

Guidelines



British Society for Rheumatology and British Health Professionals in Rheumatology Guideline for the Management of Rheumatoid Arthritis (The first 2 years)

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KEY WORDS: Rheumatoid arthritis, Guideline, Management, Disease-modifying anti-rheumatic drug therapy, Multidisciplinary care.

Scope and purpose

Background to disease

In the UK, there are ~100 new cases of inflammatory joint disease per hundred thousand per year [1], of whom 24 would have rheumatoid arthritis (RA). Similar figures apply in Sweden [2]. The definition of an early RA is still not uniform. Despite most rheumatologists agreeing that RA could be diagnosed in patients with symptoms of <3 months and only a few affected joints, this does not reduce the delay in referral from primary to specialist care. Diagnostic delay might be avoided by using a referral guideline in order to establish patients on therapy [3]. Earlier referral from primary to secondary care is encouraged [4]. The provision of more capacity for patients with suspected early RA (seen within 2 weeks of referral) in 30% of the secondary care centres should result in earlier diagnosis and treatment of inflammatory arthritis.

Although there are other published guidelines on RA [5, 6], they have usually focused on medication, whereas the current guideline reviews all the common treatment options.

The American College of Rheumatology (ACR) guidelines should be seen as providing a range of acceptable practices rather than detailed guidance [7]. The validity of a guideline for RA could be tested [8] using a composite index of disease assessment, disease activity score (DAS)-28 [9], as the primary outcome measure; drug toxicity, disability, joint damage, quality of life, satisfaction with care, use of resources and direct costs could be secondary measures. The main problem with measuring effectiveness of guidelines is the failure of clinicians to adhere to them. This can only be addressed by making guidelines practical and feasible. Training in the use of guidelines, prior to implementation, is an essential requirement. For controlled studies, 'contamination' may occur, with patients being managed along the guideline even though they are not in the control group. Such considerations should form part of any future guidelines, and lead on to audit. In a survey of 1640 American rheumatologists, 43% agreed that the ACR guidelines for RA were useful; 43% reported that they were likely to improve quality of care; and 57% agreed that they did reflect their own personal clinical decision making. Therefore only 8% felt that there would be a likely change

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Submitted 16 August 2005; revised version accepted 8 November 2005.

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in practice [10]. In most clinical circumstances, the evidence base supporting any guideline recommendation is poor [11], leading to widespread use of hybrid guidelines, which incorporate clinical evidence and expert opinion. All guidelines should be viewed as work in progress.

Need for guideline

In light of the recent Arthritis and Musculoskeletal Alliance (ARMA) standards of care guidelines, the NAROT guidelines (National Association of Rheumatology Occupational Therapists) on arthritis and the BSR's own guidelines on management of people with RA, it may seem inappropriate to produce yet another set of guidelines on RA. However, the ARMA and BSR guidelines are primarily designed to ensure that the appropriate service provision is made for managing patients with RA. The current guideline provides practical help on how best to use available services and gives supporting evidence for the effectiveness of interventions in RA. Similar guidelines are being developed by EULAR and by the Spanish Society for Rheumatology (http://www.guideline.gov/summary/summary.aspx?doc_id=3683&nbr=2909&string=rheumatoid+AND+arthritis), concentrating primarily on the pharmacological management of RA, whereas the current guideline emphasizes a team approach to managing the disease.

Tight control of early RA has been compared with similar requirements for patients with diabetes and hypertension [12]. Recognition of early RA remains a challenge which may ultimately limit the quality of care that can be provided. Despite reductions in diagnostic delay, patients who wait over a year from symptom onset to referral to rheumatology clinics still have a 73% risk of establishing erosive change prior to treatment being initiated [13].

Variation in practice is considerable amongst rheumatologists—the interval between appointments usually reflects overstretched services with dual demands of delivering shorter new patient waiting times and serving the needs of patients with chronic inflammatory joint disease. RA in its severe form is a considerable health burden—in terms of chronic disability and also in terms of cardiovascular risk (the risk is higher than in patients with type 2 diabetes). We propose a model of care, based on the best existing evidence for early diagnosis and intervention in the ‘window of opportunity’, using disease modifying anti-rheumatic drugs (DMARDs) or biologic agents, with intense early education and secondary care management, with increasing emphasis on patient initiation and primary care management as the disease is stabilized [14], backed by a nurse-led yearly review. Expert patient programmes and self-care educational packages might prove effective in the later stages of the disease.

We aim to summarize best practice according to available evidence, whilst quantifying the evidence. The guidelines may recommend following one of the several possible management routes, where there is insufficient evidence to support the view that any one is superior to the others. This is the opposite of standardized care, but reinforces the concept of minimum acceptable standard of care. A guideline such as this one can be used to inform funding organizations of the real costs of managing complex diseases such as RA, thereby increasing the likelihood of appropriate support for patients.

In order to develop guidelines for the management of RA, we have reviewed current evidence for individual interventions. The aims of this guidance are as follows:

- (i) To develop protocol guidelines for management of rheumatoid arthritis;
- (ii) To seek to approve or recommend proven therapeutic interventions;
- (iii) To promote appropriate funding strategies for these effective remedies.

Objectives of guideline

The main aim of management of RA is to control the symptoms and signs of disease, maintain function and foster self-efficacy. All three are most likely to be achieved if inflammation is suppressed, suggesting that the rheumatologist and multidisciplinary team should aim to engage the patient in an individualized care plan, agreeing treatment goals which include an objective measure of disease. Options include the DAS (target: DAS-28 <2.6); clinical synovitis (target: undetectable; in practice, using currently available therapies, we still cannot achieve this but should be able to minimize synovitis) and C-reactive protein (target: undetectable); or, where available, ultrasound synovitis (target: undetectable; in practice, using currently available therapies, we still cannot achieve this but should be able to minimize synovitis). Ultrasound examination of joints for synovitis and erosions is possible in some centres, but there is currently no long-term evidence that its detection allows better disease control in the long-term. The aim should be remission. In practice, complete suppression may be unachievable, since it would require intensive pharmacological intervention with the potential to cause adverse drug reactions, require intensive hospital contact, resulting in significant impact on the patient's ability to work and function, and on their psychological state.

The objectives of this guidance are as follows.

Control of synovitis

This remains an essential part of the modern management of RA because synovitis causes symptoms, loss of function and loss of self-efficacy. Our aim should be to minimize clinical evidence of synovitis. Long-term outcome may improve (e.g. reduced joint replacements) as a result of treating patients within the first 3 months rather than the first 12 months; however, this needs to be tested.

Symptom control

This may be achieved using analgesics or anti-inflammatory drugs for pain relief and reduction of stiffness and swelling. Disease-modifying agents also play an important role in controlling symptoms. The symptom control measures also include the use of appropriate rest of joints when they are actively inflamed and exercise to maintain muscle power. Other examples of symptom control include the use of arch supports and MTP supports. The role of non-traditional therapies will also be discussed, such as acupuncture, herbal remedies and other alternative medical practices.

Self-management

This is an important part of the increasing empowerment for patients to learn more about their own disease and how to access the services to support them at a time that is appropriate for them. This has the dual attraction of giving patients more control over their chronic condition and making more efficient use of the primary and secondary care services in place to support them. Educational programmes are developing in rheumatology, and there is evidence to support their effectiveness, but it is likely that they will need to be ongoing and delivered at various times during the course of the disease.

Physical functioning

The role of physiotherapy and occupational therapy in early disease is to maintain or improve physical functioning and especially mobility. Most efforts should be directed at activities of daily living with particular attention to help in the workplace or for significant leisure activities. Therapy is believed to complement and enhance the contribution of pharmacological agents to improve and maintain physical functioning.

