon o doctors in training (hospital and general practitioner) o pharmacist o social worker. An MTD should also have access to voluntary organisations involved in rheumatoid arthritis management.	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service. Please see the definition of a rheumatology service in statements 1, 2, 3, 6 and 7 in the final quality standard, which describes the composition of the team.
157	027	Royal College of Nursing	Statement 6	Draft quality statement 6 **Multi-disciplinary team - Definition** If this standard is to be implemented it is stating that patients will be able to contact a psychologist directly and self-refer. Many small units will struggle to access a psychologist**.** As current service provision is patchy and access is clearly limited. This might, therefore, prove quite a challenge to achieve or ensure those identified with a clear need for a psychology assessment may not receive it. It is however reasonable to include this standard as long a percentage it is not expected to be 100% achieved. - Access to psychologists is a vitally important aspect of care for RA patients, but access to such service is quite limited. Therefore, due to their importance in the patient care pathway, we very much welcome their inclusion in this standard – and hope that this will help support the future development of this particular aspect of patient care. One other point to make is that whilst most patients are offered access to MDTs, some patients refuse these offers for various reasons (which should be documented).	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service. Please see the definition of a rheumatology service in statements 1, 2, 3, 6 and 7 in the final quality standard, which describes the composition of the team, and refers to access to supporting specialties such as psychology. As stated earlier, quality measures should form the basis for audit criteria developed and used locally to improve the quality of health and social care. As part of developing these audit criteria the audit standards or levels of expected achievement should, unless otherwise stated, be decided locally. While typical aspirational achievement is likely to be 100% or 0%, realistic standards should take account of patient safety, patient choice and clinical

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					judgment.
158	028	AbbVie Ltd	Statement 6	AbbVie is supportive of this Quality Statement and would have no further additional comments.	Thank you. This statement was not progressed to the final quality standard as the concept of access to a multidisciplinary team was considered to be covered by other statements referring to the rheumatology service.
159	012	UCB Pharma Ltd	Statement 7	UCB Pharma would suggest defining 'rapid access', for example 'must have' in relation to flares and 'expected to have' for rapid access to other patient needs	Thank you. Please see revised statement 6 in the final quality standard, which specifically refers to rapid access (within 1 working day of contacting the rheumatology service) for advice relating to disease flares or possible drug related side effects.
160	015	Roche products Ltd	Statement 7	The term multidisciplinary team is used differently by clinical services and specialities. Membership, terms of reference and expertise is well defined in some settings e.g. cancer services and may be subject to peer review. The statement needs clarification to distinguish its meaning from QS 7. Suggested: **People with rheumatoid arthritis have access to ~~a multidisciplinary team~~ individual members of a team of healthcare professionals each with inflammatory arthritis expertise.**	Thank you. Please see revised statement 6 in the final quality standard which has been amended to focus more precisely on rapid access (within 1 working day of contacting the rheumatology service) to advice relating to disease flares or possible drug related side effects.
161	015	Roche products Ltd	Statement 7	We feel an important emphasis has been lost when compared to the statement considered by the TEG which referred specifically to disease flare. The BSR include rapid access for appropriate interventions for disease flare in their Top Ten Quality Standards for RA [(1)]. Incorporating text from the definition, including the aspirational timeline, would clarify the statement and achieve consistency with the style of QS 1, 2 and 3. ***Suggested: People with rheumatoid arthritis who experience disease flare, a sudden increase in pain or loss of function are seen urgently within 1 day of contacting the rheumatology service for advice or treatment.*** The British Society for Rheumatology 2012; http://www.rheumatology.org.uk/includes/documents/cm_docs/2012/t/top_10_quality_standards_for_ra.pdf	Thank you. Please see revised statement 6 in the final quality standard which has been amended to focus more precisely on rapid access (within 1 working day of contacting the rheumatology service) to advice relating to disease flares or possible drug related side effects.
162	015	Roche products Ltd	Statement 7	An appropriate process measure would be the proportion of patients with disease flare, a sudden increase in pain or loss of function who are seen urgently within 1 day of contacting the service.	Thank you. Please see revised statement 6 in the final quality standard, which incorporates this measure.
163	017	National Rheumatoid Arthritis Society	Statement 7	Given the importance of rapid intervention as a means to improving clinical outcomes and quality of life we believe it is imperative, for sake of clarity, and ease of measurement, that a time dimension should be added to this statement.	Thank you. Please see revised statement 6 in the final quality standard, which incorporates a time dimension of "within 1 working day of

