

Anticoagulation therapy service

Commissioning guide

Implementing NICE guidance

December 2007

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Anticoagulation therapy service

This commissioning guide provides support for the local implementation of NICE clinical guidelines through commissioning, and is a resource to help health professionals in England to commission an effective anticoagulation therapy service for patients, in particular those with atrial fibrillation.

This commissioning guide should be read in conjunction with the following NICE guidance:

- [NICE clinical guideline CG36 'The management of atrial fibrillation'](#).

The clinical guideline covers clinical and cost effectiveness in detail and underpins the content of this guide.

The guide:

- [makes the case for commissioning an anticoagulation therapy service](#)
- [specifies service requirements](#)
- [helps you determine local service levels](#)
- [helps you ensure corporate and quality assurance](#).

The full text of this commissioning guide is accessed from the navigation menu on the right hand side of the screen. The associated [commissioning tool](#) is available until 25 June 2010 to primary care organisations in England who are already registered to use the tool. New registrations for the existing commissioning tool will not be possible after 31 March 2010.

From 1 April 2010 the new freely available [commissioning and benchmarking tool can be downloaded here](#). There is no need to register.

We are keen to improve the commissioning guides in order to better meet the needs of commissioners. Please [send us your ideas for future topic-specific guides or other comments](#).

Read the [NICE disclaimer](#) for information on the use and accuracy of content on the NICE website.

- [Topic-specific Advisory Group: anticoagulation therapy service](#)

Commissioning an anticoagulation therapy service

Anticoagulation therapy is most commonly required for patients at high risk of thromboembolism, either following an episode of venous thromboembolism or in those with atrial fibrillation (AF) or prosthetic heart valves.

AF is the most common sustained cardiac arrhythmia, and if left untreated is a significant risk factor for stroke and other morbidities. It is often only detected after patients present with serious complications of AF, such as stroke, thromboembolism or heart failure. Patients with AF who develop a stroke have greater mortality, more disability, more severe strokes, longer duration of in-hospital stay and a lower rate of discharge to their own homes^{[1] [2] [3]}. Appropriate anticoagulation therapy (adjusted-dose warfarin) in people with AF can reduce mortality and morbidity^[4].

Benefits

The potential benefits of robustly commissioning an effective anticoagulation therapy service include:

- **ensuring that appropriate patients receive anticoagulation therapy** and monitoring promptly, which should be in line with the [national service framework for coronary heart disease](#), and for patients with AF the [NICE clinical guideline CG36 on AF](#)
- **reducing the risk of thromboembolic stroke in AF**, which may impact positively on stroke service requirement and capacity
- **reducing inequalities** in access to anticoagulation therapy
- **improving anticoagulation control** in patients, and reducing drug-associated complications
- **better value for money**, through helping commissioners to manage their commissioning budgets more effectively and implementing more cost effective treatments – this may include opportunities for clinicians to undertake local service redesign to meet local requirements in novel ways.

Key clinical issues

Key clinical issues in providing an effective anticoagulation therapy service are:

- **accurately identifying all patients with AF who require anticoagulation therapy** in line with the [NICE clinical guideline CG36 on AF](#) according to the [stroke risk stratification algorithm](#)
- **providing effective anticoagulation therapy**
- **[providing a quality-assured service](#)**
- **ensuring there is ongoing monitoring** to reduce bleeding risk.

National priorities

National priorities and initiatives relevant to commissioning an anticoagulation therapy service include:

- [World class commissioning](#).
- [The NHS in England: The operating framework for 2009/10](#).
- Providing appropriate evidence-based care for patients with AF; see [standard 5](#) and [chapter 8](#) (Arrhythmias and sudden cardiac death) of the national service framework for coronary heart disease, and also the [NICE clinical guideline CG36 on AF](#)
- The [National enhanced service](#) for anticoagulation therapy.
- The [Care closer to home](#) initiative outlined in chapter 6 of the white paper 'Our health, our care, our say'.
- Considering the impact of [patient choice](#).
- The [Expert patients programme](#).
- Implementation of NICE clinical and public health guidelines. These are currently core standards, and performance against these standards will be assessed by the [Care Quality Commission](#) in line with [Standards for better health](#).