Psychosocial functioning

Psychological and social support should be considered an important aspect of assessment and management. The multi-disciplinary team all play essential roles in providing support for pain management, guidance on coping with the disease and encouraging positive attitudes towards self-management and adjustment to the diagnosis of RA. Individuals should have social and psychological support to enable them to stay at work and participate in normal activities of daily living. This can be achieved by working actively to support the individual in the workplace or where appropriate direct them towards support services to help them manage in their work place or home environment. This will involve liaison with patient-based organizations such as the NRAS and AC. Actual and potential psychological distress should be addressed through the multi-disciplinary team and appropriate agencies.

Screening/Monitoring

The use of DMARD therapy means that a regular monitoring programme is required to screen for drug toxicity. The individual components of the screening programme may vary from site to site depending on local availability, but the principle according to the relevant BSR guidelines for monitoring DMARDs should be adhered to. Annual assessment of potential complications of disease should also encompass the longer-term screening programmes for osteoporosis, evidence of joint failure, atherosclerosis and hyperlipidaemia. Some of the later complications may be more appropriately dealt with in primary care after the first two years. Screening will be discussed further in the next guideline on 'management of rheumatoid arthritis after the first two years'.

Target audience

The primary target of this guidance is health professionals and managers; however, it is also relevant to patients with RA, especially in the long-term.

The areas the guideline does not cover

The guidance is limited to recommendations during the first 2 yrs of onset of RA in adults. It does not deal with the management of other forms of arthritis, such as psoriatic arthritis, or give detailed guidance DMARDs or biologic therapy in RA because these areas are described in separate guidelines, and wherever appropriate, we have referenced these guidelines. A separate guideline on the management of RA after the first 2 yrs has been commissioned by the BSR for completion in 2006–07.

Stakeholder involvement

All are listed as authors.

Names and affiliations of users on the working party

All are listed as authors.

Involvement and affiliations of other people or organizations including user representative organizations and pharmaceutical companies in the development of the guideline

All are listed as authors.

Representatives from patient organizations (NRAS and AC) were involved at every stage. They made a significant contribution to the guideline development, by attending guideline group meetings, and/or contributing to the email discussions and revisions of the guideline, and are therefore listed as authors. No representatives of pharmaceutical companies were involved in guideline development.

A draft version of the guideline has been formally presented to members of the BSR for comment, and these comments have helped to formulate the current version.

Rigour of development

Statement of scope of literature search and strategy employed

A comprehensive literature search was undertaken prior to the development of this pathway and algorithm. Searches were conducted using MEDLINE, CINAHL, Cochrane, PUBMED, EMBASE, AMED and PsycINFO. MEDLINE is widely recognized as the premier source for bibliographic coverage of bio-medical literature and CINAHL for nursing literature. A manual search from the references cited by generated articles was also used. Search terms used were relevant to each section of the guideline. Evidence was graded according to the strength of literature to support each statement, using the grading suggested by the Royal College of Physicians (RCP) of London (<http://www.rcplondon.ac.uk/college/ceeu/conciseGuidelineDevelopmentNotes.pdf>) and the document was prepared in accordance with the principles outlined in the Appraisal of Guidelines Research and Evaluation (AGREE) guidelines (www.agreecollaboration.org).

Statement of when the guideline will be updated

In 2 yrs' time or earlier, if significant changes occur in the current management of RA.

Guideline itself

We have summarized the main points of the guideline in an algorithm (Fig. 1)

(1) A diagnosis of RA should be made as early as possible, on the basis of persistent joint inflammation affecting at least three joint areas, involvement of the metacarpophalangeal or metatarsophalangeal joints or early morning stiffness of at least 30 min duration. (grade of recommendation C)

The objective of early diagnosis and initiation of therapy for patients with rheumatoid arthritis may be very difficult to achieve in many patients but there is a concept of a 'window of opportunity' to treat patients. Primary care physicians tend to over diagnose RA, but the median time from symptom onset to establishing DMARDs is 19 months [15]. Skills in primary care do not always include adequate training in recognition of synovitis. Triage of patients with musculoskeletal problems can be done by primary care physicians, if they are provided with suitable training [16]. A triage service was developed for general practitioners or rheumatology nurses, in order to detect early arthritis [16]. Out of 96 patients seen, 49 were judged to have early arthritis by the supervising rheumatologist and levels of agreement were high with κ -statistics between 0.7 and 0.79. This supports the policy that diagnostic triage by trained general practitioners (GPs) and rheumatology nurses is an effective way of improving the pick-up rate of early arthritis in the community. This suggests that appropriate training/education of primary care can improve the effectiveness of early referral. It is recommended that better coordination is established between primary and secondary care in order to facilitate care for patients with RA.

Early arthritis clinics identify patients with RA, but 12.5–15% of the patients will ultimately have RA and any service provision must accept this inevitable yield of patients [17]. Early referral

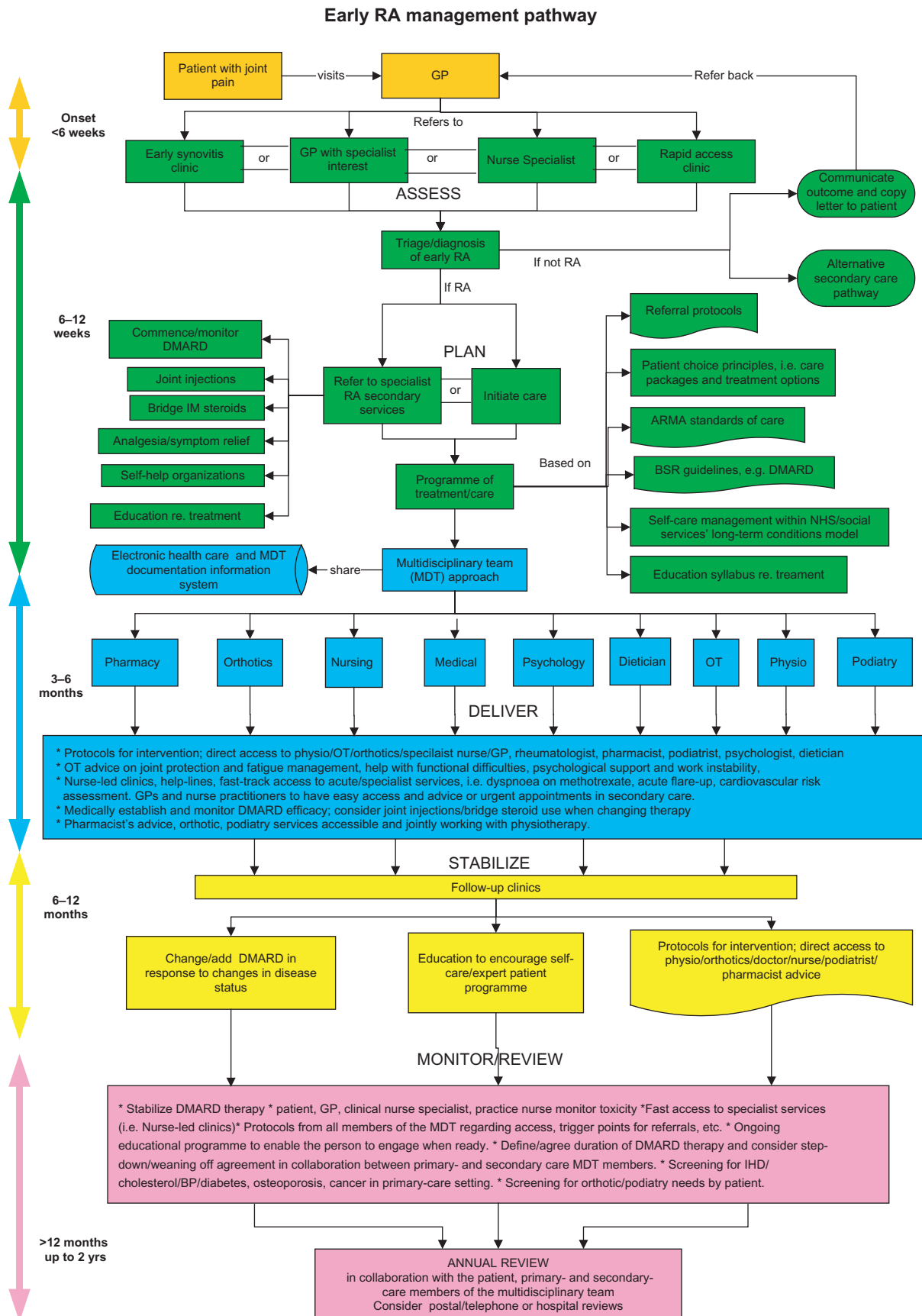


FIG. 1. Algorithm for the management of RA in the first 2 yrs.

