

Commissioning guides

Support for commissioning: anticoagulation therapy

<http://www.nice.org.uk/guidance/cmg49>

Published: 14 May 2013

NICE has accredited the process used by NICE to produce guides for commissioners. Accreditation is valid for 5 years from November 2011 and applies to guides produced since November 2008 using the processes described in 'Process manual for developing guides from NICE for commissioners: Information for internal NICE teams' (2011). More information on accreditation can be viewed at www.nice.org.uk/accreditation



Contents

| | |
|---|----|
| 1 Key issues in commissioning anticoagulation therapy | 4 |
| 1.1 Introduction to this resource | 4 |
| 1.2 New recommendations on oral anticoagulation therapy | 4 |
| 1.3 People who need anticoagulation therapy | 5 |
| 1.4 Commissioning anticoagulation therapy | 6 |
| 1.5 Source guidance | 6 |
| 2 Commissioning for outcomes and quality improvement..... | 8 |
| 2.1 NICE quality standards | 8 |
| 2.2 Outcomes | 8 |
| 3 Monitoring the safety and quality of anticoagulation therapy | 10 |
| 3.1 Safety and quality: all anticoagulants..... | 11 |
| 3.2 Safety and quality: vitamin K antagonists | 13 |
| 4 Assessing service levels for anticoagulation therapy for adults | 15 |
| 4.1 Information and data on AF | 16 |
| 4.2 Information and data on VTE | 18 |
| 4.3 Information and data on other conditions requiring anticoagulation therapy..... | 18 |
| 4.4 Conclusion | 19 |
| 5 Specifying anticoagulation therapy for adults | 21 |
| 5.1 Specifying anticoagulation therapy for people with atrial fibrillation | 22 |
| 5.1.1 Identification and assessment | 22 |
| 5.1.2 Initiation of anticoagulation therapy for people with AF | 22 |
| 5.1.3 Timely access to anticoagulation therapy | 23 |
| 5.2 Specifying anticoagulation therapy for people with venous thromboembolism | 24 |
| 5.2.1 Initiation of anticoagulation therapy for people with VTE | 25 |
| 5.2.2 Investigations for cancer | 26 |

| | |
|---|----|
| 5.2.3 Long-term anticoagulation therapy for people with VTE | 26 |
| 5.3 Specifying anticoagulation therapy for people with other conditions | 28 |
| Monitoring for people on long-term anticoagulation therapy | 29 |
| 5.4 Specifying anticoagulation therapy for all people receiving anticoagulation therapy | 29 |
| 5.4.1 Patient education and supporting people with long term medication use | 29 |
| 5.4.2 People with complex needs | 30 |
| 5.4.3 Monitoring by healthcare professionals..... | 30 |
| 5.4.4 Self-testing and self-management for people taking vitamin K antagonists..... | 32 |
| 5.4.5 Bridging therapies for people having anticoagulation therapy | 32 |
| 5.4.6 Integration and communication | 33 |
| 5.4.7 Anticoagulation therapy and social care providers | 33 |
| 5.5 Examples of practice | 33 |
| 5.5.1 Service models..... | 35 |
| 6 Service specification for anticoagulation services | 36 |
| 7 The commissioning and budgeting tool | 37 |
| 7.1 Standard assumptions | 37 |
| 7.2 Review current commissioned activity | 38 |
| 7.3 Identify future change in capacity required | 38 |
| 7.4 Model future commissioning intentions and associated costs | 38 |
| 7.5 Potential savings | 39 |
| 8 Further information | 39 |
| Policy documents | 40 |
| NICE implementation support | 40 |
| 9 Topic Advisory Group: anticoagulation | 40 |

1 Key issues in commissioning anticoagulation therapy

To print a PDF or Word version of this support for commissioning, click on the 'Select chapters to save or share' icon above the contents menu.

1.1 Introduction to this resource

The planning and commissioning of care for people receiving anticoagulation therapy can be complex. This resource supports commissioners, clinicians and managers to commission high-quality evidence-based care for adults across England, and updates and replaces the NICE guide for commissioners on anticoagulation therapy services published in 2007.

This resource supports commissioners to review how anticoagulation therapy is currently initiated, provided, monitored and reviewed in their local area with particular consideration to the introduction of the novel oral anticoagulants. [NICE recommendations](#) for rivaroxaban, dabigatran and apixaban for stroke prevention in people with atrial fibrillation and rivaroxaban for treatment of deep vein thrombosis provide people who have these conditions with more choices of medication. This will have an impact on the commissioning of anticoagulation services at a local level, with an anticipated reduction in vitamin K antagonist monitoring services.

1.2 New recommendations on oral anticoagulation therapy

Traditionally, vitamin K antagonists such as warfarin have been the most commonly prescribed oral anticoagulants. These drugs need frequent monitoring and dose adjustment to maintain therapeutic action and minimise bleeding risk^[1]. Therefore one of the main roles of an anticoagulation service is the monitoring of people taking vitamin K antagonists.

In 2012/13 NICE published recommendations for 'new-generation' or 'novel' oral anticoagulants for the management of AF and venous thromboembolism (VTE). Rivaroxaban, dabigatran and apixaban do not require the regular monitoring needed by people taking vitamin K antagonists. The novel oral anticoagulants can be readily prescribed in primary care by GPs and a dedicated monitoring service is not needed. Commissioners should consider rationalising anticoagulation services over time as increasing numbers of people are prescribed these new drugs.

In some areas there are local policies that restrict the prescribing of the novel oral anticoagulants. Commissioners should note their obligations in meeting the recommendations made in the relevant NICE technology appraisals.

Commissioners and clinicians should ensure that patients are fully informed and actively involved in the choice of anticoagulation therapy for the management of their condition.

The commissioning and budgeting (CAB) tool will assist commissioners to plan for potential changes in local care pathways taking account of the novel oral anticoagulants. The CAB tool enables commissioners to model the cost impact of implementing NICE guidance relating to anticoagulation therapy over a period of 4 years.

1.3 People who need anticoagulation therapy

Anticoagulation therapy is needed for people with a range of different conditions, who are identified in a range of settings and, in the case of deep vein thrombosis and pulmonary embolism, require urgent intervention.

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 people present with serious complications of AF, such as stroke, thromboembolism or heart failure. People with AF who develop a stroke have greater mortality, more disability, more severe strokes, longer hospital stay and a lower rate of discharge to their own homes compared with people without AF who develop a stroke^{[2],[3],[4]}. Appropriate anticoagulation therapy for people with AF can reduce mortality and morbidity through reduction in incidence of stroke^[5].

VTE is a condition in which a blood clot (a thrombus) forms in a vein, most commonly in the deep veins of the legs or pelvis. This is known as deep vein thrombosis, or DVT. The thrombus can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism, or PE. When DVT and PE occur together, it is called VTE.

VTE is treated with anticoagulation therapy and people who have had recurrent VTE or who are at high risk of recurrence may be given prescribed anticoagulants indefinitely to prevent further VTE episodes. There are a number of anticoagulants available, including low molecular weight heparin, fondaparinux, vitamin K antagonists and rivaroxaban. This is covered in detail in the NICE clinical guideline on [venous thromboembolic diseases](#).

