



Royal College  
of Nursing

# Assessing, managing and monitoring biologic therapies for inflammatory arthritis

*Guidance for rheumatology  
practitioners*

*An advisory document prepared by the RCN Rheumatology  
Biologics Working Party, in conjunction with other members  
of the Arthritis and Musculoskeletal Alliance and members of  
the RCN Paediatric Rheumatology Specialist Nurses Group.*

## **Erratum**

***Assessing, managing and monitoring biologic therapies for inflammatory arthritis, RCN 2003.***

The following acknowledgment was omitted from the publication:

**During the development of the Rheumatology Forum document the University Hospital Birmingham NHS Trust, Department of Rheumatology's *Protocol for the administration of subcutaneous methotrexate by registered nurses, patients and carers*, as drawn up by Valerie Arthur and Dawn Homer, was consulted. This protocol is one example of good practice in the administration of subcutaneous methotrexate.**

## **Update**

Please see revised British Society for Rheumatology Guidance on the use of biologic therapies: Reference: Update on the British Society for Rheumatology guidelines for prescribing TNF $\alpha$  blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001). Ledingham J; Deighton C. *Rheumatology* 2005. 44. 157-163.



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# Foreword

*Professor D.G.I. Scott, President of the British Society for Rheumatology, and Chair of the RCN Working Party for Biologic Therapies*

The introduction of targeted biologic therapies for rheumatoid arthritis is one of the most significant developments in anti-rheumatic treatment of recent years. The role of TNF alpha in inflammation and the benefits of its suppression/blockade is also an example of one of the best bench-to-bedside research programmes in rheumatology. This research was pioneered by Professor Sir Tiny Maini and colleagues at the Kennedy Institute, and funded by the Arthritis Research Campaign (arc).

These biologic agents have dramatically altered clinical practice. Current guidelines (developed by the British Society for Rheumatology in 2003) restrict their use in the UK to patients who fail two or more conventional second-line agents. Increasing numbers of patients are now being treated with good effect, though the long-term complications of such treatment are not fully known. The British Society for Rheumatology developed its Biologics Register (BSRBR) to study long-term outcomes of these treatments over a five-year period. Biologic therapies are expensive and their introduction has been variable in uptake in different parts of the country. Since their approval by the National Institute of Clinical Excellence (2002), numbers referred to the BSRBR have increased exponentially, and it is expected that between 200-300 patients per half million population will be on biologic agents once full resources are available.

Current guidelines concentrate on indications/exclusions for treatment and on dosage. The drugs are, however, given in a clinical setting (often on day units) by practitioners including nurses, physiotherapists and junior doctors. Practical guidelines for such practitioners are not available and this was the main reason for setting up the Royal College of Nursing Rheumatology Biologics Working Party, which produced this document. It involved representatives of the whole multi-disciplinary team, including patients, and was supported by the Arthritis and Musculo-skeletal Alliance, which provided invaluable help.

The introduction of any new, potentially toxic and expensive agent requires careful monitoring by appropriately trained and skilled professionals. This document should aid this process significantly by forming a template for the practical use of biologic agents across the UK. Developments in biologic therapy are rapid and evolving, so we will review any change in practice and update the document at regular intervals.

As the current President of the British Society for Rheumatology, I have been very privileged to chair the working party, and would like to acknowledge the enormous work and efforts of all my colleagues involved, particularly Sue Oliver. I encourage practitioners involved in biologic therapy to access the document, promote the appropriate use of biologic agents and to demand adequate resources from the local health economy, involving, if necessary, patient groups as well as primary care trusts, strategic health authorities and if need be, politicians. We have, with the introduction of these treatments, an opportunity to improve significantly the health and well being of our patients.

# Introduction

The role of biologic therapies in the treatment and management of patients with inflammatory joint disease is an evolving area that has significant implications for all practitioners.

The number of patients with rheumatoid arthritis eligible to receive the biologic therapies is estimated at 40-50 patients per 100,000 of the population. These calculations are based on a model business case prepared by the British Society for Rheumatology (BSR), and may underestimate the true number of eligible patients. The BSR's work has shown that many patients have not yet gained access to these treatments, so the numbers of patients currently receiving biologics is small but expected to rise rapidly, assuming adequate resources are available for delivery. Research has also demonstrated the value of anti-tumour necrosis factor alpha (anti-TNF $\alpha$ ) treatments for other inflammatory diseases such as psoriatic arthritis and ankylosing spondylitis, increasing the potential usage of these drugs.

## Developing this guidance

In 2000, the British Society for Rheumatology set out criteria for selecting patients eligible to receive treatment with biologic therapies in England and Wales (note that in Scotland, the Scottish Consensus Guidelines (SCG) are used, and all data is forwarded to the British Society for Rheumatology Biologics Register [BSRBR]). The BSR criteria were selected to support guidance published in March 2002 by the National Institute for Clinical Excellence (NICE) concerning adults receiving infliximab or etanercept to treat rheumatoid arthritis (RA).

The British Paediatric Rheumatology Group prepared similar guidance in 2000 which was incorporated into 2002 NICE guidance concerning the use of etanercept in the treatment of juvenile idiopathic arthritis (JIA).

Most rheumatology and specialist paediatric rheumatology units are already administering these treatments, and the Royal College of Nursing (RCN) Rheumatology Forum Steering Committee, in consultation with health care professionals in a range of settings, identified an urgent need to provide guidance for practitioners on administering the drugs. The

Committee presented a proposal to develop guidance for nurses on the assessment, management and monitoring of patients receiving the targeted therapies, and this proposal was approved at the May 2002 meeting of the Arthritis and Musculo-skeletal Alliance (ARMA).

An RCN Rheumatology Biologics Working Party was set up to develop this guidance. This group was chaired by the President of the British Society for Rheumatology, Professor D.G.I. Scott - for full details of the composition and remit of the Working Party, see Appendix 8.

The Working Party considered three key issues:

- ◆ provision of guidance on specific clinical issues in the assessment and management of patients receiving biologic therapies
- ◆ nursing resource implications for biologic therapies. Although the biologic therapies have been endorsed for specific groups of patients by NICE, no funding has been allocated for additional nursing support
- ◆ the need for consensus and clarity about emerging evidence and what can be agreed as best practice.

## This document

The Working Party's recommendations for care are set out in this document. The guidance will help practitioners around the UK develop a standardised approach to caring for patients receiving biologic therapies and to reviewing that care. It highlights key issues and advises on best practice.

In some areas of clinical practice, the evidence to support best practice remains unclear. In these cases, we have provided advisory documents based on pragmatic clinical experience and on information from clinicians experienced in the assessment and management of patients receiving biologic therapies. An extensive reference section includes highlighted publications that we urge you to consult.

We have included a practitioner's workbook to aid a standardised assessment and management process. This is merely advisory, and you may prefer to modify your practice according to local need. Nevertheless, we stress the need for all practitioners to recognise the importance of collecting relevant data for the BSRBR, which is an integral part of NICE guidance on the use of etanercept and infliximab (NICE, 2002). For this reason, some sections of the workbook are designed to be used in conjunction with BSRBR documentation.

Biologic therapies are an evolving area of care, and in this document we also consider some of the issues for the future, such as resource allocation and how best to develop service provision to meet the growing demand.

## Children and young people

As specialist practitioners, it is very important that you are aware that children and young people require very specific treatment, which differs from the care of adults. Even though children or young people may currently be admitted to adult wards (although in line with the Children's National Service Framework for England each trust will now need to identify alternative locations to ensure children and young people receive care and treatment in specifically designated facilities to meet their distinct needs), their clinical care should be managed according to paediatric rheumatology criteria for disease classification and treatment - whatever the setting, you should seek guidance from a paediatric rheumatology consultant.

Part 2 of this document covers specific issues for the care of children and young people. It has its own reference section and appendices which refer specifically to paediatric care.

## Part 1: Adult patients

# Section 1: Assessment and management of patients

### a. Selection of patients

To ensure that the right patients are selected to receive biologic therapies, you should undertake a risk benefit analysis of each patient which is based on:

- ◆ fulfilment of BSR criteria for selection
- ◆ adherence to the requirements of the BSR Biologics Register and adequate data collection
- ◆ the patient's physical and mental health - this assessment should be supported by medical colleagues
- ◆ co-prescribing of Methotrexate, where co-prescribing is indicated on the summary of product characteristics (SPC). A prescribing physician *may* prescribe an alternative disease-modifying drug, although this is outside the recommended product licence
- ◆ local availability of the drug for eligible patients, at the correct dosage - ie, that there are no financial or other constraints on drug availability in your trust
- ◆ active participation by the patient in all aspects of decision-making about this treatment. Make sure they are given full education in the potential risks and benefits of treatment, and written information about the drugs (*see Appendix 2 and 3*)
- ◆ clear recognition by the patient of the criteria by which the benefits of their treatment will be assessed, and the possible reasons treatment might be stopped
- ◆ for subcutaneous self-administration - assessment of the patient's ability to self-administer. This should include a training plan (*see Appendix 4*)
- ◆ the level of social support and other contributing factors that may affect the patient's ability to cope with treatment.

Where patients do not fulfil the BSR criteria for treatment, but are considered eligible by their prescribing physician, the physician's reasons for this decision should be clearly documented and supporting evidence provided.

Where patients are not selected for treatment, or can't start treatment because of constraints on prescribing the drug, you must provide them with guidance and support.

### b. Assessment of patients before and during treatment

Before treatment begins patients should, if appropriate, be given the opportunity to select their preferred route of drug administration. They must be accurately informed about the drug therapy, and have signed the relevant consent forms for the BSR Biologics Register, and for local trust policy if necessary. You should document the patient's informed consent in their medical notes.

You should either complete the BSRBR documentation about the patient, or liaise with their physician to support its completion.

Before the patient's treatment begins, and during ongoing treatment, specialist practitioners should test and monitor the following.

#### Disease activity

- ◆ Disease Activity Score (DAS) of (DAS28) joint count on two occasions (one month apart) before treatment.
- ◆ The BSR recommends that a full disease activity assessment is repeated after three months of treatment. For patients receiving infliximab, this assessment may occur after the longest time interval between treatments in the early stages of care (third to fourth infusion): patients may therefore experience a flare in symptoms, so be cautious in interpreting the DAS at this time in these patients. Additional DAS may be required in some circumstances (for example, following a flare up, infection, injury, or surgery).
- ◆ Six-monthly DAS in patients continuing treatment.

### Bloods tests

These should fulfil the criteria for monitoring other disease-modifying drugs which are co-prescribed with biologic therapies. Before starting treatment, take the following:

- ◆ full blood count
- ◆ urea
- ◆ electrolytes
- ◆ liver function tests
- ◆ antinuclear antibodies (ANA)
- ◆ DNA binding.

### Infection

Maintain a high index of suspicion of infection, and screen appropriately. Ensure the patient is aware of their own responsibility for reporting any clinical signs and symptoms that might indicate an infection.

### Tuberculosis

Pay particular attention to the risk of tuberculosis (TB) - see *Appendix 5 on TB screening*. Before treatment starts, every patient should be screened for TB, including:

- ◆ full patient history
- ◆ checking for evidence of a BCG scar
- ◆ checking for evidence of TB contact by the patient and/or a history of TB among family members
- ◆ physical examination and chest X-ray before starting treatment (it is sufficient that adult patients should have had a chest X-ray within the last six months, unless they have current respiratory problems).

If there is any history of TB exposure a heaf test may be required - see *Appendix 5*.

### Acid fast bacilli

If the patient develops a productive cough (or haemoptysis), weight loss and fever, their sputum should be tested for acid fast bacilli (AFB). You should stop treatment with biologic therapies until the results of this test, and inform the patient's prescribing physician.

### Live vaccines

Live vaccines should not be administered concurrently in patients receiving biologic therapies (BSR guidelines on immunisation and screening for immuno-compromised patients, January 2002).

### Cardiac function

Clinical examination of the patient should include an assessment of their cardiac function (looking for, for example, at signs of breathlessness, ankle oedema), to ensure that any heart failure is well controlled. If the patient shows symptoms of poor cardiac function, refer them to their prescribing physician.

### Demyelinating disease

Check there is no personal history of demyelinating disease. If there is, discuss the situation with the prescribing physician.

### Weight

Patients who are to receive intravenous treatments should be weighed and the drug dosage calculated according to this weight - see *Drug dosages on page 8*.

### For subcutaneous administration of biologic therapies

You should prepare or make available a training package for the patient, who must have a clear understanding of their own responsibilities and have signed the relevant consent. See *Appendix 4*, and note that training videos are available from some of the pharmaceutical companies which provide these drugs for subcutaneous administration (see *Section 2c: Resources available from pharmaceutical companies, page 11*).

### Surgery

Although there is limited experience as yet of using biologic therapies immediately pre- or post- operatively, where possible patients undergoing surgery should not be treated with biologic therapies immediately before or just after surgery. We suggest that treatment is stopped or deferred for at least two weeks after surgery.

## c. Managing intravenous or subcutaneous biologic therapies

Practitioners who are going to administer biologic therapies using intravenous or subcutaneous routes should:

- ◆ have received specific training on the administration of biologic therapies and their side effects
- ◆ be competent in the education and training of

patients in self-administration of subcutaneous injections and disposing of equipment (this training may need to be supported by a local trust protocol or guideline) (*See Appendix 4*)

- ◆ be skilled in the administration and management of infusions and have been given education in administering infliximab
- ◆ have written guidance on the management of anaphylaxis and infusion reactions according to trust policy, and be provided with support by the trust.