Although many or all of these priorities may be relevant to the services nationally, your local service redesign may address only one or two of them.

References

1. Wolf PA, Abbott RD, Kannel WB (1991) [Atrial fibrillation as an independent risk factor for stroke: the Framingham Study](#). Stroke 22 (8): 983–988.
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3. Jorgensen HS, Nakayama H, Reith J et al. (1997) [Stroke recurrence: predictors, severity, and prognosis. The Copenhagen Stroke Study](#). Neurology 48: 891–895.
4. Lip GY, Tello-Montoliu A (2006) [Management of atrial fibrillation](#). Heart 92 (8): 177–82.

Specifying an anticoagulation therapy service

Service components

The key components of an effective anticoagulation therapy service are:

- ensuring appropriate referral and management of patients with atrial fibrillation (AF) who require anticoagulation therapy
- effective management of patients who require anticoagulation for other reasons
- [developing a high-quality anticoagulation therapy service](#).

Appropriate referral and management of patients with AF who require anticoagulation therapy

This commissioning guide does not describe the diagnosis of patients with AF. However, it is clearly an important step towards directing appropriate patients to anticoagulation therapy services. Local organisations might wish to [develop protocols](#) for diagnosing patients with AF, based on the [NICE clinical guideline CG36 on AF](#).

Key priorities for implementation, as outlined in the [NICE clinical guideline CG36 on AF](#), include:

- “in patients with newly diagnosed AF for whom antithrombotic therapy is indicated (see section 1.8.6), such treatment should be initiated with minimal delay after the appropriate management of comorbidities”
- “the [stroke risk stratification algorithm](#) should be used in patients with AF to assess their risk of stroke and thromboembolism, and appropriate thromboprophylaxis given”.

Ensuring that appropriate patients with AF are referred for anticoagulation therapy is important both in terms of reducing the risk of stroke, but also in managing service demand.

Management of patients who require anticoagulation therapy for other reasons

NICE has not issued guidance on the management of patients who require anticoagulation therapy for other reasons, such as those who have experienced an episode of thromboembolism.

Advice on managing these patients can be obtained from [NHS Evidence Health Information Resources](#), and also from the [Clinical Knowledge Summaries service](#), which has produced guidelines for the [management of patients with deep vein thrombosis](#).

Developing a high-quality anticoagulation therapy service

Information on the detailed requirements of an anticoagulation service is available from the [national enhanced service](#) specification for anticoagulation monitoring within the General Medical Services contract.

Commissioners may wish to consider that an anticoagulation therapy service can be delivered in a number of different ways, and that mixed models of provision may be required across a local health economy. Examples include:

- full service provision in secondary care
- full service provision in primary care
- shared provision between primary and secondary care
- domiciliary provision
- patient self-management.

Services may be managed by a range of healthcare professionals including nurses, pharmacists and general practitioners.

Local stakeholders, including [service users](#), should be involved in determining what is needed from an anticoagulation therapy service in order to meet local needs. The service specification needs to consider:

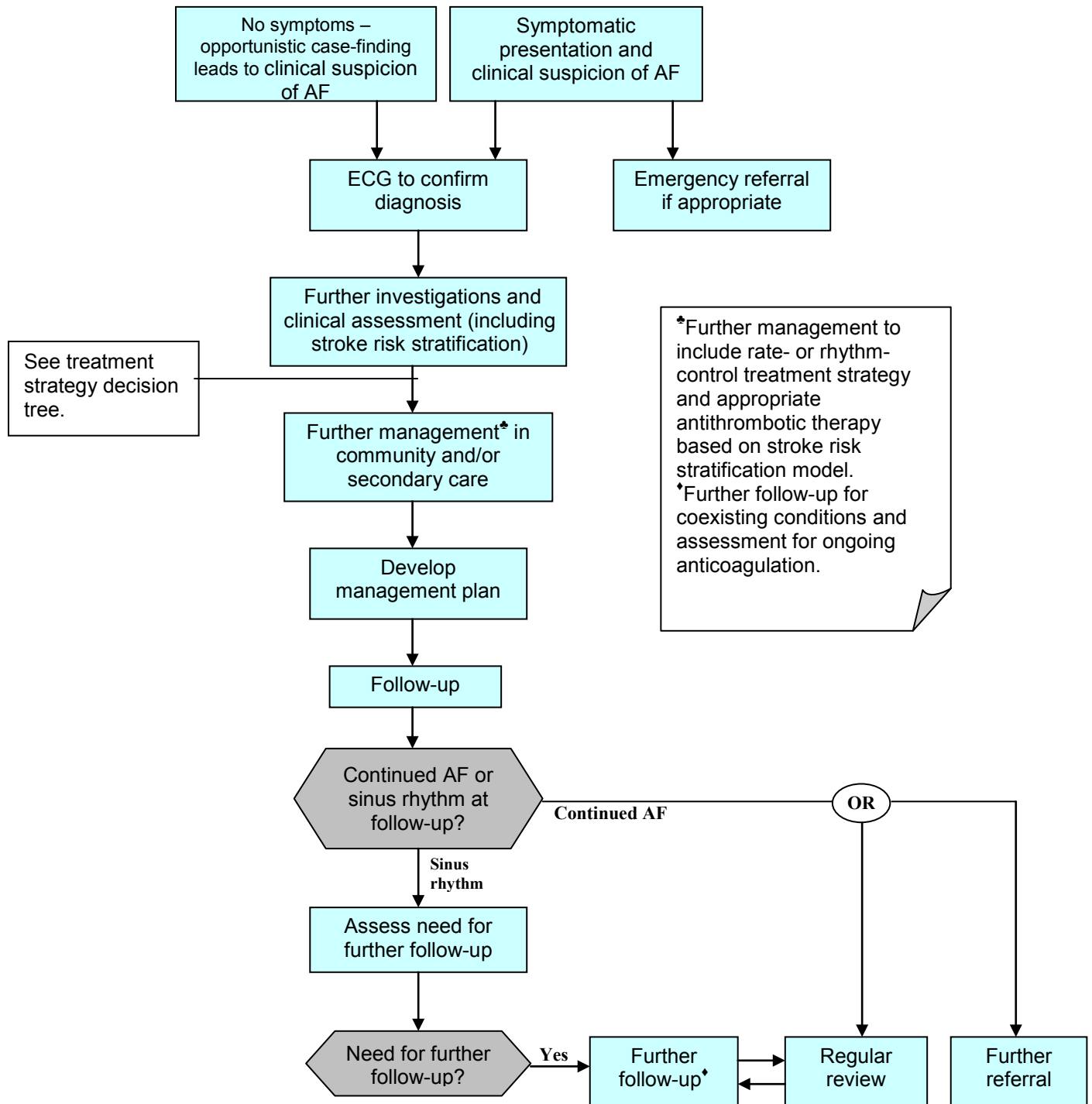
- the expected number of patients
- ease of access
- location of the service
- information and audit requirements, including IT support and infrastructure
- required competences of, and training for, staff responsible for providing anticoagulant care
- planned service improvement, including redesign, quality, equitable access, and referral-to-treatment times according to the [18 week patient pathway](#) or equitable waiting times locally for those services currently outside 18 weeks
- [service monitoring criteria](#).

Useful sources of information may include:

- [Implementation advice for NICE clinical guideline CG36 on atrial fibrillation](#)
- NICE [National Costing Report](#) for further information on costs associated with implementing the NICE clinical guideline CG36 on AF
- NHS Evidence
- [British Committee for Standards in Haematology](#) (BCSH).
- [Delivering the 18 week patient pathway: 18 week commissioning pathways](#)