1.4 Commissioning anticoagulation therapy

Commissioners need to be aware of quality and safety considerations in prescribing anticoagulants and providing monitoring services for vitamin K antagonists. The Topic Advisory Group identified the following key quality issues in the commissioning of anticoagulation therapy:

- variation in the quality and safety of anticoagulation therapy across the country
- variation across the country in the activities of anticoagulation services, because there is no standard service model or definition of an anticoagulation service
- [Venous thromboembolic diseases](#) (NICE clinical guideline 144 [2012]) and [Diagnosis and management of venous thromboembolic diseases](#) (NICE quality standard 29 [2013]), published since the original guide for commissioners, make specific recommendations on anticoagulation therapy for people with VTE.
- a large proportion of people with AF are currently not receiving anticoagulation therapy in line with NICE guidance.

There are a number of ways in which to deliver anticoagulation therapy at a local level. This resource supports commissioners to take account of key quality and safety considerations when reviewing local commissioning arrangements for people receiving anticoagulation therapy. Commissioners should ensure there are robust processes in place at a local level to monitor and act on safety and quality information relating to anticoagulation therapy. This is explored further in [section 3](#).

1.5 Source guidance

This guide for commissioners should be used in conjunction with the following NICE guidance and [quality standards](#).

Atrial fibrillation

- [Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation](#). NICE technology appraisal guidance 275 (2013).
- [WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension](#) NICE medical technology guidance 13 (2013).

- [Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation](#). NICE technology appraisal guidance 256 (2012).
- [Dabigatran etexilate for the prevention of stroke and systemic embolism in people with atrial fibrillation with one or more risk factor for stroke or systemic embolism](#). NICE technology appraisal guidance 249 (2012).
- [Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism](#) NICE interventional procedures guidance 349 (2010).
- [Atrial fibrillation: the management of atrial fibrillation](#). NICE clinical guideline 36 (2006).

Venous thromboembolism

- NICE guidance on VTE as set out in the [NICE pathway on venous thromboembolism](#) including quality standards for [VTE prevention](#) and [diagnosis and management of venous thromboembolic diseases](#)
- Further NICE guidance is also in development on [rivaroxaban for pulmonary embolism and dabigatran etexilate for venous thromboembolic events](#).

Other

- [Stroke pathway: fast, easy summary view of NICE guidance on stroke, including primary and secondary prevention of stroke](#)
- [Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence](#). NICE clinical guideline 76 (2009)

A [Topic Advisory Group](#) was established to review and advise on the content of the support for commissioning; details of membership can be found in section 9.

^[1] Baglin TP et al. (2006) [Recommendations from the British Committee for Standards in Haematology and National Patient Safety Agency](#). *British Journal of Haematology* 136: 26–9.

^[2] Wolf PA, Abbott RD, Kannel WB (1991) [Atrial fibrillation as an independent risk factor for stroke: the Framingham Study](#). *Stroke* 22: 983–8.

^[3] Lin HJ, Wolf PA, Kelly-Hayes M et al. (1996) Stroke severity in atrial fibrillation. The Framingham Study. *Stroke* 27: 1760–4.

^[4] Jorgensen HS, Nakayama H, Reith J et al. (1997) Stroke recurrence: predictors, severity, and prognosis. The Copenhagen Stroke Study. *Neurology* 48: 891–5.

^[5] Lip GY, Tello-Montoliu A (2006) Management of atrial fibrillation. *Heart* 92: 1177–82.

2 Commissioning for outcomes and quality improvement

The commissioning of anticoagulation services sits within the wider commissioning strategy for cardiovascular disease and stroke prevention.

Commissioners should work with their strategic clinical network for cardiovascular disease to develop an effective and integrated local pathway for anticoagulation therapy that takes into account NICE recommendations for the novel oral anticoagulants, patient safety, patient experience, and timely access to assessment and treatment.

2.1 NICE quality standards

The NICE quality standard for the diagnosis and management of VTE describes high-quality and cost-effective care. This resource supports the commissioning of anticoagulation therapy for people with VTE in line with the quality standard. Commissioning services in line with NICE quality standard for the diagnosis and management of VTE should improve the effectiveness, safety and experience of care for people with VTE.

Each quality statement contains measures that commissioners can use to assess their progress towards improving the quality of care for people with VTE. Commissioning care in line with the quality standard will contribute to achieving Clinical Commissioning Group (CCG) outcome indicators and a number of indicators in national outcome strategies. Relevant outcomes, indicators and measures are detailed in table 1.

2.2 Outcomes

Commissioners should refer to the Clinical Commissioning Group outcomes indicator set, NHS outcomes framework, Public health outcomes framework for England 2013–2016, and Quality

and outcomes framework when reviewing how anticoagulation services are commissioned locally.

Commissioning anticoagulation therapy, in line with NICE guidance and NICE quality standards, may contribute to achieving the outcomes in table 1.

Table 1 Outcomes for people receiving anticoagulation therapy

| Framework | Outcome domains and improvement areas |
|---|--|
| <u>NHS outcomes framework 2012/13</u> | <ul style="list-style-type: none"> • Domain 3 – improving outcomes from planned treatments (see <u>section 3.1.1</u>) and improving recovery from injuries and trauma (see <u>section 3.1.3</u>) • Domain 4 – ensuring that people have a positive experience of care • Domain 5 – treating and caring for people in a safe environment and protecting them from avoidable harm |
| <u>Public health outcomes framework for England 2013–2016</u> | <ul style="list-style-type: none"> • Domain 4 – healthcare, public health and preventing premature mortality |
| <u>Adult social care outcomes framework</u> | <ul style="list-style-type: none"> • Domain 4 – safeguarding adults whose circumstances make them vulnerable and protecting them from avoidable harm (see <u>section 5.4.5</u>) |

| | |
|--|---|
| <p><u>CCG outcomes indicator set</u></p> | <ul style="list-style-type: none"> • Domain 1 – under 75 mortality from cardiovascular disease; under 75 mortality from cancer • Domain 2 – ensuring people feel supported to manage their condition • Domain 3 – emergency re-admissions within 30 days of discharge from hospital • Domain 4 – patient experience of GP out-of-hours services and patient experience of hospital care • Domain 5 – patient safety incidents reported |
| <p><u>Quality and outcomes framework (QOF)</u></p> | <ul style="list-style-type: none"> • The percentage of patients with atrial fibrillation in whom stroke risk has been assessed using the CHADS₂ risk stratification scoring system in the preceding 15 months (excluding those whose previous CHADS₂ score is greater than 1) • In patients with atrial fibrillation in whom there is a record of a CHADS₂ score of 1 (latest in the preceding 15 months), the percentage of patients who are currently treated with anticoagulation drug therapy or anti-platelet therapy • In patients with atrial fibrillation whose latest record of a CHADS₂ score is greater than 1, the percentage of patients who are currently treated with anticoagulation therapy |

3 Monitoring the safety and quality of anticoagulation therapy

The initiation, monitoring and reviewing of anticoagulation therapy for people with AF, VTE and other conditions can take place in a number of settings across the healthcare system, including hospital outpatient, primary care and community settings. The clinical opinion of the Topic Advisory Group indicates that there is wide variation in the safety and quality of the care provided to people receiving anticoagulation therapy across all settings.