In a setting where intravenous or subcutaneous therapies will be administered:

- ◆ a designated specialist rheumatology practitioner should be available on site for advice and to support the administration of the infusions/injections if required
- ◆ preparation of the infusion/injection should be undertaken according to the drug's summary of product characteristics (SPC), and administered within the stipulated time frame.

You must fully assess patients before infusion/injection. As well as the assessment set out above (b. *Assessment of the patient before and during treatment*), you should specifically include:

- ◆ routine questioning of potential infectious contacts (for example, chicken pox, TB). If you suspect an infection, consult the patient's prescribing physician. Caution: varicella immunity should be checked if an infection is suspected - see local trust or BSR guidance. The patient should confirm that they are not aware of any inter-current infections and that they don't have difficulty in breathing or any shortness of breath
- ◆ women of child-bearing age should confirm the date of their last period and confirm that they are using an effective method of contraceptive. Re-iterate the risks of a patient receiving these therapies if the patient could be pregnant
- ◆ patients who are to be treated with infliximab and have had a previous infusion reaction should be prescribed an appropriate prophylaxis, referring to your trust's policy or seek medical advice (*see Appendices 2 and 3*)
- ◆ obtain details of the patient's known allergies and review them with the prescribing physician. It is essential that all allergies are taken seriously.

## d. Following treatment with all biologic therapies

- ◆ If your observations following a patient's treatment indicate that there may be abnormalities, infections or reactions, or if you have any other doubts about whether to continue the treatment, you should seek advice from the specialist practitioner or prescribing physician. As all treatments are protein derivatives, you must be aware of potential reactions to treatment.
- ◆ In particular, you should observe and report any signs of rashes or lupus-like syndrome. In this circumstance, repeat blood tests for anti-double stranded DNA. If the tests are positive, review them with the prescribing physician.
- ◆ Make sure the patient knows their next treatment date, and when they need to have bloods and urinalysis repeated.
- ◆ Make sure patients know they should contact their local rheumatology department if they have any concerns about their health, or any signs of possible infection. Make sure they have out-of-hours contact numbers, using either the on-call GP service or on-call rheumatologist.
- ◆ Give them the date for the planned full assessment and review of treatment, which should follow three months treatment with biologic therapies.
- ◆ The patient's GP should be informed of the details of the treatment by letter. Make sure that they are aware of the BSR website for information on biologic therapies.

## e. Drug dosages

Note that these dosages refer specifically to treatments for adult patients - see *Part 2: Children and young people* for details on paediatric treatment.

The usual recommended dose for rheumatoid arthritis for:

### Infliximab

3mg per kg body weight administered 0, 2, 6 and then 14 weekly. Benefit of treatment should then be assessed at 3 months.

Further infusions continue at 8 weekly intervals if the patient is to continue treatment. Infliximab should be co-prescribed with Methotrexate.

Infliximab is not currently licensed for the treatment of psoriatic arthritis and ankylosing spondylitis. However, research data suggests that infliximab 5mg per kg body weight may be effective in treating these diseases, although some clinicians report benefit at lower dosages.

*See f. below for details of dosage and delivery for intravenous infusions of infliximab.*

### **Etanercept**

25mg subcutaneously twice weekly. Benefit of treatment should be assessed at three months.

Etanercept has a licence for treating patients with psoriatic arthritis at a dose of 25mg twice weekly by subcutaneous injection.

### **Anakinra**

100mg administered daily by subcutaneous injection. Benefits of treatment should be assessed at 3 months.

Anakinra should be co-prescribed with Methotrexate. In America anakinra is licensed for use as a monotherapy.

### **Adalimumab (D2E7)**

Adalimumab is currently pending a licence in Europe; this is expected during 2003. The expected licence is likely to be 40mg administered by subcutaneous injection every other week.

## **f. Dosage and delivery for patients receiving intravenous infusions of infliximab**

*See algorithm in Appendix 3, page 28, for more detail.*

- ◆ The administration of infliximab should be in an environment that has readily accessible resuscitation equipment.
- ◆ Make sure these patients know they should stay in the department for one to two hours following treatment for further observations.
- ◆ The infusion should be administered using an infusion pump. A sterile low protein binding filter (pore size <1.2µm) provided by the pharmaceutical company should be used with the giving set.
- ◆ The drug will be administered in a final volume of 250mls (drug + sterile water + normal saline) over two hours. See SPC instructions for detailed advice on reconstitution.
- ◆ You should make full observations of patients every 30 minutes during the infusion. These should include temperature, pulse and blood pressure.
- ◆ Side effects:
  - ◆ if the patient experiences mild side effects, the infusion should be slowed down (*Refer to Appendix 3.*)
  - ◆ if the patient experiences moderate to severe reactions, you must stop the infusion immediately and inform the prescribing physician. The patient may require symptomatic treatment and/or discontinuation of treatment. Emergency treatment may be necessary and may include the administration of anaphylaxis treatment by the practitioner according to local trust policy.
- ◆ When the infusion is completed, you should remove the giving set and continue observations at 30 minute intervals for the next *two* hours, until after the patient receives their fourth infusion, when the time for post infusion observations can be reduced to one per hour.

If all observations are satisfactory, the patient may be discharged home or returned to the ward area.

Note: if patients are comfortable and observations

are satisfactory after three months of treatment, patients can be discharged an hour after the infusion.

- ◆ All patients should be provided with an 'alert card', documenting drug dosage. They should have access to a rheumatology helpline during normal working hours or, if unavailable, information on access to emergency support. The patient should also have details of an emergency contact number, such as the on-call general practitioner service number or local accident and emergency department.
- ◆ For follow-up care, *see above, d. Following treatment with all biologic therapies.*

**Note:** Complete elimination of infliximab from the body takes approximately six months, so you should continue to monitor for signs of toxicity or infection for this period, even if treatment is discontinued.

## Section 2: Resource issues

The emergence of these new biologic therapies means there is now an urgent need for a review of the resources available to provide effective health care provision for rheumatology patients, both at national and local level. This is essential not only to resource current provision adequately, but also to plan for the increasing number of patients who will become eligible for these treatments each year.

Although the National Institute for Clinical Excellence supports the use of etanercept and infliximab for rheumatoid arthritis (etanercept for juvenile idiopathic arthritis), and some funding is available to provide these drugs, in many regions there has been little or no financial support for additional nursing or practitioner time to manage the treatments - leading to a significant impact on the ability of units to administer treatment to eligible patients.

This situation is set against developments of the last decade, with a growing population of patients, a reduction in in-patient bed quotas and, in some areas, minimum facilities for outpatient resources or day care units with specific emphasis on chronic disease management. For some units, the provision of a day care facility or access to beds has been the greatest hurdle in administering intravenous infusions and training patients to self administer subcutaneous injections. Other units have highlighted the lack of specialist practitioner staff or a shortage of equipment.

As a specialist practitioner, it is your responsibility to ensure that appropriate resources are available to provide safe and effective treatment in your unit. Each unit will have particular strengths and weaknesses in their team skill mix, level of medical support and facilities. In this section, we highlight resource issues to help identify acceptable standards in service provision, and to aid you in identifying and meeting service needs in your area.

To make sure your unit can access the resources you need to deliver these therapies, you will need to undertake a full analysis of current resources, needs and costs, and then prepare a business case to present to your trust which sets out a long-term strategy for service development.

Note that if you are planning services which include the care of children and young people, you should refer to Part 2, Paediatric Section 2, which highlights particular issues you will need to consider.

## a. Analysis of resources and costs

You should identify and include in your analysis:

- ◆ practical data on providing the service, for example, the number of infusions given before a patient's treatment is reviewed, frequency of treatments once established, the approximate number of episodes to train one patient in subcutaneous self-administration
- ◆ practitioners' time in the assessment, administration and monitoring of patients. It can be useful to demonstrate practitioner time per patient (*see Appendix 7*)
- ◆ training costs for computer skills, venepuncture, cannulation or teaching patients subcutaneous administration skills
- ◆ screening costs, including pathology, radiology and heaf testing, plus specialist support in interpreting tests and managing TB treatment
- ◆ equipment costs, including infusion pumps, infusion chairs or access to beds during the infusion, dressing packs and equipment for use during training for self-administered subcutaneous injection
- ◆ facilities costs, including clinic space for assessment and review, and treatment space for training or administration, and resuscitation support
- ◆ specialist personnel needs and costs, covering the provision of specialist practitioner expertise to ensure effective and safe practice. Each service's need for specialist practitioners will vary according to outpatient facilities and day unit facilities. It may be necessary to identify training or supervision time, rather than additional nursing resource, depending on your team's skill mix and expertise in the management of these patients. *For more detail, see also b. Specialist expertise below.*
- ◆ Clerical and information technology provision, such as the need for good local data collection and BSRBR data.

## b. Specialist expertise

The RCN Rheumatology Biologics Working Party prepared a competency framework to guide practitioners in this area, which is included as Appendix 6.

These competency levels will support you in recognising the range of skill mixes that can be used in providing rheumatology care. It is important to highlight, though, that this skill mix must include adequate specialist practitioner support for patients receiving biologic therapies. For detailed information of practitioner competencies please refer to *The Arthritis Research Campaign Proceedings 12* (2001).

The responsibility of a specialist practitioner is to:

- ◆ ensure that patients are adequately educated, assessed and monitored
- ◆ provide an opportunity for the patient to review their treatment options and, in particular, route of administration where appropriate
- ◆ ensure adequate supervision and training opportunities for junior medical or allied health care professionals
- ◆ cascade knowledge and expertise, crossing primary and secondary care boundaries to ensure that primary care teams are informed about new therapies. Enhance awareness of new therapies in secondary care (for example, in orthopaedics and general medicine)
- ◆ provide an effective patient telephone helpline and emergency service
- ◆ prepare documentation to support practice and set out a framework for good practice, including providing patients with supporting literature
- ◆ review service developments and continue to enhance care using evidence-based practice and keeping up-to-date with evolving provision of care
- ◆ support practitioners and their own learning needs by assessing and reviewing competencies and specific educational needs to reflect the changes in service needs.

## c. Resources available from pharmaceutical companies

The pharmaceutical companies which produce biologic therapies provide extra support to rheumatology units – support which has been crucial in keeping up current delivery of care. You need to be aware of the various packages of support available, which vary across the UK, so that you can use them when you are planning service development.

Before engaging pharmaceutical company support, you must get its use approved internally by seeking the department and trust's authorisation.

The following are examples of resources available from pharmaceutical companies.

- ◆ Home care services for patients using subcutaneous injections: home care services are available from each of the pharmaceutical companies producing drugs for subcutaneous injection. These services will provide nurses to train patients in self-administration (in the patients' home), arrange regular delivery of their treatment and collect clinical waste. Treatments delivered directly to the patient's home reduce the overall cost of purchasing the drug (VAT exempt). The service includes patient information literature, training videos and alert cards.
- ◆ Nurse support for intravenous infusions: the company Remicare provides two forms of nurse support. A liaison nurse with experience in rheumatology can provide support, advise on key elements of business planning and the clinical needs of the service; a 'sprint' nurse can be booked to support specialist practitioners in administering infusions to patients.
- ◆ Educating patients: all the pharmaceutical companies have a range of patient information literature, videos and equipment. There are a number of websites that the patient can access – these are listed in the reference section.
- ◆ Practitioner education: Remicare offers training modules that are supported by nurse advisers. Educational packages include distance learning, access to a website service and study days.
- ◆ Equipment: a Remicare grant programme may be accessed to provide finances for infusion chairs,

pumps or other essential items for departments where equipment shortages mean they can't provide treatment.

## d. Preparing a business case

The business case should be prepared and reviewed with your line manager, and in liaison with the rest of the rheumatology team to ensure you recognise all service needs.

Your case should include:

- ◆ calculations which predict how effective your unit could be in patient turnover, staffing levels, etc.
- ◆ the long-term resource savings in comparison with short-term costs (*see a. Analysis of resources and costs*)
- ◆ the patient population currently receiving treatment, and those currently eligible but not receiving treatment
- ◆ the number of patients likely to be eligible for treatment in subsequent years
- ◆ emphasis of the potential reduction in hospital admissions (for example, for orthopaedic surgery and co-morbidity), requests for urgent outpatient appointments, associated social care costs
- ◆ emphasis of the potential reduction of clinical risk and the improved quality of life for patients (for example, opportunities to return to work)
- ◆ emphasis of the potential improvements in patient care and satisfaction, and in data collection for local and national audit
- ◆ the need for local audit.

It is also important to include:

- ◆ details of the NICE Guidance, where relevant in the UK
- ◆ details of the British Society of Rheumatology Biologics Register, and the time implications involved in data collection for it
- ◆ brief overview of research evidence demonstrating reduction in joint erosions.

*For resources about business case planning, see Reference section page 14.*

## e. Unified lobbying for services

The patient organisations, together with all members of the Arthritis and Musculoskeletal Alliance (ARMA), recognise that the provision of biologic therapies remains patchy across the UK.

Treatment can only be prescribed in some areas after each case is presented on individual clinical need, rather than every patient who fulfils the BSR criteria being offered treatment. The Health and Technology Board for Scotland (HTBS) has endorsed the NICE guidelines for use in Scotland, but there is significant variation in the implementation of the guidelines between different health boards. It's as yet unclear whether, or how, the NICE guidance will be implemented in Northern Ireland.

Patients are not aware of these difficulties, but simply want and need the best treatment. Where they are aware of the new therapies, they have even greater expectations. Others receive treatment but don't derive sufficient benefit for it to be continued. It is vital that all patients, whether they receive these treatments or not, are given proper support and information on the situation regarding these therapies.