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				The current wording of the quality statement does not provide sufficient guarantees to the patients that they will actually receive rapid access. In line with the recommendations of the British Society for Rheumatology's exercise on the proposed rheumatoid arthritis quality standard (Top Ten Quality Standards for RA, 2012), we believe people with rheumatoid arthritis should have rapid access to the rheumatology service for advice or treatment within 48 hours. The process section of the draft quality measure should therefore be amended to make explicit reference to the 'proportion of people with suspected rheumatoid arthritis who are offered advice or treatment within 48 hours'. A numerator should be introduced to measure the number of people in the denominator who are assessed within 48 hours, and a denominator should be introduced to measure the number of people that contact the rheumatology service. We suggest a new paragraph is introduced in the 'Definitions' guidance on page 16 that states rapid access should be achieved within 48 hours of first contact by the patient. We also suggest the text in paragraph 1 of the 'Definitions' guidance on page 16 should be strengthened to say that 'patients with rheumatoid arthritis should have access to a dedicated helpline available during normal NHS hours and staffed by the rheumatology team', this will strengthen uniformity of access for patients to their rheumatology service.	contacting the rheumatology service". The TEG did not feel they could be too prescriptive about local arrangements to facilitate rapid access given the lack of supporting evidence in the underpinning clinical guideline.
164	018	British Society for Rheumatology	Statement 7	BSR supports this statement.	Thank you for your support.
165	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 7	A time period should be added to this statement. A time frame of up to 48 hours is sufficed as it is in line with the British Society for Rheumatology's Top Ten Quality Standards for RA, 2012.	Thank you. Please see revised statement 6 in the final quality standard, which incorporates a time dimension of "within 1 working day of contacting the rheumatology service".
166	027	Royal College of Nursing	Statement 7	Draft quality statement 7 - **Rapid access**… This statement is essential and seems fine, although a next day appointment might be a challenge as some centres will struggle with urgent or next day appointment. Again we presume there would be qualifiers on these standards with regard to what can or is reasonable to offer? For example if a comprehensive telephone	Thank you. Please see revised statement 6 in the final quality standard, which has been refined to specifically refer to rapid access (within 1 working day of contacting the rheumatology service) for advice relating to disease flares or possible drug related side effects.

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				assessment and satisfactory support is provided by the nurse specialist then a next day appointment would not be necessary. Although there might be disparity between some patients' opinions of the most appropriate next step following a totally acceptable telephone advice. Although this would only be a very small group of patients we wonder how a service can reconcile this in the sense of managing the very few patients who may have a high emotional need for very regular access to rapid access service?	The TEG did not feel they could be too prescriptive about local arrangements to facilitate rapid access given the lack of supporting evidence in the underpinning clinical guideline.
167	027	Royal College of Nursing	Statement 7	As patient experience has been identified as an outcome measure for this standard, to help quantify such patient experiences, it may also be helpful to undertake parallel internal audits of the patient's experience/pathway, as this should aid and ensure that the overall information gained and conclusions drawn are more collaborative and qualitative and quantitative in nature.	Thank you. It is anticipated that audits will need to be conducted locally in order to assess achievement of the quality statement.
168	028	AbbVie Ltd	Statement 7	AbbVie is supportive of this Quality Statement and would have no further additional comments.	Thank you for your support.
169	013	University Hospitals Birmingham NHS FT	Statement 8	I do not know how this could be audited. There is likely to be considerable practice variation. Judgments about appropriateness of particular actions, that individual patients and doctors agree upon in consultations, and the evidence for a range of surgical procedures is wanting.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality standard.
170	017	National Rheumatoid Arthritis Society	Statement 8	We agree fully with the proposed wording of this quality statement.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality standard.
171	018	British Society for Rheumatology	Statement 8	BSR supports this statement.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality

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					standard.
172	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 8	ARMA supports this statement.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality standard.
173	027	Royal College of Nursing	Statement 8	Draft quality statement 8 - **Surgery - quality measure.** We are not sure which units will be able to identify the number of people for whom surgery may be indicated. The number of patients referred however can be identified We also presume referral to surgery will be supported by protocols/guidelines to encourage appropriate referral or specialist opinion.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality standard.
174	028	AbbVie Ltd	Statement 8	AbbVie is supportive of this Quality Statement and would have no further additional comments.	Thank you. This statement was not progressed to the final quality standard because it was considered to be subjective, difficult to audit, and covered by the statement on annual review, which includes a requirement to assess the need for referral for surgery. Please see revised statement 7 in the final quality standard.
175	002	Gloucestershire Hospitals NHS Foundation Trust	Statement 9	At present in Occupational Therapy we don't offer people with RA a comprehensive annual review. It is a good idea, but I would question whether we and other departments have the resources available to do this.	Thank you. Please see statement 7 in the final quality standard, which has been revised to clarify that the annual review is coordinated by the rheumatology service.
176	010	British Medical Association	Statement 9	The comprehensive annual review should be performed by clinicians with particular expertise in rheumatology, which would normally be in secondary care. This review would require a level of expertise above that of the ordinary General Practitioner, and if it is to take place outside secondary care would need specific commissioning arrangements.	Thank you. Please see statement 7 in the final quality standard, which has been revised to clarify that the annual review is coordinated by the rheumatology service.
177	011	The Work Foundation	Statement 9	The statement on an annual review is welcome, especially as the content includes 'assessing the effect that the disease is having on a person's life'. Around 30 per cent of people with chronic musculoskeletal conditions (e.g. back pain, arthritis)	Thank you. Please see revised statement 7 in the final quality standard, where employment status is now explicitly referenced (in the

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				also have depression or anxiety. However, work should specifically be included as a point for discussion during these annual assessments as part of inclusion of work in the overall programme of care.	definitions section) as part of the annual review discussion with the patient about how the disease is affecting their life.
178	015	Roche products Ltd	Statement 9	To ensure comprehensive annual review is offered to all RA patients and in addition to other review appointments we feel the definition would be clarified by the following additional text, reflecting NICE clinical guideline 79: **~~A comprehensive annual review includes~~ Patients with established uncontrolled and controlled RA require review appointments at a frequency suitable to their needs. In addition, a comprehensive annual review should include:"**	Thank you. Please see revised statement 7 in the final quality standard, where the definitions section has been extended to clarify that elements of the review may need to occur more or less often than the annual timeframe. For example, it may be most appropriate to assess for fracture risk at 24-month intervals, whereas advice on self-management or treatment review may occur more regularly.
179	017	National Rheumatoid Arthritis Society	Statement 9	We suggest the bulleted list of items to be covered in the comprehensive annual review should be extended to include specific reference of the need to discuss pain management, as this is mentioned in NICE Clinical Guideline 79 on Rheumatoid Arthritis (2009) but not mentioned at all within the quality standard. There is also no explicit mention of care plans even though the NHS Commissioning Board has set a specific objective to ensure that all people with a long-term condition are offered a personalised care plan that reflects their preferences and agreed decisions (NHS Commissioning Board Mandate, 2012). Care plans therefore ought to be referenced in the bulleted list of items to be covered in the comprehensive annual review. The list should also be extended to include reference to work as this is a key opportunity to ensure the quality standard contributes to employment objectives specified in Domain 1 of the Adult Social Care Outcomes Framework 2013-14 and Domain 2 of the NHS Outcomes Framework 2013-14.	Thank you. Please see revised statement 7 in the final quality standard, where symptom control, pain management, care planning and employment status are now explicitly referenced (in the definitions section) as part of the annual review discussion with the patient.
180	018	British Society for Rheumatology	Statement 9	BSR supports this statement.	Thank you for your support.
181	019	The Arthritis and Musculoskeletal Alliance (ARMA)	Statement 9	ARMA supports this statement.	Thank you for your support.
182	020	MSD Ltd	Statement 9	MSD is concerned that an annual review is too infrequent and is misaligned with the monthly to six-monthly reviews advocated by the EULAR treatment-to-target guidelines ("Measures of disease activity must be obtained and documented regularly, as frequently as monthly for patients with high/moderate disease activity	Thank you. Please see revised statement 7 in the final quality standard, where the definitions section has been extended to clarify that elements of the review may need to occur