The consensus of the Topic Advisory Group was that no single measure should be used to evaluate the safety and quality of anticoagulation therapy at a local level and that robust

processes should be in place to monitor and act on safety and quality assurance information. Commissioners should review all quality measures and outcomes used to monitor anticoagulation therapy. Commissioners should ensure that the safety and quality measures to be used and the process for monitoring and acting on these are built into relevant contracts. They may wish to consider the quality assurance measures set out in this section when specifying contracts with providers.

Commissioners may wish to consider a range of methods to review and act on quality measures, such as a locally agreed traffic light system. Commissioners may also wish to use the quality assurance measures discussed in this guide to develop local goals based on the Commissioning for Quality and Innovation payment framework to incentivise performance (see [section 5.5](#)).

Commissioners should refer to the [National Patient Safety Alert](#) for the alert on actions that can make anticoagulant therapy safer (for vitamin K antagonists and low molecular weight heparin) when reviewing the initiation and provision of anticoagulation therapy.

3.1 Safety and quality: all anticoagulants

3.1.1 All anticoagulation therapy: adverse events

Anticoagulants are one of the classes of medicines that most frequently cause preventable harm and admission to hospital, but it is very difficult to collect and use data on adverse events relating to anticoagulation therapy. This is because of limitations in data collection and hospital coding, particularly across multiple providers.

Commissioners should work with clinicians locally to agree methods to monitor adverse events associated with anticoagulation therapy. This may include monitoring admissions to secondary care with bleeds associated with anticoagulation therapy; prescribing errors and cases of harm/near harm from the use of anticoagulants.

Commissioners should also review and monitor rates of stroke in their area in relation to local strategies for the identification of AF and management through anticoagulation therapy.

3.1.2 Service user and carer involvement

Commissioners should ensure that service users are actively involved in any discussions that have an impact on the initiation, monitoring and review of anticoagulation therapy.

Commissioners should expect providers to demonstrate that they are implementing recommendations from the NICE clinical guideline on [patient experience](#) and changing practice to meet the NICE quality standard on [patient experience in adult NHS services](#).

Commissioners should expect providers to collect and act on service user and carer feedback and comment on anticoagulation services. This should include a number of factors particularly relevant to anticoagulation therapy, including:

- accessibility of venue(s) or domiciliary visits
- availability of convenient appointment times, particularly for working-age adults
- waiting times support and information provided by staff
- choice of anticoagulation therapy.

Commissioners should consider the role of their strategic clinical network for cardiovascular disease and [HealthWatch](#) in ensuring that the views and feedback from service users and carers are an integral part of local commissioning arrangements.

3.1.3 Training and competency of staff

Commissioners should ensure that healthcare professionals who initiate, monitor and/or review anticoagulation therapy have the training, skills and competencies to meet the requirements of their role.

The quality and content of patient education, and the message that healthcare professionals give patients, directly influences the uptake of and compliance with anticoagulation therapy. Healthcare professionals therefore need to be adequately trained in order to provide education and support to patients, including education on the novel oral anticoagulants rivaroxaban, dabigatran and apixaban.

While there are nationally recognised courses available on anticoagulation therapy there is currently no national consensus on the minimum competencies required for healthcare professionals working in this area of care. Commissioners may therefore wish to specify minimum standards for training and competency for different healthcare professionals at a local or regional level, taking into account the different conditions or disease groups addressed in this guide.

Commissioners may also wish to refer to information from the [University of Birmingham](#) and the [University of Hertfordshire](#) for examples of accredited courses.

3.2 Safety and quality: vitamin K antagonists

3.2.1 Monitoring international normalised ratio control for people taking vitamin K antagonists

People receiving vitamin K antagonists are at risk of under-coagulation, which can result in thrombosis, and over-coagulation, which can result in haemorrhage. Both of these can cause serious illness or death. People receiving these drugs therefore need regular monitoring of their international normalised ratio (INR) to allow adjustments to be made to the dose of their vitamin K antagonist and to minimise bleeding risk.

Commissioners should specify that information about INR control is accurately collected, reviewed regularly and acted on. If indicators of INR control for a service remain persistently below expected standards, commissioners may wish to consider more formal measures to improve performance. See [section 5.4.3](#) for information about the monitoring of all people taking anticoagulants.

The Topic Advisory Group agreed that the following 4 measures should be used to monitor the overall quality of INR control in people taking vitamin K antagonists. Commissioners may wish to consider the audit requirements for the following measures, including frequency of data collection and formal reporting measures.

Service time in therapeutic range

Time within target INR range is an accepted indicator of the standard of anticoagulation therapy^[6].

The Topic Advisory Group agreed that after the initial stabilisation of dose, a minimum of 60% of people under the care of an anticoagulation service should be within therapeutic range at a given point in time. The Topic Advisory Group agreed that it would be desirable that 65% of people should be within therapeutic range. Time in therapeutic range for people in the first 6 weeks on treatment should not be included in these calculations.

Proportion of people with a high INR

An INR of over 3.0 indicates an increased risk of bleeding. Commissioners should specify systems for monitoring the number of people with a high INR under the care of an anticoagulation service, including the percentage of people with an INR over 5.0 and the percentage of people with INR over 8.0^[7].

Commissioners should expect providers to demonstrate that systems are in place to review the management of people with consistently high INR results. This may include monitoring the number of people offered novel oral anticoagulants where appropriate and in line with NICE guidance.

Proportion of people with a low INR

A low INR indicates that the person is not receiving sufficient protection from the risk of thrombosis. Commissioners should specify systems for monitoring the number of people with a low INR under the care of an anticoagulation service, including the percentage of people with an INR over 1.0 INR unit below target (for example, the percentage of people with an INR under 1.5 with a target INR of 2.5)^[7].

Minimum number of INR tests per year per person

Commissioners should specify the minimum number of tests per year expected per person under the care of an anticoagulation therapy service.

3.2.2 Patients missed to follow-up

Commissioners should specify that providers have systems in place to identify and act quickly when a person has failed to attend an appointment to have their INR measured.

3.2.3 Computer-assisted dosing

The consensus of the Topic Advisory Group was that computer-assisted dosing should be used by all services responsible for INR monitoring and therefore commissioners may wish to specify this when commissioning services for the monitoring of vitamin K antagonists.

3.2.4 Quality control mechanisms for INR testing

Commissioners should specify that providers have quality assurance methods in place for INR testing. This is particularly relevant for services that use non-laboratory methods, such as near-patient or point-of-care testing.

Point-of-care testing devices should only be used by trained personnel. Support should be available from an external quality assessment scheme – either a national scheme (such as the [United Kingdom National External Quality Assessment Service](#)) or a local hospital laboratory scheme. For further information see:

- the Medicines and Healthcare products Regulatory Agency (MHRA) document on [management and use of in vitro diagnostic point of care test devices](#)
- the International Council for Standardization in Hematology guideline on [point-of-care testing in haematology](#).

The [MHRA](#) is the regulatory body for point-of-care testing and should be notified of any adverse incidents.