It is the responsibility of all health care professionals to provide support structures to help individual patients, but it is also important to provide guidance on how patients can voice their views. The Arthritis Care website has prepared a letter that patients can personalise and print off to send either to their own trust, primary care trust, strategic health authority or Member of Parliament/Assembly Member. Arthritis Care and the National Rheumatoid Arthritis Society are actively lobbying for improved provision of care for patients with arthritis, including access to biologic therapies.

It is the responsibility of all of us to ensure that provision of care is of the highest standard, and that adequate resources are provided across the UK.

## References

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- Children's Chronic Arthritis Association: Tel: 01905 745595 [www.ccaa.org.uk](http://www.ccaa.org.uk)
- GP information on the treatment and management of biologic therapies. [www.rheumatology.org.uk](http://www.rheumatology.org.uk)
- Lady Hoare Trust for Physically Disabled Children: 87 Worship Street, London. EC2A 2BE, telephone: 0207 8209989 [www.ladyhoaretrust.org.uk](http://www.ladyhoaretrust.org.uk)
- National Rheumatoid Arthritis Society (NRAS) [www.rheumatoid.org.uk](http://www.rheumatoid.org.uk)
- Patient information leaflets on tuberculosis treatment [www.Brit-thoracic.org.uk](http://www.Brit-thoracic.org.uk)
- Royal College of Nursing Rheumatology Forum - [www.rcn.org.uk](http://www.rcn.org.uk)
- Scottish Consensus Guidelines: due to be published on the Scottish Society web page in late 2003: [www.sign.ac.uk](http://www.sign.ac.uk)
- The Royal College of Paediatrics and Child Health - [www.rcpch.ac.uk](http://www.rcpch.ac.uk)
- The Source  
Young Arthritis Care, for young people aged 25 and under.  
18 Stephenson Way, London. NW1 2HD,  
Helpline: 0808 8082000

## Websites and other contacts

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- Arthritis and Musculoskeletal Alliance (ARMA) [www.boneandjointdecade.org.uk](http://www.boneandjointdecade.org.uk)
- Arthritis Research Campaign: patient information leaflets on Infliximab and Etanercept. [www.arc.org.uk](http://www.arc.org.uk)
- [www.abbottuk.com](http://www.abbottuk.com)
- [www.kineretrx.com](http://www.kineretrx.com)
- [www.remicare.co.uk](http://www.remicare.co.uk). This website has additional practitioner support including educational programmes. For further information speak to the local Schering Plough representative or Remicare team.
- [www.wyeth.co.uk](http://www.wyeth.co.uk)
- Summary of Product Characteristics (SPC) for Biologic Therapies [www.EMC.vhn.net](http://www.EMC.vhn.net)  
A full summary of product characteristics of licensed therapies can be found on this site. These are regularly updated. Practitioners will need to register using their professional registration number to access this website.

## Appendix 1: Patient management workbook

**Patient label:**

**Request sheet:**

**Referral slip:**

**First 1 month**



**2ndDAS**



## Patient management workbook: section 1

### Initial screening

**Patient label:**

---

**Date screened:**

---

Requesting physician	Position	Hospital
Physician address	Contact telephone no	Fax
Hospital address	Helpline number	Phone number
Email address	Date of request	Diagnosis
Date of diagnosis	Complies with inclusion criteria for treatment? Yes/No	Justification for considering treatment if fails inclusion criteria?
<u>If fails inclusion criteria:</u>	<u>consensus statement</u>	
Presenting consultant	Reviewing consultant	
Date:	Criteria fulfilled: Yes/No	Comments:

## Failure of disease-modifying anti-rheumatic drugs (DMARD)

**NOTE: Also Biologics Register Data: Advisory data but avoid duplication**

**Patient label:**

**Pre-treatment Screening:**

Weight

Height

Current DMARD Target doses	Dose	Time on DMARD	If stopped, give reason: Date and discontinuation code	
Previous DMARDs				
Azathioprine 2mg/kg/day*				
Hydroxychloroquine 6.5mg/kg/day*				
Gold 50mg/wk*				
Methotrexate 20mg/wk*				
Penicillamine 500-750mg/day*				
Sulphasalazine 40mg/kg/day*				
Leflunomide				
Ciclosporin				
At least two DMARDs at target dose		Eligibility criteria achieved?	Yes	No

Discontinuation codes:

- 1) inefficacy
- 2) toxicity
- 3) intolerance
- 4) rash
- 5) unknown

\* Target dosages where specified

## Exclusion criteria

### Patient label:

<b>Exclusion criteria</b> Tick when checked and refer to prescribing physician if any exclusion criteria identified		
Refer to drug data sheets for additional information		
Pregnant or breastfeeding; effective contraception must be practised		
Active infection		
Patients at high risk of infection including: <ul style="list-style-type: none"> <li>◆ chronic leg ulcers</li> <li>◆ previous tuberculosis (See BSR guidelines if previously treated TB)</li> <li>◆ septic arthritis of a native joint within the last 12 months or sepsis of prosthetic joint within the last 12 months. Indefinitely if the joint remains in situ</li> <li>◆ persistent or recurrent chest infections</li> <li>◆ indwelling urinary catheter</li> </ul>		
Malignancy or pre-malignancy states excluding: <ul style="list-style-type: none"> <li>◆ basal cell carcinoma</li> <li>◆ malignancies diagnosed and treated more than 10 years previously (where the probability of total cure is very high) Note: Evidence not available to support this, although this is currently an exclusion criteria</li> <li>◆ moderate or severe congestive heart failure</li> </ul>		
Patient eligible for treatment?	Yes	No
If no, state reason for exclusion:		

## General and infection screen

### Patient label:

Review ANY history of TB contact or previous treatment for TB (including family TB)										
Details:										
<hr/> <hr/>										
<table border="0"> <tr> <td>TB Screening: BCG</td> <td>Yes/No</td> <td rowspan="4">           If increased risk factors identified discuss with clinician re: additional screening            TB Screening necessary <span style="float: right;">Yes/No</span>            Check result of TB testing before proceeding         </td> </tr> <tr> <td>Born outside UK:</td> <td>Yes/No</td> </tr> <tr> <td>Scar:</td> <td>Yes/No</td> </tr> <tr> <td>Chest X-ray in last 6 months:</td> <td>Yes/No</td> </tr> </table>	TB Screening: BCG	Yes/No	If increased risk factors identified discuss with clinician re: additional screening TB Screening necessary <span style="float: right;">Yes/No</span> Check result of TB testing before proceeding	Born outside UK:	Yes/No	Scar:	Yes/No	Chest X-ray in last 6 months:	Yes/No	
TB Screening: BCG	Yes/No	If increased risk factors identified discuss with clinician re: additional screening TB Screening necessary <span style="float: right;">Yes/No</span> Check result of TB testing before proceeding								
Born outside UK:	Yes/No									
Scar:	Yes/No									
Chest X-ray in last 6 months:	Yes/No									
Chest X-ray within the last 6 months? If repeat chest X-ray not required indicate date of last chest X-ray Date: Must be reviewed by a senior medical practitioner before commencing treatment, as a medical assessment for cardiac/respiratory function is required	Assessment for respiratory symptoms – productive cough/wheezing/ breathlessness/sore throat/hoarseness If respiratory symptoms – specify:									
If evidence of heart failure review with prescribing physician	Date reviewed:									
History of demyelinating disease	If yes - review with prescribing physician									
Exposure to recent infections: (eg. chicken pox, shingles) If yes specify type of contact	Recent vaccinations? If yes specify date and vaccination:          Review with prescribing physician									

NOTE: If necessary, use additional attached sheet to document infection/malignancy history.

## Documentation of malignancy/infections

### Patient label:

#### Malignancy:

Type:

Date of diagnosis:

Treatment:

**Note:** Exclude basal cell carcinoma or malignancy treated > 10 years ago.

#### Infections:

Type:

Date of infective episode:

Treatment:

Date of last treatment:

## Review following initial screening for treatment criteria

### Patient label:

Use this review before starting treatment, and ensure all BSR criteria have been fulfilled.

If in doubt review with prescribing physician or specialist practitioner.

	Yes	No
Has the patient been fully informed about treatment?		
Has the patient had an opportunity to ask questions?		
Has the patient been provided with written information?		
Has the patient given informed consent to treatment?		
Has the patient given informed consent to their details being submitted to the BSR Biologics Register?		
Is the patient's consent documented in the notes?		
Are all the pre-treatment screening tests completed?		
If appropriate, has the patient been prescribed methotrexate?		
Has the BSR Biologics Register data been collected?		
If any answers are ticked <b>NO</b> , review and discuss with rheumatology team or prescribing physician.		

## Patient management workbook: section 2

### Check list for pre-infusion observations

**Patient Label:**

**Date:**

Use this check list before starting each treatment.

Weight  Height

Blood Pressure	Temperature	Pulse	Respirations
Urinalysis			

**Record blood results before starting treatment - see sequential data chart, Patient management workbook: section 4**

Check all observations and blood results. If observations or blood results are abnormal review with consultant or clinical nurse specialist

First treatment - ensure baseline Anti-Nuclear Antibodies (ANA) and ds DNA tested.

**Proceed with treatment if:**

- ◆ all screening questions in patient management workbook: section 2 answered yes
- ◆ if observations and results normal.

If in doubt, seek advice from consultant or clinical nurse specialist.

## Patient management workbook: section 3

### Pre-administration check list for infusions

	Tick
Are the observations (temperature, pulse, and blood pressure) satisfactory?	
Are the blood results satisfactory?	
If appropriate, ensure patient is not pregnant and is using an effective method of contraception	
Is the patient free of infection?	
If local policy regarding prophylaxis, has the patient taken their prescribed oral prophylaxis treatment (e.g. 4mg Chlorpheniramine and 1G paracetamol, for infusions only)	

#### See algorithm, Appendix 3, for more detail

For infusions:

- ◆ check pump
- ◆ check filter available
- ◆ check infliximab solution and dosage
- ◆ record observations half hourly throughout infusion
- ◆ observe for side effects throughout and for at least one hour post infusion.

## Patient management workbook: section 4

### Infliximab progress sheet

#### Patient label:

#### Disease Activity Scores (DAS)

This is an advisory progress sheet.

- ◆ \* denotes essential components for DAS Score. (DAS)\*
- ◆ # denotes suggested additional data to collect
- ◆ VAS = Visual analogue scale
- ◆ DAS is not essential for each treatment. *See section b Disease activity page 5.*

Review date: after 4th infusion. DAS <3.2 or improvement of >1.2

If patient shows no benefit from treatment at review, discuss with consultant.

Date of treatment	Pre Tx	Date 0	Date 1	Date 2	Date 3	Date 4	Date 5	Date 6	Date 7
Tender joints*									
Swollen joints*									
Patient global *									
CRP/ESR*									
DAS Score*									
#EMS									
HAQ									
#Patient Pain VAS									
Dose given									
weight									
Pre Treatment:									
◆ Temp									
◆ Pulse									
◆ BP									

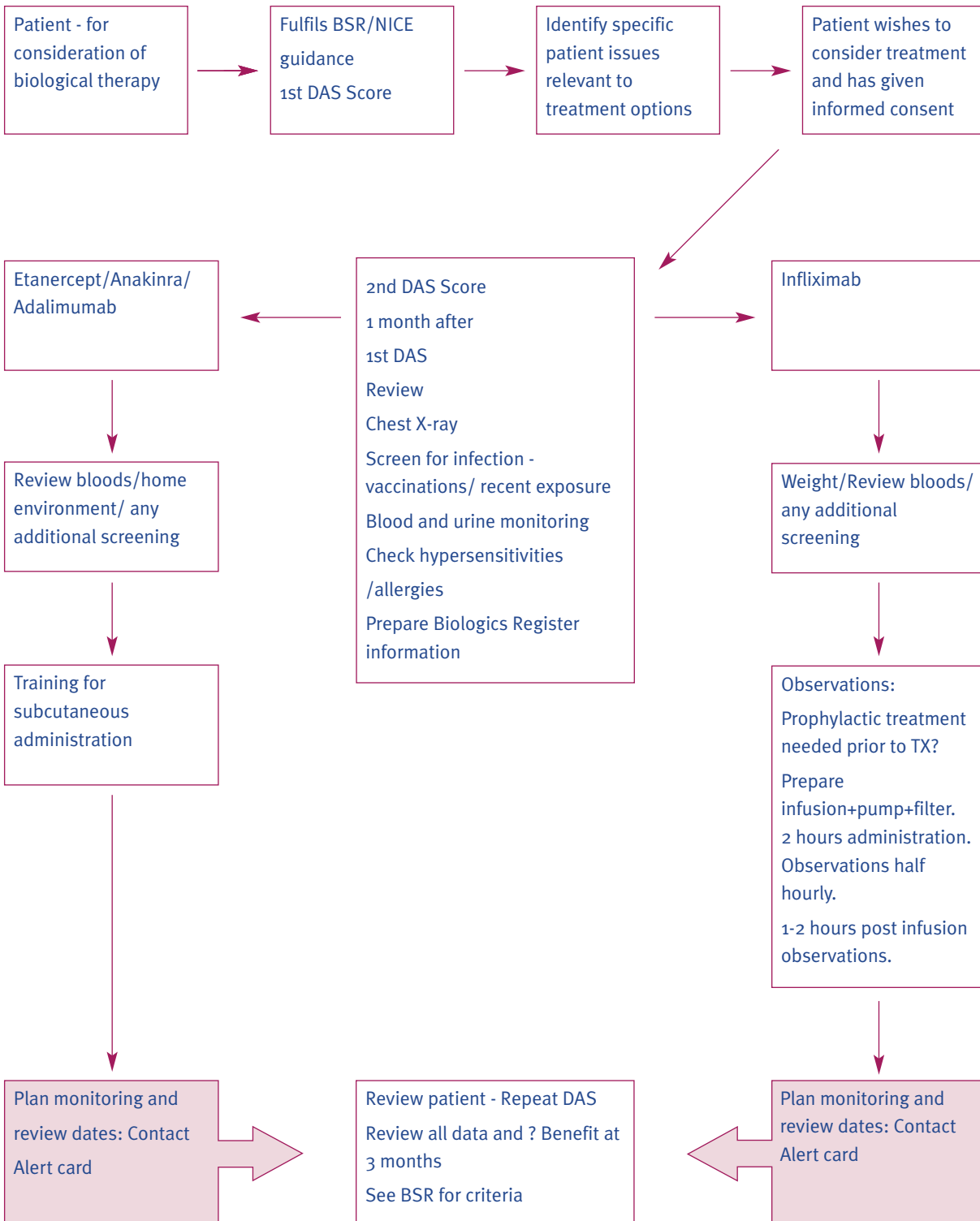
Sequential data:





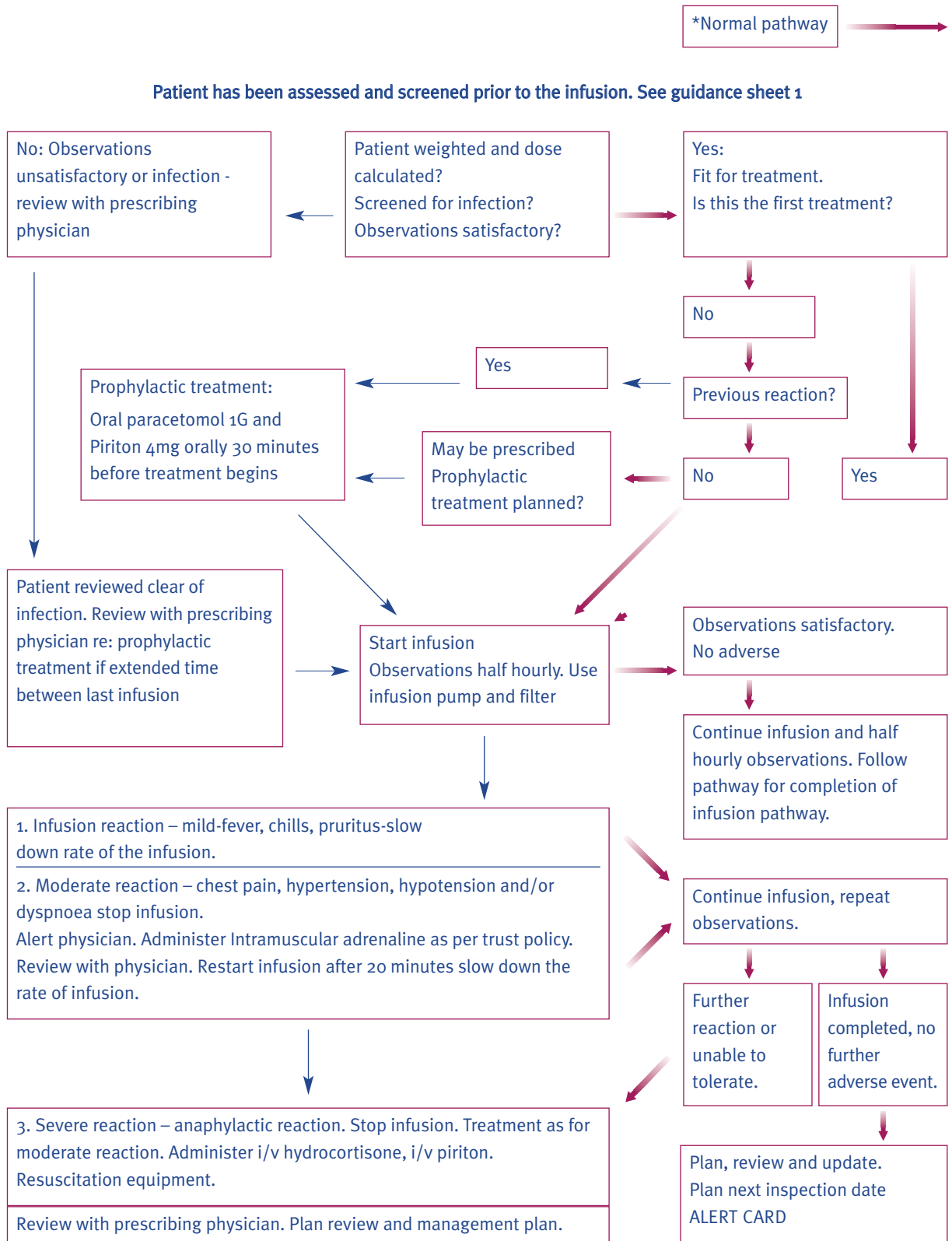
## Appendix 2

### Flow chart: selection and management of patients for biologic therapies



## Appendix 3

### Algorithm for patients receiving infliximab



## Appendix 4

### Instigating a patient subcutaneous self injection programme

#### Appendix 4 includes:

- ◆ Introduction
- ◆ Rationale
- ◆ Therapies available
- ◆ Planning, training for, and delivering care
- ◆ Professional competencies
- ◆ References

Plus:

- ◆ Education package for patients
- ◆ Form: Requirements for home administration of subcutaneous biologic therapies
- ◆ Patient agreement form for home administration of subcutaneous biologic therapies
- ◆ Check list: Requirements of home administration of subcutaneous biologic therapies
- ◆ Patient consent form
- ◆ Evidence of supervised practice by patient

#### Introduction

This document will help specialist practitioners who want to instigate a programme of patient self-administration of subcutaneous biologic therapies. This programme will support patients in making decisions about how their care is delivered and in learning how to administer it at home.

The document forms an appendix to, and should be used with, the Royal College of Nursing's publication (2003) *Assessing, managing and monitoring biologic therapies for inflammatory arthritis: guidance for rheumatology practitioners*, which looks in detail at the total care of patients receiving biologic therapies. This guidance should be used in conjunction with the British Society for Rheumatology Guidelines (2001), British Society for Rheumatology Biologics Register (BSRBR) and National Institute for Clinical Excellence (NICE) guidance on the administration of Biologic therapies (2002).

If you plan to begin an educational programme in your trust, it may be appropriate to audit its use. Seek guidance and support from the trust's audit department.

### Rationale for implementing a self-administered subcutaneous injection programme

The *NHS Plan* (2000) highlighted the need to develop services designed around patients' needs, and further reports have focused on the needs of chronic disease patients (*The Expert Patient – A new Approach to Chronic Disease Management, 2001*). This drive to provide a more patient-centred approach to care has meant the service, and individual units, have re-evaluated services. For example, shared care monitoring guidelines for patients taking disease modifying drugs (DMARDs) have now been provided.

The expertise of you, the specialist practitioner, is to recognise and provide support in administering the most appropriate treatment for each individual patient. Patient preference for a specific treatment option will vary depending on a number of factors, including:

- ◆ the patient's medical history and functional ability
- ◆ social factors
- ◆ the psychological aspects of treatment options.

The aim of developing a patient self-administration programme is to improve patient choice and reduce their need for extra clinical sessions to administer subcutaneous injections.

### Therapies available for subcutaneous injection

There are two biologic therapies that can be administered by subcutaneous injection. It is also expected that one further anti-tumour necrosis factor alpha treatment (Adalimumab) will be licensed in mid 2003 (Adalimumab has already been granted approval for use in treating rheumatoid arthritis in the USA).

Etanercept 25mg twice weekly.

Anakinra 100mg administered daily.

Adalimumab 40mg every other week (licence pending suggested dosage regime).

The National Institute of Clinical Excellence (NICE, 2002) has provided guidance on the use of Etanercept for adults with rheumatoid arthritis (RA) and also for children and young adults with juvenile idiopathic arthritis (JIA).

#### Etanercept

Etanercept is an agent used in the treatment of RA and JIA. It is a soluble fusion protein that blocks the normal activation of TNF receptors by blocking TNFalpha.

### Anakinra

Anakinra, is recombinant form of the human interleukin-1 receptor antagonist (IL-1RA). IL-1Ra is an anti-inflammatory cytokine. Anakinra actively competes with IL-1RA locking into the receptor and thus disarming the potential of IL-1 (a pro-inflammatory cytokine) in activating an inflammatory response.

### Adalimumab

Adalimumab is a human monoclonal antibody against Tumour Necrosis Factor alpha. Adalimumab binds to and neutralises TNF alpha, inhibiting its action.

For more detailed information on these drugs, refer to their Summary of Product Characteristics (SPC) and to the research evidence set out in the reference section of the main RCN guidance.

## Planning, training for and delivering care

### Outline of care

The consultant rheumatologist will assess the patient prior to treatment, and refer the patient to you and your colleagues in the rheumatology nursing service for assessment and education. The patient will need to be fully assessed and fulfil the British Society for Rheumatology (BSR) criteria for treatment with biologic therapies (2000). In some cases, patients will fail the BSR criteria, but the prescribing physician may instigate treatment if the patient has specific clinical need that falls outside the BSR criteria. In these circumstances clinical details should be clearly documented in the notes.

If the patient is eligible, and would like to be considered for the treatment, you will plan the educational programme with the patient. The consultant rheumatologist will write formally to the patient's general practitioner requesting support in the monitoring of treatment, subject to the patient completing a successful educational programme. The consultant rheumatologist and rheumatology team will continue with regular follow-up of the patient's overall management.

## Support from pharmaceutical companies

The pharmaceutical companies providing biologic therapies have developed specific home care services. These services will arrange a package of care for patients starting biologic therapies. This package includes teaching the patient to self administer their injections, ensuring prompt delivery of the appropriate treatment and equipment necessary to support

the administration. The service will also arrange disposal of sharps box and clinical waste. This service has the additional advantage to NHS trusts in that it is exempt from Value Added Tax (VAT) charges. It will be at the discretion of the rheumatology specialists, with reference to local trust policy (with the support of the pharmacy department), to decide on the package of care most appropriate for a patient.

## Criteria for patient selection

To select patients and carers for self-administration of subcutaneous injections, you must ensure that the patient:

- ◆ fulfils the criteria for treatment of biologic therapies\*
- ◆ consents to taking part in the educational programme
- ◆ gives their consent to treatment and to self-administration of the drug (or administration by nominated carer)

and that the patient or carer:

- ◆ is willing to administer injections
- ◆ has the ability to administer injections
- ◆ has the ability to store syringes/drugs safely
- ◆ understands how to deal with any drug spillage and sharps disposal
- ◆ can be provided with an effective and safe method of collection and disposal of the drug and equipment.

\* For more details of eligibility and selection of patients to receive biologic therapies, see Section 1 of the main RCN guidance, plus the BSR guidance on patient eligibility (2000).

Exclusion criteria:

- ◆ the registered practitioner believes the patient's condition necessitates withholding treatment. In this circumstance, you should refer the patient to the prescribing consultant rheumatologist
- ◆ The patient is unable to adhere to any of the above eligibility criteria.

## Planning care

Your aim is to enable the patient to develop skills in the self-administration of subcutaneous injections, so they can undertake these injections at home. They may choose to administer treatment themselves, or with the support of a partner or carer. Once the patient (or carer) is competent and stable, you can arrange delivery of treatment and equipment to their home through pharmaceutical company home care services or by the rheumatology department.

You may wish to instigate the patient's training programme within your specialist unit, and then follow up with

pharmaceutical company support. This will mean you can continue to support the patient throughout the process of treatment with biologic therapies. Your tasks will include:

- ◆ providing education
- ◆ obtaining informed consent
- ◆ assessing, administering and providing regular follow up care (including blood monitoring)
- ◆ data collection and Biologics Register
- ◆ telephone helpline support.

It is important to remember that treatment with biologic therapies must be supported by regular patient assessment and monitoring for any signs of infection. Even where the patient is responsible for their own subcutaneous injections, you must carry out blood monitoring, telephone review and regular review of disease control.

## Training the patient or carer

The number of practice sessions which need supervision will vary for individual patients. You should take into account the patient and carer's learning needs after discussion and assessment of their competence in technique. This will be based upon a mutually agreed educational package provided to the patient. The number of training sessions to achieve competency will be determined by you and the patient

A suggested education package is set out below which you can use to help train the patient in subcutaneous administration.

## Procedure

- ◆ The consultant rheumatologist formally requests and prescribes the initial treatment, stating dose and route of administration.
- ◆ Ensure the patient satisfies the above criteria and will adhere to routine blood monitoring and outpatient follow up.
- ◆ The specialist nursing practitioner is satisfied that the patient understands the process and responsibilities of administering the injection.
- ◆ The patient is aware and able to comply with Health and Safety regulations on the storage and disposal of drugs and equipment
- ◆ The patient attends educational sessions and satisfies the nursing service of their competencies in:
  - ◆ administering the drug by the subcutaneous route
  - ◆ compliance to the correct storage and disposal of equipment
  - ◆ attendancy regularly for follow up and blood monitoring.

- ◆ If the patient fails in any of the above criteria the nursing service will liaise with the prescribing consultant and patient to plan their treatment options.
- ◆ If the patient has successfully completed the programme a letter will be sent to the patient's general practitioner.
- ◆ The patient has access to a telephone helpline service or emergency contact number.