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				or less frequently (such as every 3-6 months) for patients in sustained low disease activity or remission" - Smolen et al., Ann Rheum Dis. 2010; 69: 631-97) MSD kindly suggests that at a minimum, patients should receive a 3-monthly disease review including the key components, i.e. "assessing disease activity and damage, and measuring functional ability", with other components of the review perhaps being assessed only annually to limit the burden to the rheumatology service	more or less often than the annual timeframe. For example, it may be most appropriate to assess for fracture risk at 24-month intervals, whereas advice on self-management or treatment review may occur more regularly. Please see statement 5 for reference to more regular monitoring to achieve disease control.
183	021	Napp Pharmaceuticals Limited	Statement 9	There are a number of quality statements where it would be useful to include pain assessment (other than indirectly within DAS28). We suggest adding this as a specific quality measure within the initial assessment (statement 2), initiating treatment (statement 3), disease control (statement 5) and in the annual review (statement 9). Recording of pain scores and sharing information on pain levels between HCPs should take place. It may also be useful to provide information on when appropriate referrals should be made to the pain team, either via the RhA team or directly by the GP. Controlling the disease may be the mainstay of the RhA teams, whilst controlling the pain is as important to the patient as the disease itself. Therefore, involvement with the pain team as early as possibly in conjunction with the RhA team could be recommended. The mandate from the DOH to the NHS Commissioning board identifies that improving quality of life for patients with long term conditions is a key objective. Ensuring that pain is controlled in parallel with improving disease state in RA is a way of improving QOL for this LTC.	Thank you. A statement on symptom control was not progressed to the final quality standard as it was considered to represent standard care. It may also be covered by cross-cutting quality standard topics that have been referred to NICE, such as pain management, and long term conditions. However, symptom control and pain management has now been included as a key aspect of the review process (please see reference to this in statement 7 in the final quality standard).
184	026	ABPI Pharmaceutical Rheumatology Initiative (ABPI PRI)	Statement 9	The ABPI PRI considers it desirable for this statement to make explicit that a disease activity score and HAQ assessment is conducted as part of the annual review. This would support quality statement 5.. An annual review may not be frequent enough, especially for patients with high disease activity who may require more frequent monitoring to measure the disease activity (as stated in EULAR guidelines, monthly to six-monthly reviews are recommended (Smolen et al ann Rheum dis 2010; 69:631)	Thank you. Please see revised statement 7 in the final quality standard, where the definitions section has been extended to clarify that elements of the review may need to occur more or less often than the annual timeframe. For example, it may be most appropriate to assess for fracture risk at 24-month intervals, whereas advice on self-management or treatment review may occur more regularly. Please see statement 5 for reference to more regular monitoring to achieve disease control.