^[6] Rosendaal et al (1993) A method to determine the optimal intensity of oral anticoagulant therapy. *Thrombosis and Haemostasis* 69, 236–9

^[7] Baglin TP et al. (2006) [Recommendations from the British Committee for Standards in Haematology and National Patient Safety Agency](#). *British Journal of Haematology* 136: 26–9

4 Assessing service levels for anticoagulation therapy for adults

Data suggest that the proportion of adults aged 18 years or older needing anticoagulation therapy is up to 2.4% of the adult population of England, per year, or 2400 per 100,000 population.

For the purposes of this guide for commissioners, information and data on the following conditions are considered in relation to anticoagulation therapy:

- atrial fibrillation (AF) ([section 4.1](#))
- venous thromboembolism (VTE) ([section 4.2](#))
- other conditions ([section 4.3](#)).

Commissioners can use the [commissioning and budgeting \(CAB\) tool](#) to determine the level of service that might be needed locally, including the number of appointments needed annually in an anticoagulation service for each condition. Commissioners can also use the CAB tool to calculate the cost of commissioning an anticoagulation therapy service using the indicative information contained in this section and/or local data.

4.1 Information and data on AF

4.1.1 Prevalence of AF

The prevalence of AF is high and rising, with current estimates ranging between 1.48%^[8] and 1.81%^[9] of the whole population in England^[10]. For the purpose of this guide, the Topic Advisory Group agreed that an estimate of 1.6% of the whole population in England is appropriate.

Assuming that only a small number of people with AF are aged 17 years or under, the prevalence of AF is equivalent to around 2% of the adult population aged 18 years or over, in England^[11].

4.1.2 Proportion of people with AF at high or moderate risk of stroke

If the CHADS₂ score is greater than 1 the patient is at high risk of having a future stroke and the patient should be offered treatment with anticoagulation therapy^[12]. Just over 57% of people with AF have a CHADS₂ score of greater than 1, and therefore should be offered anticoagulation therapy^[13].

The number of adults aged 18 years or older in England, who have AF and a CHADS₂ score of greater than 1 has been calculated by applying this proportion to 2011 population data^[14] (table 2).

Table 2 Proportion of people diagnosed with atrial fibrillation at high risk of future stroke

| Condition | Adult population (England) with a diagnosis of AF | Number England | AF and CHADS ₂ score > 1 | Number England |
|----------------------------------|---|----------------|-------------------------------------|----------------|
| Atrial fibrillation (prevalence) | 2% | 835,000 | 57% | 476,000 |

There are an additional 226,000 adults with a diagnosis of AF in England where the CHADS₂ score is 1^[13] (moderate risk) and where either an antiplatelet or anticoagulation therapy can be offered.

Therefore between 476,000 and 702,000 adults in England aged 18 or over with AF could need anticoagulation therapy and up to 226,000 adults aged 18 or over with AF could need antiplatelet or anticoagulation therapy.

A similar proportion of people with AF and a CHADS₂ score of 1 are currently receiving anticoagulation therapy (47%) as people with a CHADS₂ score of more than 1 and who are receiving anticoagulation therapy (54.6%)^[13]. For the purpose of estimating service levels for an anticoagulation therapy service, adults with a CHADS₂ score of 1 (table 4) have been included.

4.1.3 Demographic profile of atrial fibrillation in primary care

Primary care information shows that diagnosed AF is more common with advancing age, with 85% of people diagnosed with AF aged 65 or over. The 2012 journal article^[13] suggested that the total number of people with AF in a practice could be predicted as 10.15% of the number of people aged 65 and over.

The England population aged 65 or older is predicted to rise by 23.6% between mid-2011 and 2021^[14]. This is likely to have a significant impact on the number of people with AF who will need anticoagulation therapy.

4.1.4 Under-prescribing of anticoagulant drugs in people with AF

A large proportion of people with AF who need anticoagulation therapy are not currently receiving it. It is estimated that just less than half (49.3%) the number of patients with a history of AF are currently receiving anticoagulation therapy^[13].

4.2 Information and data on VTE

People with newly diagnosed VTE, including pulmonary embolism (PE) and deep vein thrombosis (DVT), are likely to be prescribed anticoagulation therapy for short periods of time (3–6 months). There is an additional group of people with VTE who will be on anticoagulation therapy long term.

Primary care data was obtained for the period 2011/12^[16] from a sample of GP practice systems. This was used to estimate the number of new cases of VTE (including PE and DVT) at 0.2% of the adult population (200 per 100,000 population) or around 83,500 people in England.

An additional 0.1%^[16] of the population (100 per 100,000 population) or around 42,000 people in England with VTE are likely to need long-term anticoagulation therapy.

4.3 Information and data on other conditions requiring anticoagulation therapy

Other conditions needing anticoagulation therapy are listed in table 3.

Table 3 Other conditions requiring anticoagulation therapy

| Condition ¹ | Adult population (England) with a diagnosis | Number (England) ^[a] |
|---|---|---------------------------------|
| Chronic rheumatic heart diseases (prevalence) | 0.13% | 54,000 |
| Antiphospholipid syndrome (prevalence) | 0.02% | 8,400 |
| Cardiomyopathy (prevalence) | 0.02% | 8,400 |
| Prosthetic heart valve ^[b] | 0.2% | 84,000 |

¹The prevalence of chronic rheumatic heart diseases, antiphospholipid syndrome and cardiomyopathy have been estimated from primary care information, obtained for the period 2011/12 from a database that holds data from a sample of GP practice systems^[c]. The number of people living with prosthetic heart valves is estimated from hospital activity.

^[a] Office for National Statistics (2012) Mid-2011 Population Estimates: England; estimated resident population by single year of age and sex

^[b] Data from the UK heart valve registry (UKHVR) indicate that approximately 0.2% of the population has prosthetic heart valves.

^[c] IMS disease analyser collects data from a sample of GP practice systems. Around 100 are currently delivering data and the database has about 2.7 million patient records, almost 1 million of which were registered for the whole of the study year. These records are anonymised and are available for analysis via a tool called Disease Analyzer. The sample includes practices from England, Wales, Scotland and Northern Ireland and has a representative UK sample by age and sex. Disease Analyzer data have been collected from a stable panel over a period of more than 14 years. The database holds significant clinical events relating to any period in a patient's life where summarised into computer records by the practice. As in any observational database, data entered by panel doctors may be incomplete.

The number of people living with prosthetic heart valve replacements and other conditions requiring lifelong anticoagulation therapy is 0.37% of adults in England or 370 per 100,000 population.

4.4 Conclusion

Based on the epidemiological data and other information outlined above, it is concluded that the number of adults aged 18 years or older in England who require anticoagulation therapy and therefore may need access to an anticoagulation therapy service includes:

- diagnosed AF, with a CHADS₂ score of 1 or more (1.7%)
- newly identified VTE requiring short-term anticoagulation therapy (0.2%) and ongoing VTE requiring long-term anticoagulation therapy (0.1%)
- prosthetic heart valve replacement and other conditions requiring anticoagulation therapy (0.37%).