## Ongoing management

At the end of the educational programme, when the patient has demonstrated that they are competent in all areas of administration, you should provide them with information about their follow-up care. If a pharmaceutical company home care package is to begin, you must ensure that the home care team are adequately informed of the patient's progress.

The patient must be provided with the following equipment (either by the unit or the pharmaceutical company team):

- ◆ a cool bag for collection of pre-filled syringes (for patients collecting their medication)
- ◆ sharps disposal bin
- ◆ mediswabs
- ◆ micropore
- ◆ cotton wool balls
- ◆ plasters.

The patient should be provided with:

- ◆ the date and time of their next blood test and outpatient appointment
- ◆ advice on telephone contact (telephone helpline and/or general practitioner services).

## Professional competencies

Rheumatology support nurses and specialist rheumatology nursing practitioners providing this service must ensure they are competent and of course that they maintain their knowledge and skills as set out in the *Code of Professional Conduct* (Nursing and Midwifery Council 2002), *Scope of Professional Practice* (United Kingdom Central Council, 1997), *Guidelines for the administration of medicines* (Nursing and Midwifery Council, 2002), and any local NHS trust policies. A competency framework for specialist practitioners is available in Appendix 6 of the main RCN Guidance biologic therapies (2003).

These nurses will need to demonstrate the following competencies:

- ◆ able to discuss the rationale for administration of subcutaneous biologic therapies

- ◆ able to discuss the indications for the administration of biologic therapies
- ◆ able to discuss nurses' accountability in administering biologic therapies
- ◆ able to provide patient and carers with evidence-based information and education
- ◆ able to demonstrate accurate record keeping of all patient/carer interactions relating to the administration of biologic therapies
- ◆ recognise limitations of their own practice, knowledge and skills.

Summary of Product Characteristics: Anakinra, Etanercept and Adalimumab. [www.EMC.vhn.net](http://www.EMC.vhn.net).

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## Education package:

# Information for patients and carers about administering your own injections of biologic therapies at home

## Rheumatology department:

### Patient's name:

---

Make sure that these instructions are always nearby in case you have any queries or problems.

Remember that you can telephone the rheumatology specialist nurse on their helpline number

### Helpline telephone number:

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An answerphone service will record calls whilst the nurses are in clinic. A nurse will get back to you as soon as possible.

If the problem is more urgent, or it is out of normal working hours, please telephone your own doctor. If the health centre is closed there will be advice to tell you how to access help out of hours.

### Your doctor's number:

---

## Equipment

You will be provided with a package containing pre-filled syringes of the treatment you have been prescribed. The syringes should be stored in your fridge.

The package will also contain:

- ◆ alcohol wipes
- ◆ cotton wool swabs (small pads of cotton wool)
- ◆ plasters
- ◆ a 'sharps box' for disposing of used needles and syringes
- ◆ information leaflet.

## Information leaflets

The company providing your treatment has prepared a patient information leaflet that provides specific information on how to inject yourself using the specific treatment

prescribed for you. This information is included in the package containing your injection and equipment. Please read the details carefully. Your rheumatology department may also provide additional information about the treatment you are receiving.

## Supplies of treatment and equipment

Make sure you know when and how your treatment will be delivered to you at home, and how the sharps box and other clinical waste will be disposed of. Do not put the sharps box into the dustbin. Used needles and syringes are a hazard. The box must be disposed of safely and should be collected by your home care team or delivered to the hospital or community hospital.

## How to give biologic therapies by subcutaneous injection

### Getting ready

1. Don't rush - make sure you have plenty of time. As you get used to giving the injection, you will find it much easier. Do make sure that there are no distractions such as children or dogs in the room.
2. Wash your hands and dry them.
3. Take your injection pack from the fridge. Put it on a clean, flat surface.
4. Take out the pre-filled syringe, alcohol wipe, a cotton wool swab and a plaster and put them in a small polythene container. Have sharps box close at hand.
5. Decide where you will put the injection – either under the skin of your tummy or in the front of your thigh. This is your injection site. Choose a different side of your tummy or opposite thighs each time you inject.
6. Read and check the label, dosage and expiry date on the bottle. If the expiry date has passed, do not inject the drug but contact your pharmacist or specialist nurse to arrange replacement supplies.
7. Clean the area of skin you are going to inject with an alcohol wipe (mediswab). Allow a few seconds for the skin to dry.

### Giving the injection

- ◆ Open the injection pack on a flat clean surface.
- ◆ Wait for a few minutes for the liquid to become clear. Do not shake the syringe.
- ◆ If the liquid in the syringe has particles or is not clear, do not inject the fluid but contact the pharmacy or specialist nurse.
- ◆ Remove the sheath from the needle. Make sure that you do not touch any part of the needle whilst preparing the injection.
- ◆ Pinch the skin around the area you have wiped clean and insert the needle into the skin at 90 degrees (pointing directly down onto the skin). The needle is only half an inch long and will deliver the injection just below the skin (this is called 'subcutaneously').
- ◆ Push down the plunger of the syringe to give the injection.
- ◆ Withdraw the needle and syringe and cover the injection site with a cotton wool swab.
- ◆ After a few seconds remove the swab, and cover the injection site with a plaster.
- ◆ Do not put the cover back on the needle or you may prick yourself. Just discard the syringe and needle into the sharps box, along with the alcohol wipe and cotton wool swab.
- ◆ You may notice bleeding or bruising at the injection site. Don't worry, this happens when a small blood vessel is punctured by a needle. If there's bleeding, apply a cotton wool swab and maintain gentle pressure for a minute or two until bleeding stops. The bleeding will soon stop and any bruising will disappear.
- ◆ Make a note of when your next injection will be due – and ensure that you have enough of the treatment available.

**IMPORTANT NOTE:** Do not put any of the equipment you have used in your normal household rubbish.

### If you experience a rash or discomfort around the injection area

- ◆ Sometimes when people receive a subcutaneous injection, some of the injected fluid may leak into the surrounding skin and cause irritation around the injection area. This will normally settle in a few days.

However, if you notice irritation or redness in the area of the injection that does not settle after three days, you should contact your GP who may consider a hydrocortisone cream to stop the irritation.

Form:

## Requirements for home administration of subcutaneous biologic therapies

Patient's name	Address
Carer's name	
Hospital number	Telephone number
Drug	Dosage
Consultant	GP
DAS scores 1: 2:	Follow-up date

## Patient agreement form for home administration of subcutaneous biologic therapies

**Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

You have been taught how to give your injections by the subcutaneous route.

On \_\_\_\_\_ occasions you have given the injection under the supervision of the rheumatology nurses. They now consider that you are competent to give these injections at home, using the techniques you have been taught. Before this happens it is important to check that you are happy to do this and that you fully understand the procedure.

Please read the statements below and tick the appropriate box:	Yes	No
1. I have been given written information on how to give injections		
2. I have been given information about my treatment		
3. I have a fridge at home where I can safely store the injections		
4. Young children have access to my fridge and home If you have answered yes to question 4, please answer question 5		
5. I understand that I must keep the injections in the fridge and out of reach of young children		
6. I can manage the syringe without difficulty		
7. I can show the areas where I can give injections		
8. I am confident that I can give the injection subcutaneously (under the skin)		
9. I know that I must safely dispose of the needle and syringe in to the sharps box provided		
10. I know what to do if I have a problem		
11. I understand how my sharps box and other waste material will be disposed of		
12. I recognise my responsibilities in: reporting infections promptly, and attending for monitoring and follow up care		

## Check list: requirements of home administration of subcutaneous biologic therapies

	Yes	No
1. Is the patient/carer happy to undertake this procedure?		
2. Does the patient have a fridge at home to safely store the injections?		
3. Can the patient/carer manipulate the syringe?		
4. Can the patient/carer identify the areas where the injection can be given?		
5. Can the patient/carer administer the subcutaneous injection safely?		
6. Can the patient/carer safely dispose of the needle and syringe in the sharps box?		
7. Does the patient/carer understand what to do should a problem arise?		
8. Does the patient/carer understand how sharps boxes should be disposed of?		
9. Has the patient/carer been given written information on subcutaneous administration?		
10. Do children have access to the patient/carer's fridge?		

If the answer to question 10 above is Yes, please answer question 11 and 12

11. Does the patient/carer have a safe method of storage that prevents young children gaining access to treatment?		
12. Has the patient/carer completed and signed a consent form to undertake this procedure at home?		

## Patient consent form

### To be completed by the patient and carer

#### Administration of subcutaneous injection

Patient consent:

I \_\_\_\_\_  
 have read the information and have had the procedure explained to me. I have undertaken this procedure under the supervision of the rheumatology nurse specialist and I am happy to administer subcutaneous injections using the procedure taught.

Patient's name \_\_\_\_\_

Patient's registration number \_\_\_\_\_

Name of rheumatology clinical nurse specialist (CNS) \_\_\_\_\_

Signature of CNS \_\_\_\_\_

Carer consent (if applicable)

I \_\_\_\_\_  
 have read the information sheet and have had the procedure explained to me. I have undertaken this procedure under the supervision of the rheumatology nurse specialist and I am happy to administer subcutaneous injections to \_\_\_\_\_ (patient's name) using the procedure taught.

Carer's name and address \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Carer's signature \_\_\_\_\_

I am happy for the above named carer to administer my subcutaneous injection using the procedure taught in my own home.

Patient's name \_\_\_\_\_ Signature \_\_\_\_\_

Patient's Registration Number \_\_\_\_\_

Name of rheumatology clinical nurse specialist (CNS) \_\_\_\_\_

Signature of CNS \_\_\_\_\_ Date: \_\_\_\_\_

# Evidence of supervised practice by patient

Patient label:

Date	Procedure	Location	Observed	Signature

## Appendix 5

### Guidance on screening for tuberculosis

Evidence shows that there is an increased risk of infections and emergence of latent tuberculosis (TB) in patients receiving some biologic treatments, so it is essential that practitioners ensure patients are thoroughly screened. Many patients receiving biologic therapies have complex chronic disease and will have been receiving immuno-suppressant therapies in the form of disease-modifying drugs and steroids. They are also at risk from other co-morbidity factors associated with their complex disease and poor general health.

#### Screening

If local trust or British Thoracic Society Guidelines are available you should follow these in screening patients. However, if there are no alternative guidelines, the following process should be part of routine screening for patients before treatment with biologic therapies is begun.

All patients should be assessed for risk of TB by taking a full patient history and reviewing the chest X-ray and physical examination.

#### Detailed patient history

- ◆ Current respiratory symptoms.
- ◆ Personal or close family history of TB.
- ◆ Previous BCG vaccination, observe for evidence of a scar. White patients born before 1942 will not have been part of the routine BCG immunisation programme. Patients from ethnic minority groups should have been given BCG at birth if born in the UK, or have been tuberculin tested and BCG vaccinated if negative, after arrival - but it is known that coverage of these immunisation programmes was not complete.
- ◆ Place of birth. Has the patient lived outside the UK for six months or more in an area with high prevalence of TB (40/100000pa: all countries, apart from the current EU, Australia, New Zealand, USA and Canada).
- ◆ Identify patients who currently live in an area with high prevalence of TB in the local community. For guidance on local prevalence seek advice from the local respiratory consultant.

#### Chest X-ray

Patients should have had a chest X-ray within the last six months. If they are currently experiencing persistent respiratory symptoms, they need to be given a repeat chest X-ray. This should be reviewed by the prescribing physician.

#### Physical examination

This should include examination of the chest, noting any abnormal clinical signs. Report to prescribing physician or member of the medical team.

#### Tuberculin test (skin test)

In the UK, this is normally a Heaf test. Skin testing should not be undertaken on:

- ◆ patients who have had previous treatment or chemoprophylaxis for TB, have evidence that TB is present or have X-ray evidence of TB scarring
- ◆ patients who have been recently prescribed immuno-suppressive therapy (< 2 months) such as steroids, azathioprine, methotrexate, ciclosporin etc.

Note: False negative skin tests are common. Immuno-suppression due to drug therapy, active inflammatory disease or advancing years all weaken or even abolish the skin test response to tuberculin.

#### High-risk patients

Patients who have any of the high risk factors listed below should be identified for review by the prescribing physician. It may be appropriate to involve the local chest physician for further assessment and investigation.

- ◆ Current respiratory symptoms.
- ◆ A personal or close family history of TB.
- ◆ Lived in a community with a high prevalence of TB.
- ◆ An abnormal chest X-ray.

#### Treatment for TB

Patients with symptoms or radiological signs suggestive of active TB must be investigated appropriately. If active TB (i.e. tuberculous disease) is diagnosed, then treatment following the British Thoracic Society Guidelines should be started. We suggest that treatment with biologic therapies for inflammatory disease should be postponed until the patient has received anti-TB therapy for two months with monitored

compliance. If cultures for *M. tuberculosis* are available, antibiotic susceptibility data should be known to ensure the patient is receiving appropriate treatment.

For patients who may have been previously infected with TB, but who do not have active TB at the time of assessment, there is a risk that treatment with biologic therapies will reactivate their tuberculous infection. TB therapy (chemoprophylaxis) can reduce the risk of reactivation. However, the possibility of reactivation of TB has to be balanced against the risks of morbidity and mortality from the anti-tuberculous drugs – risks which are increased in the elderly. A working party of the Joint Tuberculosis Committee for the British Thoracic Society (BTS) is preparing an evidence-based review of this balance of risk, with advice and management strategies for patients at risk of TB reactivation. This report should become available on the BTS website ([www.brit-thoracic.org.uk](http://www.brit-thoracic.org.uk)) during 2003.