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					Disease activity and HAQ assessment are explicitly referenced (in the definitions section) as part of the annual review discussion with the patient.
185	027	Royal College of Nursing	Statement 9	Draft quality statement 9 - **Annual review** This is excellent. Although we would like to see an emphasis on some component that includes patient centred approach to this annual review.	Thank you. All quality statements are patient-centred.
186	028	AbbVie Ltd	Statement 9	AbbVie supports the principle behind this quality statement which augments the complimentary Quality and Outcomes Framework indicator. This alignment should help to further drive best practice. However, AbbVie believe that further definition is required for this quality statement to have a meaningful impact on clinical practice because "comprehensive" is a subjective term. This could mean a thorough and detailed 30 minute conversation for one clinician but for another it could entail a DAS28 assessment. Whilst AbbVie recognise that supporting information is provided in the "definition" section of this quality statement, regular and careful disease activity measurement has not been specifically stressed and AbbVie would therefore suggest consideration is given to expanding the statement to: "People with rheumatoid arthritis have a comprehensive annual review, including disease activity score measurement and HAQ assessment." AbbVie welcomes the focus in the "definition" section of this quality statement referring to functional ability through the use of the Health Assessment Questionnaire given the wider societal impact of RA, such as on an individual's ability to walk, eat or dress. However, given the consultation notes that one third of patients will cease to be in employment after 2-years of symptom onset, AbbVie believe the assessment of an individual's ability to work is a glaring omission. Domain 2 of the NHS Outcomes Framework has employment for patients with long-term conditions as an indicators and this omission is incongruent with this NHS Outcomes Framework indicator given the high burden of worklessness associated with RA. AbbVie therefore suggest that a review on an individuals and workability and productivity should be assessed as part of the annual review.For those individuals beyond working age this could focus on ability to undertake usual daily activities. This assessment could be carried out using the Work Productivity and Activity Impairment (WPAI) questionnaire.	Thank you. Please see revised statement 7 in the final quality standard, which includes a definition of what a comprehensive annual review should entail. Employment status is now explicitly referenced (in the definitions section) as part of the annual review discussion with the patient about how the disease is affecting their life.

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187	029	Royal College of General Practitioners	Statement 9	This statement is meaningless unless the content of such a review is defined. What? Who? With what objective?	Thank you. Please see statement 7 in the final quality standard, which has been revised to clarify that the annual review is coordinated by the rheumatology service. The definitions section sets out what a comprehensive annual review should include.

Department of Health responded but had no comments

These organisations were approached but did not respond:

A.Menarini Pharma U.K. S.R.L.
Abbott GmbH & Co KG
Abbott Laboratories
Action on Hearing Loss
Action on Pain
Acupuncture Association of Chartered Physiotherapists
Aintree University Hospital NHS Foundation Trust
Alder Hey Children's NHS Foundation Trust
Allocate Software PLC
Amgen UK
Anglian Community Enterprise
Arrowe Park Hospital
Association for Family Therapy and Systemic Practice in the UK
Association of Anaesthetists of Great Britain and Ireland
Association of British Healthcare Industries
Association of Clinical Pathologists
Astrazeneca UK Ltd
Bailey Instruments Ltd
Barnsley Hospital NHS Foundation Trust
Barnsley Primary Care Trust
Bedfordshire Primary Care Trust
Birmingham City Council
Black and Ethnic Minority Diabetes Association
Boehringer Ingelheim
Bolton Council
Bolton Primary Care Trust
Bradford and Airedale Primary Care Trust

Bradford District Care Trust
Brahms UK Limited-Thermo Fisher Scientific
Bristol and Avon Chinese Women's Group
British Acupuncture Council
British Association for Psychopharmacology
British Association of Endocrine and Thyroid Surgeons
British Association of Hand Therapists
British Association of Prosthetists & Orthotists
British Cardiovascular Society
British Dietetic Association
British Geriatrics Society
British Health Professionals in Rheumatology
British Healthcare Trades Association
British Hip Society
British Lymphology Society
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Orthopaedic Association - Patient Liaison group
British Orthopaedic Association
British Pain Society
British Psychological Society
British Society for Surgery of the Hand
British Society of Rehabilitation Medicine
BSN Medical
Calderdale Primary Care Trust
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Capsulation PPS
Care Quality Commission (CQC)
Celgene UK Ltd
Central & North West London NHS Foundation Trust
Central Homecare Ltd
Clarity Informatics Ltd
College of Occupational Therapists
Commission for Social Care Inspection
Community District Nurses Association
Croydon Health Services NHS Trust
Department for Communities and Local Government
Department of Health