Table 4 Estimated service level for an anticoagulation therapy service

| Condition | Anticoagulation therapy service |
|-----------|---------------------------------|
|-----------|---------------------------------|

| | |
|--|---------|
| Atrial fibrillation (CHADS ₂ score=1) | 226,000 |
| Atrial fibrillation (CHADS ₂ score>1) | 476,000 |
| VTE including PE and DVT | 125,000 |
| Others | 155,000 |

Therefore, it is suggested that the indicative rate for people needing **anticoagulation therapy** is up to 2.4% or 2400 per 100,000 of the population aged 18 years or over.

Commissioners should use this and local data to facilitate local discussion on optimum service levels. There is considerable variation in the prevalence and identification of AF, VTE and other conditions in adults. This is influenced by the demographic profile of the local population. Commissioners should note that the rates included here do not represent NICE's view of desirable, or maximum or minimum, service levels, therefore commissioners are encouraged to consider local assumptions.

Use the anticoagulation therapy [commissioning and budgeting tool](#) to determine the level of service that might be needed locally and to calculate the cost of commissioning the service using the data contained here and/or local data.

^[8] The Information Centre for Health and Social Care (2012) 2011/12 Quality and Outcomes Framework prevalence of AF in England

^[9] IMS disease analyser, sample of GP practice systems. Patients available in their practice for the 12 months from 01/07/2011 to 30/06/2012 with a diagnosis of atrial fibrillation anywhere in their record up to the end of the study year.

^[10] Office for National Statistics (2012) Mid-2011 Population Estimates: England; estimated resident population by single year of age and sex.

^[11] In line with [Quality and Outcomes Framework](#) guidance for 2012/13, a distinction has been made in this guide for people with AF in whom stroke risk has been assessed using the CHADS₂ risk stratification scoring system and the score is 1 or more. The NICE clinical guideline on [AF](#) is currently being [updated](#). The [final scope](#) for the updated guideline indicates that risk stratification for stroke or thromboembolic events and for bleeding will be covered by the partial update.

^[12] The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC) (2010) Guidelines for the management of atrial fibrillation. *European Heart Journal* 31: 2369–429

^[13] Cowan C et al. (2012). The use of anticoagulants in the management of atrial fibrillation among general practices in England. *Heart* doi:10.1136/heartjnl-2012-303472

^[14] Office for National Statistics (2012) Mid-2011 Population Estimates: England; estimated resident population by single year of age and sex

^[15] IMS collects data from a sample of GP practice systems. Around 100 are currently delivering data and the database has about 2.7 million patient records, almost 1 million of which were registered for the whole of the study year. These records are anonymised and are available for analysis via a tool called Disease Analyzer. The sample includes practices from England, Wales, Scotland and Northern Ireland and has a representative UK sample by age and sex. Disease Analyzer data have been collected from a stable panel over a period of more than 14 years. The database holds significant clinical events relating to any period in a patient's life where summarised into computer records by the practice. As in any observational database, data entered by panel doctors may be incomplete.

^[16] Based on the view of the Topic Advisory Group.

5 Specifying anticoagulation therapy for adults

The guide focuses on:

- [Section 5.1](#) Specifying anticoagulation therapy for people with atrial fibrillation
- [Section 5.2](#) Specifying anticoagulation therapy for people with venous thromboembolism
- [Section 5.3](#) Specifying anticoagulation therapy for people with other conditions
- [Section 5.4](#) Specifying anticoagulation therapy for all people receiving anticoagulation therapy
- [Section 5.5](#) Service models and examples of practice.

5.1 Specifying anticoagulation therapy for people with atrial fibrillation

This section focuses on:

- identification and assessment (see [section 5.1.1](#))
- initiation of anticoagulation therapy for people with AF (see [section 5.1.2](#))
- timely access to anticoagulation (see [section 5.1.3](#)).

Monitoring people on long-term anticoagulation therapy is addressed in [section 5.4.3](#).

5.1.1 Identification and assessment

This guide for commissioners does not cover the identification and diagnosis of patients with AF in detail. However, it is clearly an essential step towards directing appropriate patients to anticoagulation therapy and in reducing the incidence of stroke. Local organisations may wish to develop protocols for diagnosing patients with AF, based on [NICE clinical guideline 36](#).

Commissioners should specify that the need for anticoagulation therapy for people with AF is identified in line with [NICE clinical guideline 36](#). Assessment should include assessment of risk factors for stroke and thromboembolism, assessment of bleeding risk and risk of long-term anticoagulation therapy.

Commissioners should take account of the increasing prevalence of AF when reviewing anticoagulation therapy locally to ensure that services have capacity. This is particularly important if local projects are in place to improve detection rates in AF.

5.1.2 Initiation of anticoagulation therapy for people with AF

Commissioners should expect providers to demonstrate that people with AF are offered the full range of anticoagulation therapy in line with NICE guidance.

Commissioners should consider the different settings in which anticoagulation therapy for people with AF is currently initiated and ensure that these services are implementing recommendations

made in NICE technology appraisals for [rivaroxaban](#), [dabigatran etexilate](#) and [apixaban](#). The novel oral anticoagulants can be prescribed in primary care and do not require regular monitoring. Commissioners should therefore review the level of capacity required within local anticoagulation monitoring services as the prescribing of novel oral anticoagulants within primary care increases. Commissioners should note that the choice of anticoagulation therapy should be a clinical decision made by a competent healthcare professional in consultation with the individual patient. Commissioners should have regards to their obligations in meeting the recommendations made in NICE technology appraisals and as set out by the Department of Health in [Innovation, Health and Wealth](#):

'We are committed to ensuring that NHS patients have access to clinically and cost effective drugs and technologies and that NICE appraisal guidance is promptly delivered throughout the NHS. There should be no local barriers in accessing technologies recommended in NICE appraisals beyond a clinical decision relating to an individual patient'.

Commissioners should therefore specify local arrangements for assessing and auditing compliance with NICE technology appraisal guidance on [dabigatran etexilate](#), [rivaroxaban](#) and [apixaban](#).

Commissioners should consider how anticoagulation services can support practices with any changeover from warfarin to the newer agents. Commissioners and clinicians should work together to identify the local barriers to implementing NICE recommendations regarding dabigatran etexilate, rivaroxaban and apixaban.

5.1.3 Timely access to anticoagulation therapy

Commissioners should ensure that people with AF can start anticoagulation therapy within a reasonable time. Commissioners should set targets for referral-to-treatment time for people with AF, and the consensus of the Topic Advisory Group was that a person who has been referred to an anticoagulation service to start anticoagulation therapy should be assessed within 2 weeks.

Cardioversion

Cardioversion of AF is associated with an increased risk of stroke and thromboembolism. To minimise this risk, anticoagulation therapy with warfarin is conventionally recommended for a minimum of 3 weeks before cardioversion, and for a minimum of 4 weeks after cardioversion^[17].

The longer a person has atrial fibrillation the less successful the outcome of cardioversion. Commissioners should ensure that people undergoing elective cardioversion have access to prompt, timely and well-monitored anticoagulation therapy and a comprehensive care plan to ensure that there are no delays in a person receiving the procedure.

Monitoring for people on long-term anticoagulation therapy

See [section 5.4.3](#).