## Information for patients

Patient information sheets on anti-tuberculous therapy are available on the BTS website (these are also available in Punjabi, Hindi, Gujarati, Somali Turkish, Urdu and Bengali).

## Appendix 6

### Core competencies for practitioners administering biologic therapies

The management of patients receiving biologic therapies should be undertaken in a secondary care setting, with skilled specialist support. Nurses administering infusions should have easy access to specialist medical as well as practitioner support.

If you are reviewing your unit's staffing needs, it is important to evaluate the skill mix, level of medical support and nature of the facilities in your individual unit. The competency levels set out here will help you recognise the range of skill mixes that can be used in providing rheumatology care. The following are several factors to bear in mind while planning staffing.

#### Skill mix

The support needed to manage patients receiving biologic therapies includes the pre-assessment process, management during treatment, monitoring and on-going care. If a specialist practitioner provides support and supervision, some tasks can be undertaken by nurses who have a more basic knowledge of rheumatology patients and biologic therapies. It is for this reason that we have included basic level competencies, as well as competencies for specialist practitioners.

#### Nature of the department/unit

Rheumatology departments may vary in a number of ways.

- ◆ A large research unit with research practitioners and satellite units.
- ◆ A department with dedicated day unit facilities.
- ◆ A department with access to a planned investigation or medical day care facility.
- ◆ A department administering biologic therapies within a ward environment or supporting a day care facility.

#### Supervision

The basic competency framework set out here is for day care nurses who administer infusions, but have no overall responsibility for on-going care of patients receiving biologic

therapies. When you are reviewing staffing and practice, you must ensure that appropriate practitioner supervision is provided for these nurses with minimal experience in providing day unit care. If no rheumatology specialist practitioner support is provided in the day care unit, it will be the responsibility of the hospital's rheumatology specialist practitioner to provide support and supervision for patients. This will include the pre-assessment, documentation, BSR Biologics Register data and on-going management and follow up.

## Basic practitioner competencies

Nurses working in day care facilities who administer infusions, but have no overall responsibility for ongoing care of patients on biologic therapies, should have the following skills and knowledge:

- ◆ relevant and current statutory training and experience in the administration of intravenous infusions, emergency resuscitation and anaphylaxis procedures
- ◆ expertise in venepuncture and cannulation techniques is preferable but not essential
- ◆ basic understanding of chronic disease management including the risks of immuno-suppression and opportunistic infections
- ◆ able to recognise the need to seek specialist support if a patient highlights new issues that may affect treatment (for example, recent contact with chicken pox, changes in general health that may indicate problems, such as neurological problems)
- ◆ undertaken basic training sessions in the management of rheumatology patients, including an awareness of painful joints and appropriate siting of venflon, pain control, the use of joint protection and mobility issues
- ◆ be aware of biologic therapies, mode of action, risks and benefits, and possible side effects
- ◆ understand the assessment and management issues that form the total care of patients receiving biologic therapies
- ◆ be aware of specialist practitioner support and know how to access this.

Many specialist practitioners have expertise that extends far beyond competencies documented above. Service needs may determine whether practitioners will need further education to meet these competencies - for example, a practitioner might want to acquire cannulation skills to improve patient care and support the medical team in preparing patients for treatment, and they would need to undertake training in intravenous administration and cannulation skills in accordance with local policies; similarly, day care unit nurses with infusion expertise will need additional specific training

and supervision in the management of patients receiving biologic therapies.

## Essential specialist practitioner knowledge and skills

All practitioners responsible for assessment and monitoring of treatment should have undertaken a period of study in, and feel confident that they have an understanding of, the following areas.

- ◆ Inflammatory joint diseases.
- ◆ Functional assessments.
- ◆ Social and psychological aspects of chronic disease.
- ◆ Management, assessment and therapeutic options for chronic pain.
- ◆ The role of disease-modifying drugs, side effects and monitoring.
- ◆ The basic mechanism how biologic therapies act, and their routes of administration.
- ◆ The side effects of biologic therapies including the side effects of subcutaneous injections or intravenous infusions. The practitioner should be competent in acting on observed changes, including knowledge of procedures in the case of emergency resuscitation and anaphylaxis.
- ◆ Proficiency in the administration and training of subcutaneous injections.
- ◆ The value of multi-disciplinary team support for patients.
- ◆ The value of providing patient information literature and the use of telephone helpline services.
- ◆ Knowledge of NICE recommendations, BSR Biologics Register and BSR Eligibility Criteria.
- ◆ The ability to collect accurate data for audit and research purposes.
- ◆ Recognition of the limits of their expertise and clinical competencies, and an ability to access appropriate clinical support.

If practitioners don't feel confident or don't have the relevant training in a particular area, adequate supervision by a competent nurses should be provided.

The specialist practitioner should also be competent in:

- ◆ the ability to educate patients about disease-modifying drugs and biologic therapies. This includes providing appropriate patient information
- ◆ clear and concise documentation in the medical records
- ◆ joint assessment including the use of the EULAR 28 joint count score
- ◆ managing patients receiving intravenous infusions

- ◆ relevant and current statutory training for emergency resuscitation and anaphylaxis procedures
- ◆ experience in routine assessment and screening of patients with chronic disease including observations of blood results, routine screening for possible infections, exacerbation of disease, blood pressure, temperature, and urine testing
- ◆ management of patients receiving intravenous infusions via an infusion pump
- ◆ knowledge of the statutory legal responsibilities of ensuring adequate documentation of care, including routine observations and follow-up care arranged
- ◆ managing a telephone helpline service
- ◆ training patients in self administration of subcutaneous treatments, if appropriate.

The practitioner should be practising using a trust policy document to support their practice.

### **Non-essential specialist practitioner knowledge and skills**

- ◆ Practitioners may wish to develop local policies and training procedures for patients to be trained in the self administration of subcutaneous injections.
- ◆ Cannulation skills.
- ◆ Competence in managing patients receiving intravenous infusions via an infusion pump - where adequate competent practitioners are available to support nurses administering infusions, specialist nurses won't necessarily need to be competent in this area, but they may choose or need to extend their skills in this.

## Appendix 7

### Calculating nursing and practitioner time and costs

These time allocations will help you calculate the cost of staffing in your unit/department. Costs will vary according to how many patients can be treated in a department at the same time and the skill mix of the nurses or practitioners competent in providing care for biologic therapies. There will be an optimum number of patients that the department can safely manage.

Less time can be allocated per patient in a department where more than one patient can be treated at one time.

Nursing/practitioner time can also be significantly reduced where appropriate clerical support is available.

Specialist practitioners should also take into account the time necessary to provide education, training and support to other health care professionals caring for patients receiving biologic therapies.

The times set out below are based upon one patient episode at the beginning of treatment. Individual aspects of the time analysis can be used to calculate ongoing costs of care. It is important that you discuss with the department business manager the grades of staff and additional staffing costs which include cover for holidays, national insurance and other 'on costs' before submitting a detailed cost analysis.

Procedure	Time
Patient educational session to discuss treatment and provide patient information literature	30 minutes x 2 Initial session information giving, second session to review and answer specific questions following review of patient information literature
Screening and assessment of joints	30 minutes Basic screening and assessment of joints
Preparation of documentation and Biologics Register Data	30 minutes + 15 minutes preparation time with patient prior to treatment for consent and questionnaire completion
Documentation in medical records, nursing reports and clerical time arranging inpatient admission and review of results	30 minutes
Specialist practitioner - providing support for nurses in ward/day care facilities, administering/training and resolving clinical decision-making issues. Liaising with rheumatology team	60 minutes
Management of intravenous infusion therapy including all observations and post infusion care	Total first treatment costs - Total: 4 hours 15 minutes
Office administration, telephone review and ongoing support	30 minutes

## Appendix 8

# The RCN Rheumatology Biologics Working Party - members and remit

## Members of the RCN Rheumatology Biologics Working Party

### Representation

All the appropriate members of the Arthritis and Musculoskeletal Alliance (ARMA) were represented on this group. Members represented included:

- ◆ Arthritis Care
- ◆ Arthritis and Musculoskeletal Alliance (ARMA)
- ◆ Arthritis Research Campaign (arc Education sub-committee)
- ◆ British Healthcare Professionals Allied to Rheumatology
- ◆ British Paediatric Rheumatology Group (BPRG - Nursing, medicine and allied healthcare professionals - a specialty group within the Royal College of Paediatric Child Health)
- ◆ British Society for Rheumatology (clinical affairs committee)
- ◆ National Rheumatoid Arthritis Society (NRAS)
- ◆ Paediatric patient groups including: The Lady Hoare Trust and Young Arthritis Group
- ◆ Royal College of Nursing.

RCN Paediatric Rheumatology Specialist Nurses Group contacted via the RCN Paediatric Nurse Adviser via the RCN website, [www.rcn.org.uk](http://www.rcn.org.uk)

### Members

(All members and contributors have documented their vested interests with the working party.)

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### Representing Wales

Mrs Lisa Howie

Clinical Nurse Specialist

Mr B. Rhys Dillon, RGN

Clinical Nurse Specialist

- ◆ Documentation and competencies.
- ◆ Monitoring post treatment reviews/contact.
- ◆ Troubleshooting – prophylactic and anaphylactic treatment issues, infections, blood results.
- ◆ Review/Consensus on best practice and areas of management.
- ◆ Review of patient information provided.
- ◆ Specific needs of paediatric patients.
- ◆ Biologics Register information.
- ◆ The role of pharmaceutical companies.
- ◆ New biological therapies. (Awaiting review by the National Institute of Clinical Excellence or pending licence.)

### b. Resource issues in administration of treatment

- ◆ Where treatments are administered and by whom.
- ◆ Admission and discharge policies.
- ◆ Facilities to administer treatment.
- ◆ Paperwork and clerical administration.
- ◆ Disparities in implementation of NICE guidance.
- ◆ Management of patient expectations.
- ◆ Role of voluntary organisations.
- ◆ The role of pharmaceutical companies.

### c. Review of current pharmaceutical company strategies for supporting the development of service provision

(for example, Remicare nurses and Wyeth home care plan.)

- ◆ How should pharmaceutical support be utilised?
- ◆ What do we need and how should it be delivered?
- ◆ Developing expertise and succession planning.

### d. Unified lobbying for service provision

- ◆ What are the issues?
- ◆ Where should the guidance and working party review be distributed?

## The remit of the RCN Rheumatology Biologics Working Party

### a. Administration and management

- ◆ Roles and responsibilities of practitioners in the care of patients receiving biologic therapies.
- ◆ Practical issues of assessment, counselling and administration of treatment.

## Part 2: Children and young people

# Introduction

The role of biologic therapies in the treatment and management of children and young people with inflammatory joint disease is an evolving area with significant implications for all paediatric rheumatology clinical nurse specialists, paediatric rheumatologists and allied health practitioners who provide the supportive therapies to children and young people.

Children and young people with juvenile idiopathic arthritis (JIA) are significantly fewer in number than the adult population with rheumatoid arthritis. JIA is a relatively rare disease, with an estimated incidence in the UK of 0.1 per 1,000 children, which is equivalent to 1,000 new cases per year. About 10,000 children and young people in the UK are affected (NICE 2002). *For classification of juvenile idiopathic arthritis, see Paediatric Appendix 1.*

## This guidance

Part 2 of the Royal College of Nursing's *Assessing, managing and monitoring biologic therapies for inflammatory arthritis: Guidance for rheumatology practitioners* has been developed to highlight the key issues for treating children and young people. It provides guidance for paediatric rheumatology clinical nurse specialists caring for children and young people of 16 years and under who are receiving biologic therapies for juvenile idiopathic arthritis (JIA).

It will also help paediatric rheumatology clinical nurse specialists to develop a standardised approach to reviewing care for children and young people receiving biologic therapies. The experience gained in the assessment and management of children and young people receiving these drugs provides an opportunity for paediatric rheumatology nurse specialists and paediatric rheumatologists to develop a framework for practice and a consensus on areas of management.

## Developing this guidance

The guidance on paediatric care set out in Part 2 was developed in conjunction with the main RCN Rheumatology Biologics Working Party, which was chaired by Professor DGI Scott, President of the British

Society for Rheumatology (BSR). A full list of the working party members and contributors appears in Part 1: Appendix 8. You will find references, resources and additional guidance on treating children and young people in the Part 2 paediatric appendices.

The RCN Working Party identified three key national issues in the care of children and young people with JIA:

1. nursing resource implications for anti-TNF $\alpha$  treatments. Although biologic therapies have been endorsed for children and young people by NICE, the funding for necessary additional nursing support has not been addressed
2. the need to provide guidance on specific clinical issues in the assessment and management of children and young people receiving biologic therapies
3. the need for consensus and clarity about emerging evidence and about what can be agreed as best practice.

## The special needs of children and young people

As a specialist practitioner, it is essential that you are aware that the care of children and young people of 16 years and under should be managed according to paediatric rheumatology criteria for disease classification and treatment.

This applies even though young people are sometimes currently admitted to adult wards and rheumatology units (although in line with the Children's National Service Framework for England, each trust will now need to identify alternative locations to ensure children and young people receive care and treatment in specifically designated facilities to meet their distinct needs). Whatever the setting, it is always advisable when managing young people's care to seek guidance from a paediatric rheumatology consultant - and this is particularly important when the young patient is being cared for in an environment where the health care professionals are expert in the care of adults. It may also be necessary to seek specific guidance for patients with juvenile idiopathic arthritis (JIA) to ensure that the appropriate treatment guidelines are used.