Department of Health, Social Services and Public Safety - Northern Ireland
Derbyshire Mental Health Services NHS Trust
Dorset Primary Care Trust
East and North Hertfordshire NHS Trust
East Sussex County Council
Equalities National Council
Expert Patients Programme CIC
GE Healthcare
General Chiropractic Council
General Osteopathic Council
George Eliot Hospital NHS Trust
Gloucestershire LINk
Great Western Hospitals NHS Foundation Trust
Grunenthal Ltd
Guy's and St Thomas' NHS Foundation Trust
Hammersmith and Fulham Primary Care Trust
Harrogate and District NHS Foundation Trust
Harrow Local Involvement Network
Health and Safety Executive
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Hertfordshire Partnership NHS Trust
Hockley Medical Practice
Home Office
Humber NHS Foundation Trust
Institute of Biomedical Science
Integrity Care Services Ltd.
KCARE
L.IN.C.Medical
LABORATORIOS ALMIRALL - R&D CENTER
Lancashire Care NHS Foundation Trust
Leeds Community Healthcare NHS Trust
Leeds Primary Care Trust (aka NHS Leeds)
Lilly UK
Liverpool Primary Care Trust
Luton and Dunstable Hospital NHS Trust
Manchester Metropolitan University
Meat & Livestock Commission
Medac GmbH

Medicines and Healthcare products Regulatory Agency
Menarini Diagnostics UK
Mental Health Act Commission
Mental Health and Substance Use: dual diagnosis
Merck Sharp & Dohme UK Ltd
Ministry of Defence
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Institute for Health Research Health Technology Assessment Programme
National Institute for Health Research
National Patient Safety Agency
National Pharmacy Association
National Prescribing Centre
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NDR UK
Neonatal & Paediatric Pharmacists Group
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Commissioning Board
NHS Connecting for Health
NHS Cornwall and Isles Of Scilly
NHS County Durham and Darlington
NHS Kirklees
NHS Plus
NHS Plymouth
NHS Sheffield
NHS Trafford
NHS Warwickshire Primary Care Trust
North and East London Commissioning Support Unit
North West Clinical Effectiveness Group for the Foot in Rheumatic Diseases
North Yorkshire & York Primary Care Trust
Oxford Health NHS Foundation Trust
Parenteral and Enteral Nutrition Group
Peninsula Community Health Services
PERIGON Healthcare Ltd
Pharmacosmos
Pharmametrics GmbH

Pilgrim Projects
Public Health Wales NHS Trust
RioMed Ltd.
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Roche Diagnostics
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Physicians
Royal College of Physicians of Edinburgh
Royal College of Psychiatrists
Royal College of Surgeons of England
Royal Pharmaceutical Society
Royal Society of Medicine
Sandoz Ltd
Sandwell and West Birmingham Hospitals NHS Trust
Sandwell Primary Care Trust
Sanofi
Scottish Intercollegiate Guidelines Network
SEIKAGAKU CORPORATION
Sheffield Primary Care Trust
Sheffield Teaching Hospitals NHS Foundation Trust
SNDRi
Social Care Institute for Excellence
Society of British Neurological Surgeons
Society of Chiropodists & Podiatrists
Solvay
South London & Maudsley NHS Trust
South Staffordshire Primary Care Trust
South West Yorkshire Partnership NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
St Helens and Knowsley Teaching Hospitals NHS Trust
St Mary's Hospital
Stryker

Teva UK
The Association of the British Pharmaceutical Industry
The British Homeopathic Association & Faculty of Homeopathy 131134
The British In Vitro Diagnostics Association
The Rotherham NHS Foundation Trust
The Stroke Association
The University of Glamorgan
UK Clinical Pharmacy Association
United Kingdom National External Quality Assessment Service
University Hospital Aintree
University of Nottingham
Vifor Pharma UK Ltd
Walsall Local Involvement Network
Welsh Government
Welsh Scientific Advisory Committee
West Midlands Ambulance Service NHS Trust
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Westminster Local Involvement Network
Wiltshire Primary Care Trust
Worcestershire Acute Hospitals Trust
York Hospitals NHS Foundation Trust