^[17] The National Collaborating Centre for Chronic Conditions (2006) [Atrial fibrillation](#). NICE clinical guideline 36. London: Royal College of Physicians

5.2 Specifying anticoagulation therapy for people with venous thromboembolism

This section focuses on the following:

- Initiation of anticoagulation therapy for people with VTE (see [section 5.2.1](#))
- Investigations for cancer (see [section 5.2.2](#))
- Long-term anticoagulation therapy for people with VTE (see [section 5.2.3](#)).

For monitoring of people with VTE on long-term anticoagulation therapy see [section 5.4.3](#) on monitoring.

The assessment and diagnosis of suspected VTE in people in hospital or in the community is not within the scope of this commissioning guide. Commissioners can refer to the [NICE support for commissioners using the quality standard for the diagnosis and management of VTE](#) for information on the commissioning of services for the investigation and diagnosis of VTE in line

with the NICE clinical guideline on [venous thromboembolic diseases](#) and the [NICE quality standard for the diagnosis and management of venous thromboembolic diseases](#).

Further NICE guidance is also in development on [rivaroxaban for pulmonary embolism](#) and [dabigatran etexilate for venous thromboembolic events](#).

5.2.1 Initiation of anticoagulation therapy for people with VTE

Commissioners should consider the different settings in which anticoagulation therapy for people with VTE is currently initiated and ensure that anticoagulation therapy for people with VTE is provided in line with the NICE clinical guideline on [venous thromboembolic diseases](#).

Commissioners should be aware that the NICE clinical guideline on [venous thromboembolic diseases](#) was published before the NICE technology appraisal guidance on [rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism](#), and therefore rivaroxaban is an additional treatment option for people with a confirmed deep vein thrombosis (DVT). Commissioners should therefore ensure that services are implementing recommendations on [rivaroxaban](#), which has the potential to change the way that services for VTE are commissioned and provided. Commissioners should also specify local arrangements for auditing compliance with NICE technology appraisal guidance.

Commissioners should also be aware that NICE is currently developing guidance on [rivaroxaban for pulmonary embolism](#).

Commissioners should ensure that anticoagulation services and services for people with cancer are taking steps to achieve quality statement 7 from the [NICE quality standard for the management of venous thromboembolic diseases](#):

People with active cancer and confirmed proximal deep vein thrombosis or pulmonary embolism are offered anticoagulation therapy. (Quality statement 7)

People with proximal DVT should also be offered below-knee graduated compression stockings, and where this is not under the remit of anticoagulation services commissioners should ensure services are in place to meet the following quality statement.

People with proximal deep vein thrombosis are offered below-knee graduated compression stockings within 3 weeks of diagnosis. (Quality statement 4)

See [NICE support for commissioners using the quality standard for management of VTE](#) for more information on below-knee graduated compression stockings.

5.2.2 Investigations for cancer

Commissioners should ensure that anticoagulation services are integrated with other services for people with VTE and with cancer care pathways so that people with an unprovoked VTE^[18] receive investigations for cancer in accordance with the NICE clinical guideline on [venous thromboembolic diseases](#) in order to meet the [NICE quality standard for management of venous thromboembolic diseases](#):

People with unprovoked deep vein thrombosis or pulmonary embolism who are not already known to have cancer are offered timely investigations for cancer. (Quality statement 5)

Commissioners should specify that people with unprovoked VTE are offered investigations for cancer and specify whether the anticoagulation service is responsible for ensuring that this takes place.

5.2.3 Long-term anticoagulation therapy for people with VTE

Expert clinical opinion of the Topic Advisory Group indicates that around one-third of people with VTE will need anticoagulation therapy for more than 3 months.

Commissioners should be aware that the NICE clinical guideline on [venous thromboembolic diseases](#) was published before the NICE technology appraisal guidance on [rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism](#) and therefore rivaroxaban is an additional treatment option for people with a confirmed DVT.

Commissioners should ensure that people carrying out reviews as above have expert skills and competencies, particularly when making decisions about whether a person should receive life-long anticoagulant therapy.

Commissioners should agree with clinicians locally which services are best placed to decide that a person needs lifelong anticoagulation therapy, thereby implementing NICE recommendations and, if necessary, changing practice to achieve statements 8 and 9 from the [quality standard for management of venous thromboembolism](#):

People without cancer who receive anticoagulation therapy have a review within 3 months of diagnosis of confirmed proximal deep vein thrombosis or pulmonary embolism to discuss the risks and benefits of continuing anticoagulation therapy. (Quality statement 8)

People with active cancer who receive anticoagulation therapy have a review within 6 months of confirmed proximal deep vein thrombosis or pulmonary embolism to discuss the risks and benefits of continuing anticoagulation therapy^[19] , ^[20]. (Quality statement 9)

Monitoring for people on long-term anticoagulation therapy

See [section 5.4.3](#).

^[16] Unprovoked VTE is defined as a DVT or pulmonary embolism PE in a patient with no antecedent major clinical risk factor for VTE who is not having hormonal therapy (oral contraceptive or hormone replacement therapy). Patients with active cancer or a family history of VTE should also be considered as having an unprovoked episode because these underlying risks will remain unchanged in the patient.

^[19] At the time of publication of [NICE clinical guideline 144](#) (June 2012) some types of LMWH did not have a UK marketing authorisation for 6 months of treatment of DVT or PE in patients with cancer. Prescribers should consult the summary of product characteristics for the individual LMWH and make appropriate adjustments for severe renal impairment or established renal failure. Informed consent for off-label use should be obtained and documented.

^[20] Although this use is common in UK clinical practice, at the time of publication of [NICE clinical guideline 144](#) (June 2012) none of the anticoagulants had a UK marketing authorisation for the treatment of DVT or PE beyond 6 months in patients with cancer. Informed consent for off-label use should be obtained and documented.

5.3 Specifying anticoagulation therapy for people with other conditions

Long-term anticoagulation therapy is needed for people with a number of other conditions, including but not limited to:

- prosthetic heart valves
- cardiomyopathy
- recurrent transient ischaemic attack or stroke
- rheumatic valve disease
- antiphospholipid syndrome
- genetic thrombotic disorders.

Patients with prosthetic heart valves are at increased risk of both valve thrombosis and arterial thromboembolic events, including stroke^{[21],[22]}. Anticoagulation therapy is therefore used to reduce the risk of thromboembolism.

Although vitamin K antagonists are currently prescribed for the conditions listed above, novel oral anticoagulants are not currently recommended for these conditions. Commissioners should therefore ensure that clear care pathways are in place for initiating, dosing and monitoring appropriate anticoagulation therapy for people with these conditions.

Where commissioners are reviewing how anticoagulation therapy is provided locally in response to recommendations made on rivaroxaban, dabigatran and apixaban for VTE and AF, the needs of people with the conditions above (for which these drugs are not recommended) should be taken into account.

NICE has not issued guidance on anticoagulation therapy for people with the conditions listed above. Advice on anticoagulation therapy for people with these conditions can be obtained from the [British Society of Haematology](#).

Monitoring for people on long-term anticoagulation therapy

See [section 5.4.3](#).