## Treating JIA with biologic therapies

In March 2002, the National Institute of Clinical Excellence (NICE) published guidance on the anti-tumour necrosis factor alpha (anti-TNF $\alpha$ ) treatment, etanercept and infliximab for adults. At the same time, NICE (2002) published guidance on the use of etanercept for children and young adults with JIA.

Currently, the only biologic therapy licensed and recommended for use in patients with JIA aged 4 - 17 years is etanercept.

There are, however, research trials in both the UK and USA for the use of infliximab in treating JIA. In the future, infliximab, anakinra and adalimumab may all be used in paediatric treatment. The RCN Paediatric Rheumatology Specialist Nurses Group will be monitoring the evolution of these therapies and will develop further guidance in accordance with NICE recommendations (*see Part 1: Appendix 8 for details of how to contact this group*).

Most paediatric rheumatology units are already administering etanercept, although prescribing remains restricted by the availability of treatment and resource implications, and service provision varies around the UK.

Midwifery Council Register (NMC, 1997).

The RCN Paediatric Rheumatology Nurse Specialists Group advocates the expansion of the paediatric rheumatology CNS role, although it recognises that this may be achieved initially through shared care arrangements, until sufficient paediatric rheumatology nurse specialists are appointed.

## The need for specialist nurses

The expansion of numbers of paediatric patients prescribed etanercept has been limited by insufficient numbers of paediatric rheumatology clinical nurse specialists (CNS). In writing this guidance, therefore, the RCN Working Party had to recognise that at present children and young people may not be exclusively cared for by designated paediatric rheumatology CNS. Care may be shared by other health care professionals, including adult rheumatology nurse specialists, community children's nurses (CCNs), paediatric nurses or allied health professionals (AHPs).

As a matter of urgency, the RCN believes that individual NHS trusts should develop strategies to ensure that children and young people receive care and treatment from nurses who have received specific training (RCN, 2003). A non-registered children's nurse currently providing care to children and young people must only do so under the direct supervision of a registered children's nurse on Part 8 or 15 of the Nursing and

## Paediatric Section 1

# Assessment and management of patients

Note that in preparing this guidance, the Working Party found that in some areas of clinical practice, the evidence to support best practice remains unclear. In these cases, we have provided advice based on pragmatic clinical experience and information gained from clinicians who are experienced in the assessment and management of children and young people receiving biologic therapies.

### a. The Biologics Register

While managing all patients receiving biologic therapies, it is important to collect data for the British Society of Rheumatology Biologics Register (BSRBR). The British Paediatric Rheumatology Group is currently developing a Biologic and New Drugs Register (BNDR) for children and young people, which forms an integral part of the NICE guidance document on the use of etanercept (NICE, 2002). The BNDR is being designed to ensure linkage of data to the adult Biologics Register so that young people's transition to adult services is properly recorded.

### b. Special skills for working with children and young people receiving biologic therapies

Paediatric rheumatology CNS's and nurses who assist the administration of biologic therapies should:

- ◆ have specialist expertise in biologics and the side effects of treatment
- ◆ be skilled in teaching children and young people about their treatment, recognising their patients' level of physical and cognitive abilities
- ◆ be competent in the administration of subcutaneous injections and have the ability to teach and assess the competence of children, young people and their

families /carers in such techniques. When learning these techniques, children and young people need time to play and explore placebo equipment, and time to practice the techniques under the supervision of the specialist nurse or delegated colleagues, until both the family and the nurse feel they are safe and competent

- ◆ involve other specialists such as hospital play specialists who can be invaluable in supporting children and young people who require injections, particularly those who are needle phobic.

### c. Selection of patients

*For eligibility criteria for treatment with etanercept in children and young people, see Paediatric Appendix 2.*

To ensure that children and young people under 16 years of age are selected appropriately to receive biologic therapies, you should undertake a risk benefit analysis of each patient which is based on:

1. fulfilment of British Paediatric Rheumatology Group (BPRG) criteria for selection
2. adherence to the Biologic Register (BNDR) and adequate data collection
3. potential for self-administration: the child/young person or their parents/carers may decide to administer treatments themselves, after appropriate training. You should take into account the family's level of emotional and social support and their home circumstances when deciding whether home administration is an option
4. involvement in decision-making: the child, young person, parents and carers should be actively involved in decision making about their treatment. You can help achieve this by making sure:
  - ◆ information is given to them in a form and at a level which they can understand
  - ◆ information includes the risks and benefits of the treatments offered
  - ◆ the child/young person and family/carers are given time with a paediatric rheumatology CNS after their initial consultation with medical staff, so that they have an opportunity to review the information, and make an informed decision
  - ◆ children/young people together with their parents/carers should be provided with support, education and training plans for home administration.

5. alternative protocols: children and young people may be given the treatment, after consultation with their consultant paediatric rheumatologist, using an alternative protocol, based upon another indication. This should be clearly documented and supporting evidence written in the patient's medical notes. (Royal College of Paediatrics and Child Health (RCPCH) *Medicines for Children* gives helpful information on the use of off-licence drugs)
  6. drug availability: you must contact your unit's pharmacy department to ensure that the drug will be available at the appropriate dosage for the child/young person
  7. managing expectations: the parent or carer, and where appropriate the child/ young person should recognise that there are criteria by which the benefit of treatment with etanercept will be assessed. They should be advised that if the treatment doesn't bring them significant clinical improvement, it is likely that treatment with etanercept will be stopped. The family also need to know that whilst the NICE guidance recommends the use of etanercept, there is as yet no additional funding to support the delivery of treatment, and these resource issues could lead to a delay in treatment beginning.
- ◆ children and young people who have had TB should be excluded from biological therapies
  - ◆ attention must be given to the presentation of TB in children and young people, whilst biological therapies are being administered. If the patient has any of these high risk factors listed below, their case should be reviewed by the prescribing physician. You may also need to involve the local paediatric respiratory consultant for further assessment and investigation. High risk factors are:
    - ◆ a personal or close family history of TB
    - ◆ lived in or visited a community with a high prevalence of TB.

4. Live vaccines: live vaccines, including BCG for TB, should not be administered concurrently in patients receiving biologic therapies (See RCPCH (2002) *Immunisation of the Immuno-compromised child, best practice statement* at [www.rcpch.ac.uk](http://www.rcpch.ac.uk). See also *treatment eligibility criteria Appendix 2*). Live vaccines must not be given during treatment and for six months following the completion of treatment.

You should reinforce this information about live vaccines with parents and carers, and liaise with health visitors and school nurses to make sure they know live vaccines must not be given. Problems can arise as immunisations in school are usually administered without the parent/carer being present, further complicated by the fact that parents/carers often give consent to the full immunisation schedule months before it is actually administered, and may not be aware of the need to inform the school that they have withdrawn their consent due to their child's treatment with biological therapies, long-term steroids or methotrexate.

## d. Detailed assessment of patients

Full assessment of the child or young person, and accurate data collection about them, is essential both before treatment begins and throughout its course. *The BPRG guidance (2000) is set out in Appendix 2.*

The assessment should include the following:

1. Haematology and biochemistry (including Urea and Electrolytes), according to BPRG or local trust guidelines. These tests should fulfil the criteria for monitoring of other disease-modifying drugs co-prescribed with etanercept. It is not essential for blood monitoring to be undertaken immediately before treatment, although ideally monthly blood monitoring should be planned to be near the time of the treatment.
2. Height and weight checks before commencement of treatment, and drug dosage calculated according to this weight.
3. Tuberculosis (TB):
  5. Consent: the child/young person as appropriate and their parents/carers are accurately informed and prepared to continue with treatment. They must have signed the relevant consent form (if necessary for local policy). If no consent form is used in your trust, ensure you document what information was given to the child/young person and their family/carers, and document the consent of parent/carers (or if appropriate the child/young person) in their medical notes.
  6. BPRG Criteria and BNDR: you should complete, or liaise with prescribing physician to support completion of, the BPRG criteria and biologic register (BNDR) (currently under development)
  7. Psychological preparation: children and young

people must have been prepared psychologically for the treatment, and given preparation which is age appropriate, so they know what to expect. They need to know, and assist the decision about, how, where and by whom subcutaneous administration will be delivered. Parents and carers also need to be prepared adequately, to ensure they can meet the needs of the child/young person.

8. Training for subcutaneous administration of biologic therapies at home: a training package is required to ensure the child/young person and their parent/carer understands their responsibilities in ensuring a supply and keeping up treatment. The family also needs to understand about the safe handling, storage and disposal of etanercept and the associated equipment at home.

## e. Before subcutaneous biologic therapies are administered

1. A paediatric rheumatology CNS or a nurse with designated responsibility must be available to support and guide nurses or practitioners providing care for paediatric rheumatology patients.
2. The preparation of the injection must be undertaken according to the Summary of Product Characteristics (SPC) of the drug, and administered within the stipulated time frame.
3. The paediatric consultant rheumatologist or their registrar must have assessed and stated that the child/young person is fit for treatment.
4. Checks before the first administration: the first and subsequent assessments should include the following:
  - ◆ routine questioning about potential infectious contacts (for example, chicken pox, TB). If an infection is suspected, consult prescribing physician
  - ◆ confirmation from the parent/carer, and if appropriate the child/young person, that they are not aware of any inter-current infections
  - ◆ with young girls/women of childbearing age, thorough discussion of the potential risks to the foetus if the girl is pregnant whilst receiving etanercept and or methotrexate. You should ensure that young women know what local community resources are available to support

sexual health, and you should have information readily available on contraception, emergency contraception and the management of unplanned pregnancies. Reassure the patient that you and your paediatric colleagues will give them a confidential service

- ◆ young women of childbearing age should confirm that they are using an effective method of contraceptive if sexually active. The point at which this information is discussed will be dependant on the maturity of the child/young person
  - ◆ whether the child or young person has any known allergies. It is essential that all allergies be taken seriously.
5. Continued checks: after the first dose, you or an appropriately trained and competent nurse should undertake the routine checking of the child/young person to ensure they continue to be fit to receive their subcutaneous injection.

If observations by you or another nurse indicate abnormalities/infections, or raise doubts about whether the treatment should continue, seek specialist advice from the paediatric rheumatology nurse specialist or prescribing physician.

## f. Drug dosages

Etanercept for children and young people is prescribed as 0.4mg per kg twice weekly. The total dose must not exceed a maximum dose of 25mg twice weekly.

## g. Follow-up care between treatments

1. Make sure that the family are given, both verbally and in writing, contact details, both for normal hours and out-of-hours. Out of hours contact will depend on local services and on-call arrangements within your paediatric rheumatology team.
2. Make sure the child/young person and their parent/carer knows when their next treatment date is, and when they need to have drug monitoring/bloods repeated.
3. Ensure a date is set for a full assessment and review of treatment. This should be carried out monthly for the first three months of treatment, and then

## Paediatric Section 2

continue three-monthly whilst on etanercept, if the child's/young person's condition allows, and for one year after etanercept treatment has stopped. Even if families become self-sufficient in the administration of etanercept at home, they must continue to be monitored, as problems with compliance are not uncommon, particularly with adolescent patients.

4. Ensure the family and patient, if appropriate, are informed of the date for the review appointments.
5. Keep the child or young person informed by letter of the treatment schedule and monitoring. Make sure the GP is aware of the BSR website for information on biologic therapies.
6. Alert cards: the RCN Paediatric Rheumatology Specialist Nurses Group is exploring the option of an alert card for children and young people, similar to those provided for adult rheumatology patients. When available, this should be given to the young person or their family.

# Specific issues in resource planning for children and young people

As a specialist paediatric rheumatology practitioner, it is your responsibility to ensure that appropriate resources are available to provide safe and effective treatment of children and young people in your unit. Each unit will have particular strengths and weaknesses in their team skill mix, level of medical support and facilities. In Part 1 (Adult section) of *Assessing, managing and monitoring biologic therapies for inflammatory arthritis, Section 2: Resource issues* (page 10), you will find detailed help in analysing current and future provision and costs in your unit.

Here, in the Paediatric Section, we have highlighted particular issues for the care of children and young people, which you will need to take into account if you are planning services which include paediatric treatment. This is purely an advisory document, and you will need to develop guidance that is tailored to local needs.

You will find a list of key documents to access before planning service provision of biologic therapies in the reference sections of the Adult guidance.

## Biologics Register

Whatever the structure of your local paediatric rheumatology service, it is very important that you recognise the importance of collecting data for the British Society of Rheumatology Biologics Register (BSRBR) or for the new Biologic and New Drugs Register (BNDR) for children and young people being prepared by the British Paediatric Rheumatology Group.

When reviewing and planning your local service needs, you will need to take into account the time implications of collecting data for the BSRBR or BNDR.

## Providing a seamless service

Due to the distances some children and young people often need to travel to access specialist paediatric rheumatology services, shared care arrangements are often instigated. This arrangement for care must be highly organised and robust to maintain a safe and efficient service. Everyone involved in delivering care must be fully informed and competent in the specialist care required by children and young people and their parents or carers.

Close liaison is also required between the specialist hospital services, primary health care teams and educational teams, especially when these professionals are directly involved in the administration and support of children and young people receiving biologic therapies.

## Tailoring support from pharmaceutical companies

Some rheumatology units are supported by pharmaceutical companies in employing nurses to support the care of children and young people. It is important that these nursing staff are specifically assessed for their competency to work with children and young people. This includes assessment regarding:

- ◆ child protection issues
- ◆ paediatric clinical skills
- ◆ attitudes to children and young people
- ◆ communication with children, young people and parents/families.

Not all staff employed by pharmaceutical or drug distribution companies will be able to meet these criteria. For more information, see the Nursing and Midwifery Council/UKCC1997 guidance, *Working in posts not related to your registration status*.