recommendations on the basis of swelling of three or more joints, involvement of the metacarpophalangeal or metatarsophalangeal joints or early morning stiffness of at least 30 min duration should be considered as important pointers to the diagnosis of RA and prompt early referral to secondary care [18]. We must recognize that a lack of precise diagnostic criteria means that patients with undifferentiated arthritis and strong predictors of persistence would be candidates for receiving DMARD therapy [19].

(2) In order to identify and treat patients with RA at an early stage, it is necessary for patients with suspected early synovitis to have rapid access to a multidisciplinary team that includes specialists in rheumatology, and includes members from both primary and secondary care in order to provide a seamless service for patients. (grade of recommendation B)

Primary-care physicians manage large amounts of musculoskeletal complaints, occupying 20% of their work load. Identifying patients who have RA amongst these patients can prove challenging, but it is important because of the significant impact of this disease on long-term outcome. The ongoing involvement by both primary and secondary care in the long-term management of these patients is very important especially in view of the multisystem involvement in RA over time. Primary-care physicians should remain involved in the care of these patients and be responsible for their general medical health, particularly with regard to cardiovascular risk and the increasing use of statins to manage hyperlipidaemia. The primary-care physician is in a good position to encourage patients to exert more control over their disease and their disease management and assist patients in making choices on an informed basis [20].

Early arthritis clinics provide an opportunity to observe the natural history of patient-diagnosed arthritis with symptom duration of <2 yrs. In a Dutch study [21], over 400 patients were evaluated over a 6-yr period. It was clear that over the time period that the early arthritis clinic was established, there was a falling number of patients with a classical pattern of RA compared with patients having oligoarthritis. Therefore, the outcome from this group of patients improved over time in terms of radiological progression. However, this may also be attributed to the earlier use of DMARD therapy. More than 60% of the 108 patients attending an early arthritis clinic were diagnosed with RA and the majority were given that diagnosis on the first assessment; however, it was recognized that patients with RA were being referred significantly later than patients with other forms of inflammatory arthritis [22]. The lag time for referral for RA patients was 8 weeks compared with 4 weeks.

Coordination between primary and secondary care is always going to be difficult until we have integrated information technology (IT)/electronic patient-held records. Primary care is far ahead of secondary care in this respect and probably a majority of GPs now work with an electronic record, and some with no paper record. Problems of confidentiality and access have been overcome in some areas in patients with diabetes. We should follow this lead in rheumatology.

(3) Access to individual elements of the multidisciplinary service should be available according to patient need. (grade of recommendation B)

All patients with RA should have access to a multidisciplinary team assessment and intervention, as necessary, early in the disease process [23, 24]. The team approach has been shown to be effective in the management of patients with early RA [25].

Delivery of care from specialist secondary care teams produces better outcomes in RA than that from other providers [26]. Molcard [27] reviewed the data on potential benefit of the multidisciplinary team in managing RA. Staff of the multidisciplinary team includes rheumatologists, nurses, physical therapists, occupational therapists, social workers, orthopaedic surgeons, podiatrists, psychologists and dieticians. People with risk factors for poorer functional outcome and morbidity should be identified and referred for rehabilitation early [6, 28, 29, 30] to reduce the impact on the individual, family and society of biopsychosocial problems. Some patients, however, are likely to benefit from delayed access [30]. Patients who have not come to terms with having an incurable, chronic, disabling condition are unlikely to benefit from OT advice aimed at maintaining long-term function. Psychological issues are likely to be most important in determining how receptive patients are to educational opportunities to learn about their disease.

(4) Patients with RA should be provided with a plan of care from diagnosis which outlines the principles of management including a commitment to training patients to self-manage some aspects of their disease. (grade of recommendation C)

Education certainly plays a role in terms of patient knowledge gain and whilst acknowledging its role in striving to improve self-confidence, desirable behaviour and improved functional status [31], Oliver [32] suggested that educational programmes should not be regarded as a static one-stop package; all health-care interactions are potential educational opportunities. In early disease, education has shown benefit [33, 34]; however, it must be recognized that not all units have the resources to run formal educational programmes or sessions for their RA patients. Overall, patient education has small short-term effects on disability, joint counts, patient global assessment, psychological status and depression [35]. There is no evidence of long-term benefits in adults with RA. Research should be undertaken that evaluates the contribution of regular consultation early in the disease process and its educational impact on knowledge, self-confidence, desirable behaviour (concordance and compliance) and improvement to function and pain. Cognitive-behavioural approaches to self-management training should be used rather than an education-only approach.

(5) Specialist rheumatology nurses can provide the ideal support for patients in accessing elements of the multidisciplinary team and in providing important lifestyle advice. (grade of recommendation C)

Support for patients with RA should be tailored to their individual needs enabling them to become active participants in their disease management. Support should include access to a telephone help line, as studies have shown cost savings and high levels of patient satisfaction [36]. Early support and interventions can improve the patient's psychological functioning [37]. Prompt contact begins the process of enabling the patients to be informed about their disease and options available to them. It also enables a therapeutic supportive relationship to develop between nurse and patient at a time of significant life adjustment and uncertainty for the individual [38, 39]. Developing a strong and early therapeutic relationship with the individual enhances self-esteem, positive coping strategies and reduces early negative feelings that can lead to a loss of self-efficacy (the individuals' perceived belief in their ability to have control over their lives).

(6) RA is a significant independent risk factor for ischaemic heart disease, with the risk related to the severity and duration of inflammation. Control of inflammation should also be accompanied by addressing each patient's other risk factors for ischaemic heart disease, using the established primary care services where appropriate. (grade of recommendation B)

Over the past 50 yrs many cohort studies have demonstrated that RA patients have increased mortality rates with excess mortality from cardiovascular causes when compared with the general population [40]. However, it is not clear why RA patients should develop accelerated atherosclerosis. The mechanisms that promote premature cardiovascular disease (CVD) mortality in RA are likely to be multifactorial and include traditional CVD risk factors, the inflammatory disease process and the effects of its treatment. In addition, factors other than traditional CVD risk factors appear to be important in promoting CVD in RA. Elevated levels of inflammatory markers have been shown to predict CVD mortality in a cohort of seropositive RA patients [40]. Therefore, systemic chronic inflammation associated with RA may accelerate atherosclerosis. Treatments used during the course of RA also have the potential to influence CVD risk in RA. There is evidence that statins, used to treat hypercholesterolaemia, also have anti-inflammatory effects [41]. They have been found to reduce CVD events in patients with elevated C-reactive protein (CRP) concentrations even in the absence of hyperlipidaemia and have been shown to reduce disease activity in RA. Similarly, there is evidence that treatment with methotrexate can reverse the cardiovascular risk associated with active RA [42]. The recognition that the RA patient is at high risk of CVD should encourage screening and treatment of CVD risk factors in these patients. Recognition that screening for ischaemic heart disease (IHD) risk factors can be done effectively in primary care is to be welcomed although there needs to be an increased awareness of RA as an independent risk factor for IHD [43]. Lifestyle advice should be given to all RA patients to encourage smoking cessation, dietary modification and to encourage weight control and exercise. In addition, regular blood pressure monitoring and treatment of hypertension along with screening and treatment of hyperlipidaemia would be advisable.