^[21] Chesebro JH, Adams PC, Fuster V (1986) Antithrombotic therapy in patients with valvular heart disease and prosthetic heart valves. *Journal of the American College of Cardiology* 8 (Suppl.): 41B–56B

^[22] Stein P et al. (2001) Antithrombotic therapy in patients with mechanical and biological prosthetic heart valves. *Chest* 119 (Suppl 1.):220S–7S

5.4 Specifying anticoagulation therapy for all people receiving anticoagulation therapy

This section focuses on the following for all people taking anticoagulation therapy:

- patient education (see [section 5.4.1](#))
- people with complex needs (see [section 5.4.2](#))
- monitoring by healthcare professionals (see [section 5.4.3](#))
- self-testing and self-management for people taking warfarin (see [section 5.4.4](#))
- bridging therapies for people having anticoagulation therapy (see [section 5.4.5](#))
- integration and communication (see [section 5.4.6](#))
- anticoagulation therapy and social care providers (see [section 5.4.7](#)).

5.4.1 Patient education and supporting people with long term medication use

Commissioners should ensure that people prescribed anticoagulation therapy are involved in decisions about their medication and are given high-quality information about anticoagulants to enable them to make fully informed decisions regarding their care. This should be in line with the NICE clinical guidelines on [medicines adherence](#), [atrial fibrillation](#) and [venous thromboembolic](#)

diseases. The quality and content of patient education, and the message that healthcare professionals give patients, directly influences the uptake of and compliance with anticoagulation therapy.

Commissioners may wish to consider local arrangements for supporting people taking medications over long periods or for lifelong treatment. This may include use of new medication review by community pharmacists.

5.4.2 People with complex needs

Commissioners should work with clinicians locally to agree care pathways for people with complex needs, taking account of patient choice and the NICE clinical guideline on medicines adherence. This may include:

- people taking multiple medications
- people who are unable to self-administer medication
- people who are unable to adjust the dose of their vitamin K antagonist
- people who are housebound.

5.4.3 Monitoring by healthcare professionals

Any anticoagulant

The consensus of the Topic Advisory Group is that all people taking anticoagulation therapy should be reviewed at least once a year, including:

- reassessment of stroke or venous thromboembolism (VTE) risk
- reassessment of bleeding risk
- assessment of renal function
- incidence of adverse events relating to anticoagulation therapy since last review
- assessment of compliance

- choice of alternative anticoagulant.

The review of people taking anticoagulants should also be in line with [NICE clinical guideline 76 on medicines adherence](#).

Commissioners can refer to the bottom table of the assumptions tab within the [commissioning and budgeting tool](#) for an indicative breakdown of the number of attendances per year according to a person's diagnosis.

Dabigatran, rivaroxaban and apixiban

INR monitoring is not needed for people taking dabigatran, rivaroxaban or apixiban. However, some form of review will still be needed.

The [drug safety update on dabigatran issued by the MHRA](#) states that renal function should be assessed in all patients before starting dabigatran and at least once a year in patients older than 75 years or those with a suspected decline in renal function.

The consensus of the Topic Advisory Group is that people prescribed dabigatran or rivaroxaban should be reviewed 6 weeks after starting the treatment to check for side effects and compliance, and then at least once a year, as detailed above under [Any anticoagulant](#)).

Vitamin K antagonists

The monitoring frequency for a person taking vitamin K antagonists will depend on several factors and a person who has recently started taking warfarin will need more frequent visits initially. Expert clinical opinion suggests that two-thirds of patients should be in good INR and attend on average every 6 weeks. The remaining patients in poor control may attend as frequently as once weekly. People who are established on oral vitamin K antagonists should be tested at least once every 12 weeks.

There are several different methods for monitoring international normalised ratio (INR) and adjusting a person's drug dose, including laboratory testing and/or point-of-care testing. Where point-of-care testing is available a person's dose can be adjusted promptly. Commissioners should work alongside service users and clinicians to consider the clinical and cost effectiveness of different forms of testing.

5.4.4 Self-testing and self-management for people taking vitamin K antagonists

Atrial fibrillation

The recent [full guideline](#) for the NICE clinical guideline on [VTE](#) indicates that there is insufficient evidence to support the cost effectiveness of routinely offering self-monitoring and self-management for people taking vitamin K antagonists.

The current NICE clinical guideline on atrial fibrillation ([AF](#)) recommends that self-monitoring should be considered if preferred by a patient and if certain criteria are met. However, this guideline is currently being [updated](#) and the [scope for the updated guideline](#) indicated that the recommendations will change to reflect those made within the NICE clinical guideline on [VTE](#).

Commissioners should work with clinicians to develop local protocols to support individuals who request to self-monitor or self-manage, particularly for working-age adults for whom frequent attendance at anticoagulation monitoring services can be disruptive and lead to loss of earnings, or for people who are housebound. This should include funding arrangement for testing equipment and testing strips.

5.4.5 Bridging therapies for people having anticoagulation therapy

Commissioners should ensure there are clear local policies and procedures in place for managing anticoagulation therapy for people undergoing elective procedures, including surgery, and in those with sub-therapeutic INRs at high risk of thrombosis – for example, people with prosthetic heart valves.

People taking vitamin K antagonists who are undergoing elective surgery need to switch to low molecular weight heparin for a period of time before surgery. Low molecular weight heparin is administered by subcutaneous injection. Clinical opinion of the Topic Advisory Group indicates that if a person is unable to administer the heparin independently they are brought into hospital early in some areas, with a resultant cost of bed days. Commissioners should ensure that systems are in place to ensure that patients can have access to low molecular weight heparin in primary care settings as appropriate.

5.4.6 Integration and communication

Commissioners should ensure that services responsible for initiating, monitoring and/or reviewing people taking anticoagulation therapy are integrated with other services for people with AF, VTE and other relevant conditions. Commissioners should specify that mechanisms are in place for regular communication between the services and a person's GP and community pharmacists and specialists, including:

- concerns about a person's general health
- when a person does not attend anticoagulation service appointments on a regular basis (DNAs)
- when a person transfers to or from acute, emergency or specialist services.

5.4.7 Anticoagulation therapy and social care providers

Commissioners should work with colleagues in local authorities and community pharmacies to ensure that the recommendations made in the [National Patient Safety Agency \(NPSA\) anticoagulant patient safety alert](#) (see 'Anticoagulation: advice for social care providers') are in place and monitored, including those relating to:

- documentation
- policies and procedures
- staff training and competency.

These recommendations are particularly important for care homes and therefore commissioners of health and social care should consider arrangements for independent providers.

5.5 Examples of practice

There are several models of anticoagulation services for people with AF and VTE, including hospital outpatient models, primary care and community-based models, and patient self testing and management.

Commissioners should take into account regional and local plans for [Quality, Innovation, Productivity and Prevention \(QIPP\) workstreams](#).

Commissioners may wish to work with their local QIPP lead to develop care pathways for anticoagulation therapy; example models are included in table 5.

Table 5 QIPP and anticoagulation therapy

| QIPP case study | Example output |
|---|---|
| Atrial fibrillation – detection and optimal therapy in primary care by NHS Stroke Improvement Programme | <ul style="list-style-type: none"> • Increased number of people receiving optimal therapy • Reduction in costs associated with stroke |
| Warfarin loading protocol: to improve patient safety by Northumbria Health Care Trust | <ul style="list-style-type: none"> • Trust-wide warfarin loading protocol • Improved patient safety • Reduced number of serious bleeds |

(The NICE evidence QIPP collection examples have all been assessed against a set of criteria and then subject to an external peer review process. The best of these are highlighted on the [NICE Evidence](#) website as 'highly recommended' examples).