If pharmaceutical companies support new posts, you need to ensure that the employing NHS trust is committed to ensuring that the new position will be substantive once pharmaceutical funding ceases, especially if the post is directly attributable to the administration and ongoing monitoring of treatments.

## Specialist expertise and skill mix

The RCN Working Party identified three levels of competency to help paediatric rheumatology clinical nurse specialists recognise the range of skill mixes that may be used in planning the provision of care.

Whatever the skill mix, it is essential that it includes adequate paediatric rheumatology CNS support for children and young people receiving biologic therapies. The competency levels are set out in detail in Paediatric Appendix 4.

**Note: when using Part 1 (Adult section), Section 2: Resource Issues to plan paediatric rheumatology services, you will need to substitute 'specialist rheumatology practitioner' with 'paediatric rheumatology clinical nurse specialist'. Some units will, of course, have nurse specialists in both adult and paediatric care.**

# Paediatric references and contacts

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- Wyeth (2003) *Summary of Product Characteristics Etanercept*. [www.emc.vhn.net](http://www.emc.vhn.net)

## Websites and other contacts

Abbott – request for adult licence submitted to the European Agency for the Evaluation of Medicinal Products (EMA). For specific information about Adalimumab (D2E7). Seek advice from Rheumatology Medical Adviser at Abbott UK.

[www.abbottuk.com](http://www.abbottuk.com) or telephone 01628 773355

Arthritis Care – guidance for adults and children receiving anti-Tumour Necrosis Factor alpha treatment.

[www.arc.org.uk](http://www.arc.org.uk)

Arthritis Musculoskeletal Alliance (ARMA)

[www.boneandjointdecade.org.uk](http://www.boneandjointdecade.org.uk)

Arthritis Research Campaign: patient information leaflets on Infliximab and Etanercept. [www.arc.org.uk](http://www.arc.org.uk)

British Society for Rheumatology website for guidance on preparing a business case. [www.BSR.org.uk](http://www.BSR.org.uk)

British Society for Rheumatology Biologics Register

[www.arc.man.uk](http://www.arc.man.uk)

Children's Chronic Arthritis Association: Tel: 01905 745595

[www.ccaa.org.uk](http://www.ccaa.org.uk)

GP information on the treatment and management of biologic therapies: [www.BSR.org.uk](http://www.BSR.org.uk).

Lady Hoare Trust for Physically Disabled Children: 87 Worship Street, London. EC2A 2BE, telephone: 0207 8209989. [www.ladyhoaretrust.org.uk](http://www.ladyhoaretrust.org.uk)

National Rheumatoid Arthritis Society (NRAS)

[www.rheumatoid.org.uk](http://www.rheumatoid.org.uk)

Patient information leaflets on tuberculosis treatment

[www.Brit-thoracic.org.uk](http://www.Brit-thoracic.org.uk)

Pharmaceutical companies:

[www.abbottuk.com](http://www.abbottuk.com).

[www.kineretrx.com](http://www.kineretrx.com).

[www.remicare.co.uk](http://www.remicare.co.uk). This website has additional practitioner support including educational programmes. For further information speak to the local Schering Plough representative or Remicare Team.

[www.wyeth.co.uk](http://www.wyeth.co.uk)

Royal College of Nursing Rheumatology Forum -

[www.rcn.org.uk](http://www.rcn.org.uk)

The Royal College of Paediatrics and Child Health -

[www.rcpch.ac.uk](http://www.rcpch.ac.uk)

Scottish Consensus Guidelines: these will be published on the Scottish Society web page later in 2003: [www.sign.ac.uk](http://www.sign.ac.uk)

Summary of Product Characteristics (SPC) for Biologic Therapies ([www.EMC.vhn.net](http://www.EMC.vhn.net)). A full summary of product

characteristics of licensed therapies can be found on this site. These are regularly updated. Practitioners will need to register using their professional registration number to access this website

The Source. Young Arthritis Care, for young people aged 25 and under. 18 Stephenson Way, London. NW1 2HD, Helpline: 0808 8082000

## Further reading

British Society for Rheumatology (2001) *Drug monitoring guidelines*. London: BSR

British Thoracic Society Guidelines: Joint Tuberculosis Committee (1998) Chemotherapy and management of tuberculosis in the United Kingdom: recommendations 1998. *Thorax*: 53: 536-548

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Arthritis Research Campaign (2001) Defining the extended clinical role for allied health professionals in rheumatology. *arc Conference Proceedings No.12*. London: Arthritis Research Campaign

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## Paediatric Appendix 1:

### Classification of juvenile idiopathic arthritis (JIA)

1. **Oligoarticular onset:** 5 joints involved in the first 6 months of disease
  - Persistent:** 4 or fewer total joints involved in the duration of follow up
  - Extended:** 4 joints involved in the duration of follow-up
2. **Polyarticular onset:** 5 or more joints involved in the first 6 months of disease, usually involving small joints in a symmetrical distribution
  - Rheumatoid Factor Positive
  - Rheumatoid Factor Negative
3. **Systemic Onset:** Chronic arthritis associated with systemic features. Including: high temperature, spiking fevers, transient episodic erythematous rash, Lymphadenopathy and hepatosplenomegaly
4. **Psoriatic Arthritis:** Chronic arthritis usually with asymmetrical small and large joint involvement and either or evidence of psoriatic diathesis (family history or nail pits)
5. **Enthesitis-related arthritis:** Previously known as juvenile arthropathy. Chronic arthritis associated with enthesitis (inflammation at the insertion of the tendons, ligaments or fascia to bone), with lower axial skeletal involvement. An HLA B27 related arthropathy. A significant proportion of patients will develop sacro-iliitis as adults, but back and sacro-iliac involvement is uncommon during childhood
6. **Unclassified:** Any form of idiopathic chronic arthritis which does not fit into the above categories

## Paediatric Appendix 2:

# The British Paediatric Rheumatology Group Guidelines for prescribing biologic therapies for children and young persons with juvenile idiopathic arthritis

Eligibility for treatment with etanercept in children and young people. (British Paediatric Rheumatology Group April 12 2000)

### Inclusion criteria

Juvenile Idiopathic Arthritis (JIA) of the following types (see Paediatric Appendix 1 for definitions):

- ◆ systemic
- ◆ polyarticular (sero-negative or positive for rheumatoid factor)
- ◆ extended oligo-articular
- ◆ psoriatic
- ◆ enthesitis-related

And the following features:

- ◆ 5 or more swollen joints and
- ◆ 3 or more joints with limitation of motion and pain, tenderness or both.

The measurement of disease activity must be strictly defined, objective and robust.

The standard core set data will be used to assess response to therapy:

- ◆ number of active joints
- ◆ number of joints with loss of range of movement
- ◆ physicians global assessment
- ◆ patient or Parent's global assessment
- ◆ CHAQ (Childhood Health Assessment Questionnaire)
- ◆ ESR.

Measurements should be made at 2 points, 1 month apart.

(For Information on Varicella please see Paediatric Appendix 3)

### Failure of standard therapy

Patients must have had adequate therapeutic trial of methotrexate. An adequate therapeutic trial would be defined as:

- ◆ treatment for at least 3 months at a dosage of parenteral methotrexate of 20 mg/m<sup>2</sup> weekly (unless significant toxicity limited the dose tolerated)
- ◆ ≥ 5 active joints and ≥ 3 joints with loss of motion plus pain / tenderness

- ◆ the disease is only controlled by unacceptable side effects of high doses of Corticosteroids (>0.25 mg/kg daily) and has active disease as defined above in the last 6 months.

### Exclusion criteria

Reference should be made to the drug data sheet (SPC), but important exclusions include:

- ◆ young women who are pregnant or breast-feeding or who are sexually active but with inadequate contraception
- ◆ active infection
- ◆ current or previous tuberculosis
- ◆ previous or present sepsis of a prosthetic joint still in situ
- ◆ malignancy or pre-malignancy states
- ◆ immuno-deficiency.

### Criteria for withdrawal of therapy

Treatment will be withdrawn in the event of adverse events:

- ◆ malignancy
- ◆ severe drug related toxicity
- ◆ pregnancy (temporary withdrawal)
- ◆ severe inter-current infection (temporary withdrawal).

Response should be assessed at 6 months by core set outcomes and reference made to the current guidelines on continuing treatment.

### Prescribing centres

It is recommended that consultants should only prescribe etanercept if they regularly see children and young people with JIA. They must have expertise in the use of parenteral methotrexate at the dosage described in this guidance. They must also be willing to take part in future studies of biologic agents. In addition, the centre must have a nurse specialist who is able to teach children and parents injection techniques and does this regularly. A condition of the drug licence is that all patients should be entered into the BPRG Biologic Registry. This reflects good practice for a novel therapy.

This guidance will be reviewed in line with development of the Biologics and New Drugs Register (BNDR).

## Paediatric Appendix 3:

### Varicella and vaccinations

All patients should have their Varicella antibody status measured before commencing Immuno-suppressive treatment (for example, etanercept, steroids and methotrexate).

In children and young people who do not have adequate antibodies, this test should be re-checked annually as the child/young person may have been in contact with chickenpox and sero-converted to being positive.

Children/ young people and their siblings can be considered for Varicella immunisation, if appropriate, before commencement of immuno-suppressive treatment. This does not always give full immunity and may need to be repeated. There are three issues to be considered when immuno-suppressing children and young people are following the administration of a live vaccine:

1. the risk of clinically developing the illness
2. the immune response being modified such that the vaccine will be less effective
3. the timing for the commencement of treatment should be discussed with the prescribing physician.

Zoster Immuno Globulin (ZIG) can be given to a sero-negative patient who has been in contact with chickenpox if given less than 72 hours from contact (it may attenuate infection if given up to 10 days post exposure). However, this will only provide temporary immunity of approximately 4 weeks.

Acyclovir (oral or intravenous) can be given if a child/young person displays clinical features of chickenpox (RCPC, 2002).

All live vaccines are contra-indicated, for example, polio, BCG, MMR, oral typhoid and yellow fever vaccines. Inactivated polio vaccine (Salk) should be given instead of live polio to all household contacts British National Formulary (BNF) (2002).

## Paediatric Appendix 4:

### Core competencies for paediatric rheumatology care

#### Competencies level 1:

**Paediatric rheumatology clinical nurse specialist, educated to degree standard or working towards a degree.**

#### Level 1 nurses should have a working knowledge of:

- ◆ inflammatory joint disease
- ◆ role of disease-modifying anti-rheumatic drugs (DMARDs), their side effects and monitoring
- ◆ role of biologic therapies, their side effects and monitoring
- ◆ managing the safe administration of therapies, including development of therapies and procedures, basic life support, anaphylaxis support/awareness, and able to consider environments available for administering therapies and ensure they are made safe
- ◆ cytotoxic policies and procedures (if child/young person receiving chemotherapy)
- ◆ NICE recommendations about etanercept (or relevant guidance depending on area of UK)
- ◆ knowledge of functional assessments, in collaboration with physiotherapy and occupational therapy colleagues
- ◆ pain management in chronic inflammatory disease
- ◆ psycho-social and holistic support.

#### Level 1 nurses should be able to facilitate:

- ◆ recognition of the CNS role within the multi-disciplinary team
- ◆ ensuring all members of the team understand the limitations of their authority
- ◆ ensuring that nursing practices are safeguarded when undertaking nurse-led initiatives
- ◆ development and dissemination of patient information, providing regular updates
- ◆ monitoring of the child's/young person's disease activity and outcomes
- ◆ provision of care in a safe, appropriately resourced environments, or clear identification of resource deficits to senior management
- ◆ training programmes for the multi-disciplinary team and in external settings where other health professionals are administering biologic therapies to children and young people

- ◆ access to 24 hour contact by families, by giving them the knowledge of who to contact and when.

## Competencies level 2:

### Ward or clinic nurse, in hospital setting

These nurses must be assessed as competent by the paediatric rheumatology CNS or delegated deputy, and will require information about:

- ◆ basic rheumatology knowledge
- ◆ knowledge of protocols and disease management
- ◆ understanding of drug therapies
- ◆ knowledge and understanding of safe administration of therapies
- ◆ knowledge of safe cytotoxic administration (if appropriate).

## Competencies level 3:

### Community practitioners, parents, carers, and as appropriate children and young people themselves.

These people should:

- ◆ be able to administer therapies within defined protocols
- ◆ have knowledge of safe practices in administration and disposal of equipment
- ◆ have basic knowledge of the disease and its management.

The assessment of families, children and young people as competent to home-administer therapies requires considerable skill. Practitioners based in hospital should, if possible, link with community children's nurses to draw on their considerable expertise in supporting the delivery of therapies in community settings.

When considering home administration, ensure that an adult trained in the safe administration of biological therapies supervises children and young people administering their own treatment. Safety of drugs storage and equipment in the home is also an issue for consideration.

Any non-registered children's nurse providing care/treatment to children and young people must be directly supervised by a registered children's nurse on part 8 or 15 of the NMC register. Trusts must identify a strategy to ensure that children and young people receive care/treatment from appropriately trained personnel.





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## **Erratum**

***Assessing, managing and monitoring biologic therapies for inflammatory arthritis, RCN 2003.***

The following acknowledgment was omitted from the publication:

**During the development of the Rheumatology Forum document the University Hospital Birmingham NHS Trust, Department of Rheumatology's *Protocol for the administration of subcutaneous methotrexate by registered nurses, patients and carers*, as drawn up by Valerie Arthur and Dawn Homer, was consulted. This protocol is one example of good practice in the administration of subcutaneous methotrexate.**