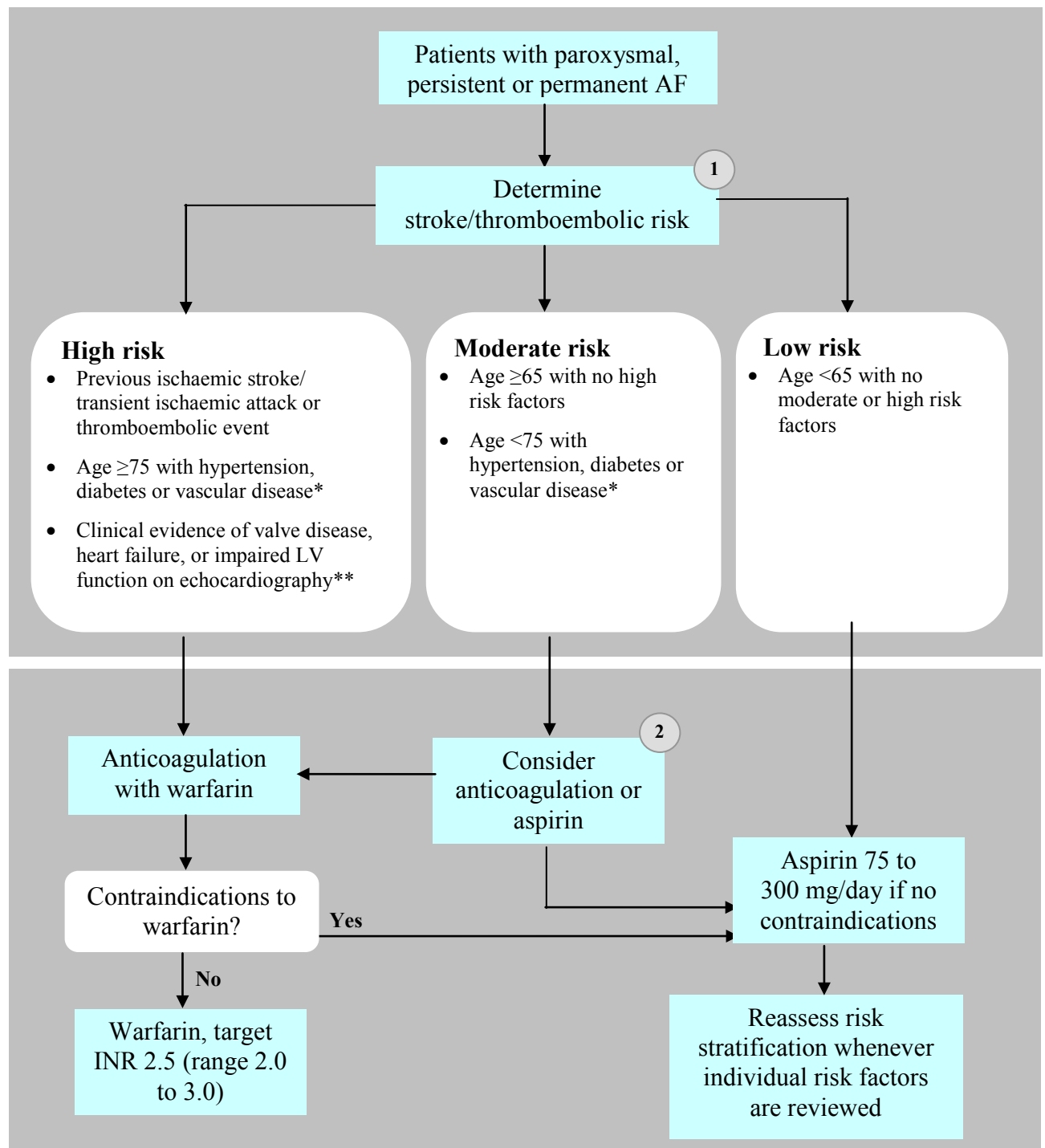
Atrial fibrillation care pathway

The following care pathway is from the [NICE clinical guideline CG36 on atrial fibrillation](#) (Appendix E).



Stroke risk stratification algorithm

The following algorithm is from the [NICE clinical guideline CG36 on atrial fibrillation](#) (Appendix E).



1. Note that risk factors are not mutually exclusive, and are additive to each other in producing a composite risk. Since the incidence of stroke and thromboembolic events in patients with thyrotoxicosis appears similar to that in patients with other aetiologies of AF, antithrombotic treatments should be chosen based on the presence of validated stroke risk factors.
2. Owing to lack of sufficient clear-cut evidence, treatment may be decided on an individual basis, and the physician must balance the risk and benefits of warfarin versus aspirin. As stroke risk factors are cumulative, warfarin may, for example, be used in the presence of two or more moderate stroke risk factors. Referral and echocardiography may help in cases of uncertainty.