(7) All patients should have their disease and its impact assessed and documented at onset, prior to starting DMARD therapy. Once established on DMARD therapy, all patients should have a formal assessment of treatment response, or lack of it, in order to justify continuing therapy or changing it. Remission should be defined and documented when achieved, in order to plan reduction or maintenance therapy. (grade of recommendation B–C)

Several studies show that irreversible damage occurs within the first 2 yrs of the disease [44], and evidence shows that therapeutic intervention at this early stage can improve the disease outcomes and reduce the progression of radiographic damage [45]. A window of opportunity in the treatment of RA has been described, a period of time when the disease is more responsive to therapy [46]. Some recent studies show that this window maybe as little as 3–4 months from the onset of symptoms [47]. This narrow time period identifies some challenges. The initial problem is the delay in presenting to a GP, and subsequently to hospital (see guidelines 1 and 2). But when the patient presents, we face the challenge of making an accurate diagnosis, clinically. The present 1987 ACR diagnostic criteria are not useful in early disease [48]. Undifferentiated arthritis is another potential drawback: a percentage of those cases will self-limit, and therefore, treatment

may not be appropriate [49]. The diagnostic process estimates the probability of the presence of disease from the information obtained through the assessment of the patient. A full clinical history and examination are essential as in any medical evaluation. Predictors of persistence such as duration of symptoms and morning stiffness seem to be the key data in making a diagnosis. Other details are useful additional information, such as presence of symmetrical polyarthritis, mode of onset and family history [50]. On examination, tenderness of MCP and MTP joints are specific but not very sensitive findings. More important is the presence of synovitis in three or more joints [51]. The presence of rheumatoid factor (RF) is part of the 1987 ACR criteria. Immunoglobulin M RF predicts persistent disease but its value decreases with age [52]. If anti-CCP (cyclic citrullinated peptide) testing becomes more widely available in future, the disease specificity and prediction value increases in conjunction with RF [53].

Prediction of the persistent cases, the ones that will end up with joint damage is the key in early RA. Studies have looked at predictive factors of arthritis outcome: including RF-positivity, disease duration, elevated erythrocyte sedimentation rate (ESR), polyarticular disease, female gender, HLA type 19. The Leiden model [50] proposed a duration of more than 6 weeks, morning stiffness of more than 1 h, arthritis in more than three joint groups, tenderness when compressing MCP/MTP joints, presence of RF and anti-CCP antibodies and erosions on hand/foot radiographs. This model could calculate predictor scores of persistence and erosive disease. This model was validated in Norfolk, but has limitations due to differences in patient characteristics and different populations [51].

Plain X-rays have been key investigations in the diagnosis of erosions, and therefore in predicting disease. Magnetic resonance imaging and ultrasound (USS) are more sensitive tools and can visualize early synovitis and erosions, not present in clinical examination and on plain radiographs. USS is becoming a popular tool in Europe, but still is limited to few units in UK and requires specific skills [54]. Imaging of the joints should be done at assessment and repeated at intervals of 6 months to 1 yr if erosions are not present, at least for the first 2 yrs [55]. In known erosive disease, this should be repeated when this would affect the management of the patient. Ultrasound assessment of erosions may be over seven times more sensitive than plain radiography [56].

Disease activity and response to treatment should be assessed with an objective method, ideally, one which can be reproduced and that can be used to monitor individual response to treatment. The DAS-28 is a validated tool to assess activity and can be used in the clinical setting. It has its limitations, such as the weight of different components such as tenderness when there are other associated painful conditions, but it is easy to use. The aim should be a DAS-28 <2.6 or at least <3.2 [57]. The EULAR response criteria are also a validated evaluation of response and based on DAS-28 [58]. If DAS-28 or EULAR response criteria are not used, objective assessments such as presence or absence of synovitis, joints affected and inflammation-markers such as ESR and CRP should be recorded in the notes. Remission should also be recorded when it occurs with a record of the criteria utilized. In the future, ultrasound may be a helpful tool in evaluating disease activity and remission, but further studies in its routine use should be done. Disability should also be assessed. Health assessment questionnaire (HAQ) is the most widely use method for functional status [59], but other validated methods can equally be used. As outlined in guideline 6, cardiovascular risk factors should form part of a routine assessment of early RA.

An economic evaluation of managing early arthritis suggests that the costs of managing early RA and early arthritis are considerable during the first few months of disease. Approximately half of the costs are associated with absence from work [60]. Measurement of outcome of treatment of arthritis could use work absenteeism as a marker of success or failure of treatment.

(8) Patients with RA should be established on disease-modifying therapy as soon as possible after a diagnosis of RA is established. Disease modifying therapy should be part of an aggressive package of care, incorporating escalating doses, intra-articular steroid injections, parenteral methotrexate and combination therapy, rather than sequential monotherapy, progressing to biologic (anti-TNF- α) therapy, when required. (grade of recommendation A)

DMARD therapy has become a mainstay of early intervention in RA (see BSR DMARD Guidelines, 2005). DMARDs are no longer regarded as 'second-line drugs', although the nomenclature is still occasionally used. Methotrexate has displaced sulfasalazine as the most commonly used first agent in the UK, with an increasing body of evidence supporting early diagnosis and intervention and aggressive packages of care, incorporating escalating doses, intra-articular steroid injections, parenteral methotrexate and combination therapy, rather than sequential monotherapy, progressing to biologic (anti-TNF- α) therapy, when required [61, 142].

There is clear evidence of disease modifying effect for methotrexate, sulfasalazine, leflunomide and intra-muscular gold [62], with less compelling, controlled data supporting reduction of erosions with hydroxychloroquine, penicillamine, oral gold, ciclosporin and azathioprine, although these agents do improve symptoms and some objective measures of inflammation. Choice of the first agent is based on the risk: benefit ratio with hydroxychloroquine an option in disease perceived as mild and methotrexate or sulfasalazine in those adjudged moderate-to-severe, or likely to progress [63].

Clinical trials using weekly methotrexate as the comparator suggest that the efficacy of methotrexate monotherapy is comparable to biologics in early disease [64]. Weekly methotrexate dosing has been shown to improve disease control compared with dosing every other week [65], whereas twice weekly dosing showed no additional benefit [66] in small randomized controlled trials. Oral methotrexate has been safely escalated in steps of 7.5 mg from 7.5 to 22.5 mg at 2-month intervals in at least one clinical trial [67], and some centres have an extensive safety experience of a weekly escalation protocol in 2.5 mg steps up to 20 or 25 mg, with adequate monitoring protocols in place [68]. Given that patient-centred goal-setting will usually be aiming to suppress measurable inflammation (see 'Objectives of Therapy'), we recommend a rapid dose escalation, titrated to patient response and side effects, to minimize the area under the curve of inflammation, which correlates closely with the progression of erosions and other surrogates for damage. The data on the efficacy and safety of high dose oral methotrexate is limited, but the bioavailability data for doses of 25–40 mg demonstrate that the parenteral route delivers a higher and more consistent serum methotrexate concentration [69].