*Coronary artery disease or peripheral artery disease.

** An echocardiogram is not needed for routine assessment, but refines clinical risk stratification in the case of moderate or severe left ventricular (LV) dysfunction and valve disease.

Determining local service levels for an anticoagulation therapy service

Benchmarks for a standard population

Available data suggest that the benchmark population rate for people requiring anticoagulation therapy at any one time is **1.40%**, or 1400 per 100,000 population, **per year**. This rate includes people who require anticoagulation therapy because of atrial fibrillation (AF), and those who have other indications such as recent deep vein thrombosis or other conditions leading to thromboembolism. Areas with a relatively elderly population might be expected to have a higher rate as there is increasing prevalence and incidence of AF with increasing age. Areas with a population with increased risk factors for AF may also be expected to have a higher rate.

For a **standard primary care trust** population of 250,000, the average number of patients expected to require anticoagulation therapy at any one time is likely to be approximately **3500**.

For an **average practice** with a list size of 10,000, the average number of patients expected to require anticoagulation therapy at any one time is likely to be approximately **140**.

This service is likely to fall under the [programme budgeting](#) category 210C (problems of circulation - rhythm). It may also fall under category 203X (disorders of blood).

Examine the [assumptions used in estimating these figures](#).

Use the anticoagulation therapy service [commissioning and benchmarking tool](#) to determine the level of service that might be needed locally and to calculate the cost of commissioning the service using the indicative benchmark and/or your own local data.

Further information

Sources of further information to help you in assessing local health needs and reducing health inequalities include:

- Annex A of the [Commissioning framework for health and well-being](#) outlines the process and data needed to undertake a joint strategic needs assessment.
- Department of Health [Delivering quality and value – focus on benchmarking](#).

- NICE [Health equity audit – learning from practice briefing](#).
- [PRIMIS+](#) provides support to general practices on information management, recording for, and analysis of, data quality, plus a comparative analysis service focused on key clinical topics.

Assumptions used in estimating a population benchmark

The assumptions used in estimating a benchmark rate of **1.40%** of the population requiring anticoagulation therapy per year are based on the following source of information:

- **epidemiological data** estimating the prevalence of conditions requiring anticoagulation therapy, namely atrial fibrillation (AF), deep vein thrombosis and patients with prosthetic heart valves.

Epidemiological data

Prevalence of atrial fibrillation

DeWilde^[1] and coworkers examined trends in the prevalence of diagnosed AF between 1993 and 2003 using data from 131 general practices (about one million registered patients annually) in the UK. They estimated, in 2003, the prevalence of active- and ever-diagnosed AF to be 1.31% and 1.49% respectively in men, and 1.15% and 1.29% respectively in women. The same research found that prevalence rose steadily with increasing age, with the prevalence of active AF in those aged 85 years and over to be 13.2% in men and 11% in women.

The proportion of people with AF who receive anticoagulation therapy (the uptake rate) currently varies in practice. DeWilde and coworkers found that 53% of males and 40% of females with AF were receiving oral anticoagulants, but in common with other research found that many who were eligible for anticoagulation therapy did not receive it. Published research^[2-6] suggests that the proportion of people with AF who are eligible for, but do not receive, anticoagulation could be between 20% and 40%.

The numbers of people diagnosed with AF and the proportion receiving anticoagulant or antiplatelet therapy is recorded in primary care as part of the revised [Quality and Outcomes Framework \(QOF\)](#). 2007/2008 QOF data indicates the national prevalence of diagnosed AF is 1.30%.

Using these data to estimate the proportion of people with AF who could potentially be receiving anticoagulation therapy, the following assumptions have been made:

- the average population prevalence of AF is 1.30% – derived from QOF data
- the average proportion of patients with AF currently receiving anticoagulation therapy is 47%

- the additional proportion of patients with AF who could be receiving anticoagulation therapy is 30% (mid point of 20% and 40%).

Therefore, the proportion of the population requiring anticoagulation therapy would be 1% based on a population prevalence of AF of 1.30%, and a maximum uptake of anticoagulation therapy of 77%.