Given that much higher doses (grams rather than milligrams) of this agent are used in chemotherapeutic regimes, there is an evidence base for safety of higher dose parenteral methotrexate. There are case series suggesting that switching to the parenteral route can improve response [70], but in the absence of controlled studies, the possibility of regression to the mean cannot be excluded. Nevertheless, the established long-term safety data on methotrexate and theoretical advantages of monotherapy make parenteral methotrexate an attractive option, especially where resource issues or clinical contraindications prevent the use of biologic agents.

Several studies have demonstrated at least equal safety and superior efficacy for combination therapy, compared with monotherapy [71]: these include the Rheumatoid Arthritis Investigational Network study [67] (methotrexate, sulfasalazine, hydroxychloroquine), COBRA (step-down prednisolone, sulfasalazine, methotrexate) [46]; and methotrexate-leflunomide [72]. Although, there was a

suggestion that a step-up regime adding ciclosporin to methotrexate improved disease activity [73], this trial design cannot exclude regression to the mean. More recently, the combination treatment with methotrexate, cyclosporine and intraarticular betamethasone compared with methotrexate and intraarticular betamethasone in early active rheumatoid arthritis (CIMESTRA) study compared an aggressive methotrexate regime with methotrexate-ciclosporin combination, where both groups had frequent intra-articular steroid injections, titrated to the abolition of synovitis [74]. This showed no benefit from the addition, with complete suppression of erosion in both groups.

Local injections of corticosteroids into joints can directly suppress synovitis and prevent the development of erosions in early RA [75]. In patients with less than five joints affected, a combination of steroid injections and aggressive DMARD therapy is particularly effective in preventing damage [74, 76, 77].

Biologic therapies available include infliximab, the prototypical humanized mouse monoclonal against TNF- α ; etanercept, a fully human soluble p75 TNF- α receptor; Fc fusion protein and adalimumab, a fully human monoclonal against TNF- α . All three biologic agents licenced for RA have similar efficacy data—the choice of agent will usually be made on the basis of cost and ease of administration in consultation with the patient and taking into account the patient's lifestyle. While infliximab was the only one originally requiring combination with methotrexate [78] (a licencing requirement latterly dropped), more recent data supports the use of methotrexate with etanercept [79] and adalimumab [80]. There is little published data on other DMARDs in combination with biologics and although the first reports from the BSR biologic register suggest that efficacy with other agents including leflunomide, ciclosporin and azathioprine [81]. Recent reports have suggested an increased rate of lymphoma with use of infliximab and etanercept [82], which may be a consequence of confounding by indication or 'channelling bias' (more severe disease leading to both lymphoma and use of a biologic [83]) in addition to the known increased risks of bacterial infections, tuberculosis and the induction of other auto-immune disease. Patients should be counselled about these risks in the context of the good short-term efficacy and the uncertainty of long-term safety and efficacy. Not all individuals respond to a given biologic agent and there is data supporting clinical response from switching agents, irrespective of the first-line biologic, although this data is also susceptible to confounding from regression to the mean. Numerous agents are in development for RA, including promising, novel B-cell approaches; however, these treatments are beyond the remit of these guidelines, which are restricted to treatments licenced for RA up to September 2004.

Most patients with early arthritis will not require biologic therapy, but where appropriate we recommend reference to the National Institute for Clinical Excellence (NICE) guidance and the separate BSR guidance on the use of biologic agents in RA.

(9) Systemic steroid therapy may have an important early role in establishing control of synovitis or bridging disease control between different DMARD therapies but long-term use is not justified. (grade of recommendation B)

The evidence for a disease-modifying effect of corticosteroids is conflicting.

There is clear evidence of the effectiveness of intra-muscular and intra-venous use of corticosteroids as bridge therapy when starting or increasing DMARDs [84, 85]. It seems that intravenous use may be associated with greater toxicity [86]. Evidence is also strong for corticosteroids helping to achieve rapid control of symptoms and maintenance of function [87, 88]. Aggressive step-down approaches including steroids seem to show superiority [89], but it is not clear if this effect could be entirely due to the steroid

component. There is conflicting evidence of the use of oral steroids in early RA. Despite studies showing a beneficial effect in radiographic changes [88, 90, 91], other studies have failed to show any differences [91] and a suboptimal use of DMARDs can be blamed for the differences. Oral steroids, even in low doses, are associated with long-term side effects and the cumulative effects of steroid therapy should be taken into account [92]. The negative effect of steroids on bone density may be counteracted by their anti-inflammatory effects, which would prevent the bone loss mediated by the inflammatory process itself [93].

Research comparing i.m. and i.v. routes, different doses and evidence of cumulative effect should be encouraged as well as more research in step-down approaches. When using corticosteroids in RA, osteoporosis prevention should always be considered following the National Osteoporosis Society/RCP guidelines [92]. The recent NICE technology appraisal for the secondary prevention of osteoporosis [94] gives clear guidance on treatment thresholds after fragility fracture and is due to report shortly on primary prevention. In conclusion, intra-articular corticosteroids and bridging therapy with intra-muscular and possibly intravenous corticosteroids are useful strategies to rapidly suppress inflammation when starting and increasing DMARDs.

(10) Patients with RA require assessment of both pain and optimum effective therapy to ensure early symptom control. (grade of recommendation A). Long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) should be at the lowest effective dose. (grade of recommendation A)

Effective therapy should combine optimum analgesia with enhancing functional status and minimizing side effects. Thus, choosing the appropriate analgesic requires assessment of both the type of pain and the patient's psychosocial situation [95]. When considering the trade off between the benefits and harms of NSAIDs and paracetamol, there is little controlled evidence that one is better than the other for RA [96], although one out of two phase three studies of etoricoxib in RA [97] showed greater improvement in pain and function with etoricoxib against both full dose naproxen and placebo, suggesting there may be real differences in efficacy. Weak and strong opiates are widely used to supplement other therapy in controlling pain, but again there is a paucity of data from controlled studies, particularly on long-term use. There is a need for one or more independently supported, high quality randomized controlled trials to determine the most effective strategy for pain relief in RA. At present, the use of single or compound analgesics or anti-inflammatory drugs (including coxibs) has to be agreed with each individual patient, in the light of rapidly evolving evidence and advice at the time of publication of this guidance. This has heightened the requirement for justifying the use of anti-inflammatory drugs rather than analgesia alone, after considering the gastrointestinal, renal, respiratory and cardiac risks for the individual [98].

(11) Current concern over the potential cardiovascular toxicity of coxibs and NSAIDs suggests that such drugs should be avoided in high risk individuals, and used with caution in others who cannot be managed with analgesia, steroid injections and one or more DMARDs. (grade of recommendation B)

There is clear evidence of efficacy of coxibs in the management of the symptoms of RA and the most consistent pattern of reduced gastrointestinal symptoms and events, including complications, of any anti-inflammatory gastroprotective strategy in clinical practice [99], despite the valid concerns that have been expressed about the selective publication of 6-month, rather than

12-month data in the Celecoxib Long-term Arthritis Safety Study (CLASS) trial [100]. Pain, function and composite measures such as the ACR 20 responses have been shown to be better than placebo for celecoxib [101], valdecoxib [102] and etoricoxib in RA [97]. Similar published data supports the efficacy of rofecoxib, which has currently been voluntarily withdrawn by its manufacturer, in the light of data from the Adenomatous polyp prevention on Vioxx (APPROVe) study demonstrating an unequivocal but small increase in thrombotic events with long-term use [103]. In this study, 46 cardiovascular or cerebrovascular events occurred over 3059 patient-years on rofecoxib 25 mg, compared with 26 during 3327 patient-years on placebo, with the effect apparent after 18 months of treatment. Subsequent analyses have suggested that this is not only a class effect of coxibs, but those conventional NSAIDs, which had been assumed to be cardioprotective, are also associated with thrombotic risk. A retrospective analysis of the Kaiser Permanente database showed that compared with celecoxib, ibuprofen had a significantly increased relative risk of myocardial infarction of 1.26 and naproxen, a relative risk of 1.36 [104]. While this retrospective analysis was susceptible to bias, the replication of the finding—an increased risk of myocardial events on naproxen 440 mg a day compared with placebo, an NIH sponsored Alzheimer's study [105]—suggests that NSAIDs also carry this risk. More information is available at <http://www.fda.gov/bbs/topics/news/2004/NEW01148.html>.