Prevalence of other conditions requiring anticoagulation therapy

Other major groups requiring anticoagulation therapy include patients with:

- deep vein thrombosis
- prosthetic heart valves.

There are no national data on the incidence of deep vein thrombosis (DVT). Anecdotal evidence^[7],^[8] suggests that the incidence could be up to 0.17%. While anticoagulation therapy following DVT is not required in the long term, patients requiring treatment at any one time has been estimated at 0.2%. The use of anticoagulants for 3-6 months is sufficient for many patients^[9].

Data from the [UK heart valve registry \(UKHVR\)](#) indicate that approximately 0.2% of the population has prosthetic heart valves. All patients who receive a mechanical valve replacement are given lifelong anticoagulation. A proportion of patients with bioprosthetic valve replacement also receive anticoagulation for a variable period of time^[10].

Conclusions

Based on the epidemiological data above, the proportion of the population requiring anticoagulation therapy is estimated to be 1.4%. This comprises 1% with AF, 0.2% with DVT, and 0.2% with prosthetic heart valves.

Therefore a benchmark rate of 1.40% of the population requiring anticoagulation therapy is considered appropriate.

Use the anticoagulation therapy service [commissioning and benchmarking tool](#) to determine the level of service that might be needed locally and to calculate the cost of commissioning the service using the indicative benchmark and/or your own local data.

References

1. DeWilde S, Carey IM, Emmas C et al. (2006) [Trends in the prevalence of](#)

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8. Hansson PO, Welin L, Tibblin G et al. (1997) [Deep vein thrombosis and pulmonary embolism in the general population](#). 'The Study of Men Born in 1913'. Archives of Internal Medicine 157(15): 1665–1670.

9. Kyrle PA, Eichinger S (2005) [Deep vein thrombosis](#). Lancet 365: 1163–1174.

10. Vaughan P, Waterworth PD (2005). [An audit of anticoagulation practice among UK cardiothoracic consultant surgeons following valve replacement/repair](#). Journal of Heart Valve Disease 14: 576–82

The commissioning and benchmarking tool

[Download the anticoagulation therapy service commissioning and benchmarking tool](#)

Use the anticoagulation therapy service commissioning and benchmarking tool to determine the level of service that might be needed locally and to calculate the cost of commissioning the service, as described below

Identify indicative local service requirements

The indicative benchmark based on the national average of the population requiring anticoagulation therapy is **1.40%**.

The commissioning and benchmarking tool helps you to assess local service requirements using the indicative benchmark as a starting point. With knowledge of your local population and its demographic, you can amend the benchmark to better reflect your local circumstances. For example, if your population is significantly younger or older than the average population, or has a significantly lower or higher rate of atrial fibrillation, you may need to provide services for relatively fewer or more people.

Review current commissioned activity

You may already commission an anticoagulation therapy service for your population. The tool provides tables that you can populate to help you calculate your current commissioned activity and costs.

Identify future change in capacity required

Using the indicative benchmark provided, or your own local benchmark, you can use the commissioning and benchmarking tool to compare the activity that you might need to commission against your current commissioned activity. This will help you to identify the future change in capacity required. Depending on your assessment, your future provision may need to be increased or decreased.

Model future commissioning intentions and associated costs

You can use the commissioning and benchmarking tool to calculate the capacity and resources needed to move towards the benchmark level, and to model the required changes over a period of 4 years. Use the tool to calculate the level and cost of activity you intend to commission and to consider the

settings in which the anticoagulation therapy service may be provided, comparing the costs of commissioning the service across the various settings. The tool is pre-populated with data on the potential recurrent and non-recurrent cost elements that may need to be considered in future service planning, which can be reviewed and amended to better reflect your local circumstances.

Commissioning decisions should consider both the clinical and economic viability of the service, and take into account the views of local people. Commissioning plans should also take into account the costs of monitoring the quality of the services commissioned.

Ensuring corporate and quality assurance

Commissioners should ensure that the services they commission represent value for money and offer the best possible outcomes for patients. Commissioners need to [set clear specifications](#) for monitoring and assuring quality in the service contract.