(12) Patients with RA require early assessment of sleep patterns. (grade of recommendation A) Early management of sleep disturbance should include tricyclic agents, behavioural therapy and consider also the use of exercise. (grade of recommendation B). Consider the impact of fatigue on quality of life in early RA. (grade of recommendation B)

Fragmented sleep and sleep disturbance is a significant problem in patients with RA, especially during disease flares [106, 107]. Management may include complementary therapy, cognitive-behavioural approaches and pharmacological management. Anti-depressants are used to aid sleep because of their effect on serotonin metabolism [106]; however, their effectiveness has yet to be proven. Tricyclic agents may improve sleep in the short-term but may induce drowsiness [108]; benefits are greater when combined with behavioural therapy and exercise [109].

Fatigue is associated with pain; sleep disturbance and depression in patients with RA; however, it does not appear to be associated to the inflammatory process [110]. A strong association between fatigue and work dysfunction and general health measures has also been reported [111].

Exploring the concepts of fatigue and patients' experiences has highlighted the impact on quality of life and the variability of professional support [112]. In addition, a survey of 143 RA patients, using checklist individual strength (CIS) (a 20-item questionnaire measuring 4 aspects of fatigue) showed that 40% of the patients reported severe fatigue calling for more research to determine its course and for the development of optimal treatment interventions [113].

(13) The evidence for the effectiveness of complementary therapy is conflicting and no firm recommendations can be made. (grade of recommendation B)

About 30% of the UK population has used, or is using, some form of complementary medicine. This increases to nearly 60% among people who have arthritis (it is likely that the majority will be OA sufferers rather than RA). Examples include acupuncture, Alexander technique, aromatherapy, chiropractic and massage. In a patient survey undertaken by NRAS in 2003,

most respondents (89% out of 200 people surveyed) used pharmacological treatments to help them control their symptoms, although 64% said they used diet and exercise programmes in addition to their drug treatment. The vast majority (95%) thought that medication, above other methods, had the most impact on their condition. Only a small percentage of respondents used alternative therapies such as evening primrose (4%) or a medical herbalist (1%) or self-help programmes (3%). Although the evidence supporting the benefits of complementary therapies in arthritis is limited, for some, these treatments can help alleviate symptoms such as pain and stiffness as well as dealing with some of the unwanted effects of taking drugs. Complementary therapies can play an important role in encouraging positive changes in lifestyle and outlook. However, it is particularly important that complementary therapies do not replace prescribed treatment. People with arthritis take a huge range of supplements, but the lack of good quality research into their benefits makes it difficult to advise patients appropriately. There is little evidence that they improve RA or its symptoms. Individuals taking complementary medicines should always be encouraged to tell their doctor, nurse or pharmacist about these therapies when being treated with other medication. The increasing popularity of the use of complementary and alternative interventions or treatments is particularly evident amongst people with chronic disease. In the treatment of RA, one therapy that has been identified as having potential benefit is herbal medicine (phytotherapy). In a review of 11 studies [114], seven compared gamma-linolenic acid (GLA) with placebo; three studies were not suitable for data pooling. The remaining studies looked at four different herbal interventions. All the GLA studies reported clinical improvement but methodology and study quality was variable. Apart from one therapy (*Tripterygium wilfordii* hook F), no serious side effects were reported. There may be potential benefit for the use of GLA in RA, but further studies are required to establish optimum dosage and duration of treatment.

There is little or no evidence base for the use of complementary therapies with regard to the impact on the disease; however, therapy such as gentle massage, reflexology, Indian head massage, use of essential oils to promote relaxation can provide temporary symptom relief and make the patient feel better within themselves and more able to cope with their disease. Unfortunately, the evidence base for these interventions does not exist. The following article by David L. Scott [115] on homeopathy is a useful reference: http://www.rheumatoid.org.uk/1/medinfo_280904_homeopathy.php.

(14) Timing and format (group/individual/written) of education to meet individual needs must be considered in early disease. (grade of recommendation A)

Patients should be offered a cognitive behavioural approach to patient education, delivered at the appropriate time in order to promote long-term adherence to management strategies. (grade of recommendation C)

Patients should be helped to contact support organizations such as NRAS, Arthritis Care (AC) and the Arthritis Research Campaign (ARC). (grade of recommendation B)

Education is important in providing knowledge to patients about their disease, but is also important in improving self-confidence and better functional status [31]. Focusing education on patients with early disease has shown benefit [33, 34]; however, not all units have the resources to run formal educational programmes or sessions for their RA patients. Patient education needs to be individually tailored and should be provided in line with the patient's needs. Educational programmes are not static one-stop packages; every consultation with a health

professional is an opportunity for increasing patient knowledge and awareness of their disease and to provide help to encourage self-management [32]. However, only 50% of the people with RA consider that attendance at group education to be useful [116]. Many self-help groups, whether attached to a multi-disciplinary team within an National Health Service (NHS) Trust or independent groups, are populated by elderly patients, which many younger and/or middle-aged people with RA can find off-putting. Self-help groups are often held during the working day or very early evening when working people or people with families find inconvenient or impossible to attend.

Physiotherapists should provide patient education in conjunction with other members of the multidisciplinary team. Areas of particular significance for physiotherapists are likely to be associated with coping/management strategies, exercise and function, and this combination has been demonstrated to significantly improve knowledge, self-efficacy and early morning stiffness for up to 1 year post intervention [117, 118].

Health professionals could make better use of the resources of accredited voluntary organizations such as NRAS, AC and ARC, including referral of patients to their websites. All the articles written on the NRAS site are written in lay-language by members of the BSR and British Health Professionals in Rheumatology (BHPR) so that their relevance, currency and accuracy can be relied upon and they are specific to the patients in the UK. Some effects of arthritis on patients may prevent them from making use of educational opportunities; patients may not want to reveal what is really causing anxiety; for example, they might be worried about sexual and relationship difficulties caused by the RA or terrified of losing their employment. Such matters affect the patient at a very deep emotional level and not all members of the rheumatology team are trained to deal with these issues. Fortunately, most rheumatology practitioners do have the knowledge and skills to support their patients appropriately, but often people have to manage the challenges of their disease effectively in their own homes using the skills and knowledge that they have attained in their experience of RA over time. Initiatives such as the expert patient programme and volunteer networks provide support to develop self-management strategies [119, 120]. The NRAS support network was set up so that patients could be put in touch with others who have the disease to provide understanding and support.

Types of education available

Most rheumatology units run some form of group educational programme which is on-going during the course of the year. Details of what is available should be provided to each patient by the clinical nurse specialist or other allied health professional as soon as possible after the diagnosis as is appropriate to each patient.

The NHS provides training for long-term chronic conditions under the Expert Patients Programme and every Primary HealthCare Trust (PCT) should be providing such courses. Details are available in general practices. The courses are not disease-specific, run for a period of 6 weeks (one afternoon per week) and focus on self-management and coping strategies including building self-confidence.

The National Rheumatoid Arthritis Society have a national network of trained volunteers (all of whom have RA) to provide telephone support, at the time it is needed. The volunteers have access to all the services and medical advisors of NRAS and work with their local rheumatology teams to improve patient communication and support at a local level. For more details, contact Louise de Haan at NRAS on 01628 823524 or email louise@rheumatoid.org.uk; NRAS Help Line: 0845 458 3969 (9.30 am to 4 pm).

Arthritis Care provides courses called 'Challenging Arthritis' for people with all forms of arthritis. The course comprises 6 sessions of about 2.5 h each over a period of 6 weeks. The course includes topics such as relaxation techniques, drawing up exercise

programmes, improving communication with your doctor and how to self-manage better. For more information, contact Arthritis Care on 0207 380 6500 or look at their website www.arthritis.org.uk; Arthritis Care Help Line: 0808 800 4050 (12 pm to 4 pm).

Independent self-help groups. There are a number of independent self-help groups for people with all forms of arthritis, but they may not be as effectively publicized as other courses, and their quality cannot be guaranteed.

(15) Patients should be encouraged to pace activities and recognize the potential lower as well as upper limits of physical activity, facilitating a realistic readjustment of the patient's own expectations, guided by members of the multidisciplinary team. Patients should be helped to participate in exercise programmes. (grade of recommendation C)

Exercise may provide psychological benefits to patients by enhancing self-efficacy and well-being [121]. Low levels of activity have been linked to an increase in self-reported stress [122]. The inclusion of exercise in people's lives allows people to take more responsibility for their own management. Patients with early RA may be anxious about exercising; fearing it may exacerbate their disease. They should be provided early in the disease process with advice/instruction on effective exercise [123]. Promotion of, and adherence to exercise, is more likely to be successful if delivered through behavioural-based education.

(16) Aerobic exercise should be encouraged to help combat the adverse effects of rheumatoid disease on muscle strength, endurance and aerobic capacity, without, in the short-term, exacerbating disease activity or joint destruction. (grade of recommendation B)

There are three types of exercise that have a role in the management of early RA and which individuals may utilize depending on their condition:

Range of movement exercises: maintenance of range of movement relieves stiffness to help maintain or increase flexibility.

Strengthening exercises (e.g. weight training) to help keep/maintain muscle strength.

Aerobic/endurance exercise: this includes cycling, swimming and running. This type of exercise can improve cardiovascular fitness, help control weight and improve overall function.

In the elderly, progressive resistance training increases strength and has a positive effect on some functional limitations [124]. However, the effect of this intervention on more substantive outcomes such as measures of disability remains unclear. It is difficult to determine the balance of risks and benefits of progressive resistance training because adverse events have generally been poorly collected and recorded. Dynamic (aerobic) exercise in RA can be undertaken without exacerbation of disease activity in the short-term [125, 126]. Long-term effects are still not known. Aerobic exercise can lead to improvements both in physical status of patients: with changes occurring in muscle strength, aerobic capacity, exercise tolerance and function.

(17) Hydrotherapy should be accessible to maximize positive effects on pain, function and self-efficacy. (grade of recommendation C)

Six trials, representing 355 people, were included in a review of spa therapy in RA [127]. Most trials reported positive findings

(the absolute improvement in measured outcomes ranged from 0 to 44%), but were methodologically flawed to some extent. A 'quality of life' outcome was reported by two trials. None of the trials performed an intention-to-treat analysis and only two performed a comparison of effects between groups. Pooling of the data was not performed; because of heterogeneity of the studies, multiple outcome measurements, and the overall data presentation was too scarce. Balneotherapy [127] trials suffer from poor methodology, analysis and lack of sensitivity of outcome measures. The available evidence suggests that hydrotherapy provides physiological, clinical and psychological benefits to patients [128].

(18) TENS use in RA patient may be effective in pain relief, but trials lack standardization. (grade of recommendation C)

There are conflicting effects of transcutaneous electrical nerve stimulation (TENS) on pain outcomes in patients with RA [129]. Acupuncture-like TENS (AL-TENS) is beneficial for reducing pain intensity and improving muscle power scores over placebo, while conversely, conventional TENS (C-TENS) resulted in no clinical benefit on pain intensity compared with placebo. However, C-TENS resulted in a clinical benefit on patient assessment of change in disease over AL-TENS. More well designed studies with a standardized protocol and an adequate number of subjects are needed to fully conclude the effect of C-TENS and AL-TENS in the treatment of RA of the hand.

(19) Heat and cold applications may provide short-term symptomatic relief of symptoms of pain and stiffness. There is no evidence of long-lasting benefit. Paraffin wax baths combined with exercise are beneficial for hands in arthritic conditions. (grade of recommendation C)

Heat and cold applications are routinely used to relieve symptoms of pain, stiffness, muscle spasm and swelling in patients with RA: heat seeming to be more effective in the relief of stiffness and cold for pain relief [130, 131]. Cold rather than heat is recommended for active joints. Superficial moist heat and cryotherapy can be used as palliative therapy. Paraffin wax baths combined with exercises can be recommended for beneficial short-term effects for arthritic hands, but the trials are hampered by poor methodology [132]. Overall, there was no measurable benefit from heat or cold therapy in seven studies involving over 300 participants. There is no evidence that heat or cold has any adverse effects on disease progression or joint destruction [131, 133].

(20) Joint protection, energy conservation and problem-solving skills training should be taught early on in the disease course. (grade of recommendation B)

OT interventions (classified as comprehensive therapy, training of motor function, training of skills, instruction on joint protection and energy conservation, counselling, instruction about assistive devices and provision of splints) for RA were tested for their ability to improve function, social participation and/or health-related quality of life [134]. The results of the best evidence synthesis shows that there is strong evidence for the efficacy of 'instruction on joint protection' (an absolute benefit of 17.5–22.5, relative benefit of 100%) and that limited evidence exists for comprehensive occupational therapy in improving functional ability (an absolute benefit of 8.7, relative benefit of 20%). Indicative findings for evidence that 'provision of splints'

decreases pain are found (absolute benefit of 1.0, relative benefit of 19%). The timing of intervention is important. Positive changes in health behaviour are more likely when the person sees it as relevant to their needs at the time.

(21) Hand function should be maintained and improved with a combination of hand exercises and appropriate devices to improve efficiency of action. OT can be helpful for those experiencing problems at work when these are due to the symptoms of arthritis. Altering work methods, posture, pacing and assistive devices can improve functional ability. (grade of recommendation C)

Approximately 60% of the people experience functional difficulties in the early course of their disease. Activities commonly affected include household tasks, leisure, work and parent and family roles. Changing the way people perform tasks, as well as the use of assistive devices, can help people regain functional independence [30].

(22) When hands and wrists are painful and/or swollen, splints (hand/wrist resting splints and functional wrist splints) should be offered, but the role of splinting at other times remains uncertain. (grade of recommendation C)

There is insufficient evidence to make firm conclusions about the effectiveness of working wrist splints in decreasing pain or increasing function for people with RA [134, 135]. Potential adverse effects, such as decreased range of motion, do not seem to be an issue although some of these splints decrease grip strength and dexterity. Similarly, preliminary evidence suggests that resting hand and wrist splints do not seem to affect range of motion (ROM) or pain, although participants preferred wearing a resting splint to not wearing one. There is evidence that extra-depth shoes and moulded insoles decrease pain during weight-bearing activities such as standing, walking and stair-climbing. Supported insoles may be effective in preventing progression of hallux abductus angle but do not appear to have any impact on pain.