Commissioners should ensure that they consider both the clinical and economic viability of the service, and any related services, and take into account [patients' views](#) and those of other stakeholders when making commissioning decisions.

An anticoagulation therapy service needs to:

- **define** the agreed criteria for referral, local protocols and the care pathway for patients requiring anticoagulation therapy
- **be patient-centred and provide equitable access**
- **audit safety indicators** to ensure the service is safe, and that any system risks are addressed
- **be involved in the planning** of changes to service provision and capacity, together with local stakeholders, in line with expected changes in need
- **demonstrate how it meets requirements under equalities legislation**
- **demonstrate value for money.**

Local quality assurance

Any mechanisms for quality assurance at a local level are likely to refer to the following:

- **service targets:** estimated caseloads, complaints procedures
- **audit arrangements:** frequency of reporting, reporting route and format, and dissemination mechanisms
- **clinical quality criteria:** appropriateness of referral, screening tests, waiting times, consenting procedures
- **equipment:** testing and calibration
- **patient satisfaction:** patient perspective and perceptions
- **patient outcomes:** level of therapeutic control, incidence of adverse outcomes
- **staff competence:** baseline requirements and training
- **information requirements:** including both patient-specific information (NHS number, referring GP) and service-specific information (referral-to-treatment times, workload trends, number of complaints)
- **the process for reviewing and changing the service with stakeholders,** including decisions on changes necessary to improve or to decommission the service

- achieving targets associated with equalities legislation.

Further information

General information on quality and corporate assurance can be obtained from the following sources:

- The [National Patient Safety Agency](#) (NPSA) oversees the implementation of a system to report and learn from adverse events and near misses occurring in the NHS. The publication 'Seven steps to patient safety' provides an overview of patient safety and gives updates on the tools that the NPSA is developing to support patient safety across the health service.
- [NHS Alliance online resources](#).
NHS Alliance is the representational organisation of primary care and primary care trusts, and provides them with an opportunity to network and exchange best practice. The alliance supports its members with an open access helpline, in-house and joint publications and briefings, internal newsletters and a website.
- NHS Institute for Innovation and Improvement support for commissioners, includes [Commissioning for Health Improvement](#) products to accelerate the achievement of world class commissioning; [The Productive Leader](#) programme to enable leadership teams to reduce waste and variation in personal work processes, and [Better care, better value indicators](#) to help inform planning, to inform views on the scale of potential efficiency savings in different aspects of care, and to generate ideas on how to achieve these savings
- The [DH commissioning framework](#) provides guidance on the commissioning process in the context of the NHS reform agenda.
- '[10 Steps to your SES: a guide to developing a single equality scheme](#)'. This guidance has been developed to assist NHS organisations that have a duty, as public authorities, to comply with the race, disability and gender public sector duties, and in anticipation of new duties in relation to age, religion and belief, and sexual orientation.

Specific information on quality and corporate assurance for anticoagulation therapy services can be obtained from the following sources:

- [UK National External Quality Assessment Service](#) (NEQAS) provides objective information and advice to clinical laboratories on the quality of

their analytical and interpretative performance to facilitate optimal patient care.

- The National Patient Safety Agency published a Patient Safety Alert '[Actions that can make anticoagulant therapy safer](#)' in March 2007 and signposts a range of support materials to help manage the risks associated with anticoagulants and reduce the risks of patients being harmed in the future.
- [British Committee for Standards in Haematology](#) (BCSH) provides up to date advice on the diagnosis and treatment of haematological disease through the production of [evidence-based guidelines](#), including [safety indicators for inpatient and outpatient oral anticoagulant care](#) produced jointly with the NPSA in August 2006.
- [Better Metrics](#) is a pragmatic project that provides clinically relevant measures of performance to support the development of measurable local targets and indicators for local quality improvement projects. The document includes indicators for heart disease and stroke.
- [Skills for Health](#) works with employers and other stakeholders to ensure that those working in the sector are equipped with the right skills to support the development and delivery of healthcare services. See details of the [coronary heart disease framework](#).

Topic-specific Advisory Group: anticoagulation therapy service

A topic-specific advisory group was established to review and advise on the content of the commissioning guide. This group met once, with additional interaction taking place via email.

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