(23) The goals of foot care for patients with RA are to relieve pain, maintain function and improve quality of life using safe, cost-effective treatments such as palliative footcare, prescribed foot orthoses and specialist footwear. An annual foot review and assessment is recommended for patients at risk of developing serious complications in order to detect problems early. Foot orthoses are an important and effective intervention in RA. (grade of recommendation B)

Podiatry services should provide a specific and dedicated service for the diagnosis, assessment and management of foot problems associated with RA. A full-time dedicated podiatry clinical specialist in rheumatology is essential [136]. Timely intervention for acute problems is important, and may require the input from other members of the multidisciplinary team. Multidisciplinary care should be available for the timely management of lower limb and foot pathologies to improve clinical outcomes and patient satisfaction. Provision of the appropriate facilities/skills for vascular and neurological assessment is necessary, since patients with RA are more at risk than the general population of generalized atherosclerosis, which results in circulatory insufficiency in the lower limb. Baseline and annual assessments of the vascular and neurological status of patients will

both identify and monitor any problems/changes [137]. Provision of appropriate facilities and skills for lower limb mechanics and foot pressure assessment is desirable [138, 139]. In-shoe foot pressure assessment will identify the effects of orthotic and footwear interventions [139, 140]. Provision of specialist footwear as retail footwear cannot accommodate some foot problems and the benefits of specialist footwear are recognized [141, 142].

(24) Health professionals should provide opportunities to discuss sexuality and relationship issues where these are affected by RA. Problems may include pain, dysfunction and changes in relationships, for example dependence and loss of role. Information and help on sexuality and relationship issues should be given backed up with written leaflets and contact details of organizations who can offer support. (grade of recommendation C)

A total of 78% of the respondents in a survey of 200 members of NRAS [143] (NRAS Beyond the Pain, 2004) reported that their condition had had an impact on their sexual relationships. For 37%, this impact was either 'major' or 'considerable'. Nearly 20% of single respondents agreed that their disease was the reason for the break-up of their relationship. Thirty-eight percent of the 25–34-yr-olds said RA made it impossible to have a lover. A total of 23% said RA prevented sexual activity, and 49% felt that RA inhibited their partner during sex.

This is a major problem area for people with RA and one which many health professionals are reluctant to discuss, and therefore do not create the right opportunities for people to open up on this subject. Men particularly have difficulty in addressing these types of concerns and worries. This is one of the reasons why a support network like the NRAS volunteer network is so important because it enables people to talk to others who really understand these issues.

Health professionals should provide opportunities to discuss sexuality and relationship issues where these are affected by RA. Problems may include pain, dysfunction and changes in relationships, for example, dependence and loss of role.

Information and help on these issues should be given, backed up with written leaflets and contact details of organizations who can offer support.

Early referral to nursing and therapies is recommended when a person with RA becomes pregnant. Problem-solving strategies should be taught and nurtured in parents with RA. These may include task analysis, alternative ways of doing things, provision of assistive devices and energy conservation. Further discussion of pregnancy is beyond the remit of this publication, but more information is available at the following website: http://www.rheumatoid.org.uk/1/ra_and_you.php#breastfeeding. http://www.rheumatoid.org.uk/1/medinfo_280904_pregnancy.php.

Applicability and utility

Potential organizational barriers to introduction

The provision of a seamless service between primary and secondary care may be hampered by a lack of IT capability. Early arthritis clinics are not widespread, mainly due to pressure on rheumatology services to provide care for the majority of patients who do not have early arthritis. Financial barriers exist, limiting the use of biologic agents, reducing the optimal provision of multidisciplinary teams, and provision of important equipment at home and in the workplace. Lack of awareness by the

multidisciplinary team of available resources to support patients (e.g. patient organizations).

Potential costs implications for introduction of Guideline

Service costs may be considerable if early arthritis clinics are to be provided.

Our goal should be to achieve a fully functional multidisciplinary team in every hospital which is managing patients with arthritis.

Mechanism for audit of the guideline

Audit for the RA guideline could be single centre or, ideally, multicentred in regions and should assess the impact of the pathway on the following outcomes:

- Synovitis
- Symptom control
- Erosive change
- Quality of life
- Self-efficacy

Patients with RA would have these outcomes measured before and after the guideline is implemented. A proposed audit of the guideline is outlined in Appendix 1.

Acknowledgements

Support from Mooka Siyomunji-Barker in the BSR office.

The authors have declared no conflicts of interest.

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Appendix 1. Proposed audit proformas and suggested analysis

Many aspects of the algorithm and guidelines could be audited. We suggest a proposed audit of the effectiveness of patient education provided by the guideline.

Evaluation of patient knowledge and its impact on self-managing behaviour using an evidence-based pathway of care for early RA patients.

Introduction

This audit aims to identify the contribution of patient knowledge and its impact on self-managing behaviour (concordance and compliance), functional status and pain levels in those with early RA using an evidence-based pathway of care.

Rationale and aims

Purpose of study

The purpose is to assess the effectiveness of a care pathway in patients with early RA using an evidence-based pathway of care, in terms of:

- Patient knowledge
- Self-managing behaviour
- Functional status
- Pain levels

Aims of project

- To test an evidence-based care pathway for RA patients which incorporates an algorithm of care.
- To evaluate the impact on patient knowledge and self-managing behaviour.

Objectives

- To produce and use a pathway of care which is evidence-based and utilizes current guidelines and standards for the management of early RA
- To identify patients newly diagnosed with inflammatory arthritis (RA) to commence on pathway and
 - Commence active management protocol
 - Commence/alter DMARD therapy
 - Control symptoms, NSAID, i.m. Depomedrone
 - Receive continuous appropriate education, drug and disease
 - Ensure monitoring programme continues
 - MDT—consultation
 - Six weekly follow-up until stable
- To evaluate pathway focusing on outcomes, processes and multiple stakeholder perspectives

Proposed outcomes

- Control disease activity
- Disease remission—DAS-28 < 2.6
- Knowledge assessment and retention
- Desirable behaviour (self-managing)
- Prevent loss of function
- Decrease pain
- Quality of life

This proposal aims to incorporate best evidence-based practice including relevant guidelines such as NICE within a care pathway for patients newly diagnosed with RA in order to streamline care, which is evidence-based (where possible) and patient-focused.

Methodology

- Design pathway
 - (1) Assess need for change in practice
 - (2) Link problem, interventions and outcomes
 - (3) Synthesize best evidence
 - (4) Design practice change
 - (5) Implement and evaluate change in practice
 - (6) Integrate and maintain
- Implement pathway and evaluate using Trident—three pronged approach to evaluation focusing on outcomes, process and stakeholder perspectives

Test outcome measures in clinic population 3 months before implementing guidelines and repeat audit 1 month after implementation and collect data for a further 3 months.

Setting

Rheumatology consultant outpatient clinics.

Audit patients and new RA patients

Potential newly diagnosed RA patients will be consecutively recruited from the rheumatology clinic.

Inclusion criteria

- Diagnosed RA according to ACR criteria
- To commence or commenced on DMARD therapy

Exclusion criteria

- Pregnant
- Under 18 yrs
- Learning disability

Evaluation research incorporating

Trident to assess patient/clinician outcomes (using HAQ, SF-36 and DAS-28, all validated tools plus recording of treatment and changes for both groups, patient diaries to record changes to physical functioning, mobility, pain, social functioning (work, hobbies), sleep, emotional status (life events, exercise), along side processes (use and evaluation of pathway) and multiple stakeholder perspectives (compliance with pathway) and recording of variance.

Case studies/questionnaire—patient/clinician compliance (Why does it work for patients/nurses?, why does it work, or why does it not work?).

Audit procedure

Conventional care (before guideline)	After implementing guideline
Patient diagnosed with RA	Patient diagnosed with RA
Treatment alteration	Patient commences RA pathway and attends early arthritis clinic
Follow-up as per conventional care	Follow-up as per pathway
Outcome measures collected 6 weeks, 12 weeks, 3 and 6 months, 12 months	Outcome measures collected 6 weeks, 12 weeks, 3 and 6 months, 12 months

References used in this document can be obtained from the BSR website, www.rheumatology.org.uk on the member’s portal in the Final Cabinet under BSR Draft Guidelines 2005.