The Commissioning for Quality and Innovation (CQUIN) payment framework enables commissioners to reward excellence, by linking a proportion of English healthcare providers' income to the achievement of local quality improvement goals. Commissioners should work with clinicians when using the CQUIN payment framework as a lever for service change.

Examples include:

- [National CQUIN VTE – risk assessment](#)

- [National CQUIN – root cause analysis](#): the number of root cause analyses carried out on cases of hospital-acquired VTE
- [National CQUIN: friends and family test](#)

See also [Everyone counts: planning for patients](#). Further examples are available from the [NHS Institute for Innovation and Improvement](#).

5.5.1 Service models

Commissioners may wish to refer to examples of service models for anticoagulation therapy (see table 6).

Table 6 Examples of practice in anticoagulation therapy

| Setting | Theme | Service model/example of practice |
|--------------|--|---|
| Primary care | Identification of AF | Systematically implementing CG36 Atrial Fibrillation across a PCT/CCG to improve the detection of AF and improve the management of AF across a PCT/CCG without adding to clinical workload. |
| Primary care | Management of patients with AF in primary care | GRASP-AF : a free, simple audit tool used in primary care to aid the stroke risk stratification and effective management of AF patients, to reduce the risk of stroke. |
| Hospital | Anticoagulation clinic | Nurse-led service in a hospital setting . |
| Primary care | Anticoagulation clinic | 'One-stop' primary care based anticoagulation clinics ; includes a domiciliary service. |

(Please note – these examples are offered to share good practice and NICE makes no judgement on the compliance of these services with its guidance).

6 Service specification for anticoagulation services

Commissioners can use the information in this guide to aid the completion of service specifications for local anticoagulation services.

Commissioners may wish to consider commissioning anticoagulation services in several different ways, and mixed models of provision may be appropriate across a local health economy.

Commissioners should collaborate with clinicians, local stakeholders and [service users](#) when determining what is needed from anticoagulation services in order to meet local needs. The care pathway should be person-centred and integrated with other elements of care for people with atrial fibrillation, venous thromboembolism and/or other relevant conditions.

In particular the service specification for an anticoagulation therapy service should consider:

- what parts of the care pathway for anticoagulation therapy will be included – for example, initiation, monitoring of INR, dosing, annual review
- the advantages and disadvantages locally of block contracting versus service activity contracts – for example, with the introduction of rivaroxaban, dabigatran and apixaban service activity contracts may offer more flexibility in terms of releasing funds as the patients change anticoagulation therapy
- the anticoagulants the service is responsible for – for example, vitamin K antagonists, low molecular weight heparin and the novel oral anticoagulants
- the level of capacity required within local anticoagulation monitoring services as the prescribing of novel oral anticoagulants within primary care increases
- the differing requirements for monitoring and review for rivaroxaban, dabigatran and apixiban and how this has an impact on local delivery of anticoagulation therapy
- quality measures (see [section 3](#)) to be used, and the process for monitoring and review
- ease of access to clinics, including location of the service
- local support for medicines adherence for people taking anticoagulation therapy
- local procedures for self-testing INR, including who is responsible for paying for testing strips

-
- required competencies of, and training for, staff responsible for providing anticoagulation therapy care and service monitoring criteria
 - communication between service provider and other services, particularly for the safe transfer of a person's care between an anticoagulation service and secondary care
 - information and audit requirements, including IT support and infrastructure.

Commissioners may wish to take action to stimulate the local market if there are identified shortages of providers at any point in the pathway. They should note that willing and qualified providers may include health, local authority, and other statutory partners.

Further information can be found at [Supply2Health](#), including examples of any qualified provider offers for anticoagulation services.

7 The commissioning and budgeting tool

Download the [anticoagulation commissioning and budgeting tool](#).

A **commissioning and budgeting (CAB) tool** for anticoagulation therapy accompanies this guide. The CAB tool can inform commissioners of potential service costs when commissioning an anticoagulation service.

The CAB tool should be used to determine the activity and capacity requirements of the anticoagulation service that might be needed locally. It can be used to model the desired future activity and capacity requirements. This includes the cost impact of reducing capacity in traditional vitamin K antagonist monitoring services as more people are prescribed the novel oral anticoagulants in primary care setting. The changes in activity and capacity from current levels are modelled over time. The changing cost of providing the service is seen per year.

7.1 Standard assumptions

The CAB tool uses the data from the information and data subsections in [section 4](#) in this guide. These data are used to show the typical number of people who may need anticoagulation therapy in your local population. This is identified as the standard assumptions in the CAB tool. Throughout the CAB tool these rates may be changed.

With knowledge of your local population and its demographic, you should amend the rates to better reflect your local circumstances or preferred rates. For example, you may wish to amend the standard assumptions if your population has significantly different factors that affect the conditions that require anticoagulation therapy. Making adjustments to the standard assumptions will tailor the CAB tool providing a revised benchmark that is a 'target' that you wish to commission.

7.2 Review current commissioned activity

You may already commission anticoagulation services for your population. You should adjust the values in the CAB tool in the 'current local assumptions' blue fields to represent the services currently commissioned.

7.3 Identify future change in capacity required

By using the standard assumptions or having modified them, and by inputting your local current assumptions, changes in capacity requirements will be calculated. This includes the reduction in capacity driven by the reduced need to monitor the condition of people taking vitamin K antagonist drugs. Your inputs will therefore show how your future provision may decrease.

7.4 Model future commissioning intentions and associated costs

The CAB tool will calculate the capacity and resources needed to move towards your defined 'target' level, and to model the required changes over an indicative period of 4 years as there is increased uptake of the novel oral anticoagulants.

The tool is prepopulated with typical cost elements that may need to be considered in future service planning. These can be amended to accurately reflect your local commissioning and service provider environment.

The CAB tool will calculate the cost of providing the service. It is shown across an indicative period of 4 years showing the change in service provision from current local levels to local 'target' levels.

7.5 Potential savings

AF is associated with an increased risk of stroke. If anticoagulation therapy is received then the risk of stroke is reduced. If currently undiagnosed people are identified and anticoagulation therapy started, it could have a positive impact on reducing the incidence of strokes. There will be savings on the costs of health and social care associated with stroke and stroke rehabilitation. The point at which a stroke is avoided and hence the saving generated is subject to much variation. This is not modelled in the commissioning and budgeting tool.

7.5.1 Root cause analysis

Detailed analysis of the treatment costs for individual patients may be used to proactively identify where efficiencies may be gained or resources released.

Root cause analysis that identifies all the cost components in a patient's treatment may be used to start this level of analysis.

The CAB tool includes a template that may be used to break down the cost components of the treatment given to 2 patients. By having a comparison of 2 sets of costs side by side, areas or themes may be identified that may be analysed further. This can be used to analyse two patients who are treated in different types of setting, or 2 patients who use different types of anticoagulant.

This template may be used as a first step in undertaking this type of patient-level costing. Further work will be necessary to investigate the reasons why cost elements are incurred, or the resources that are consumed before changes to practice or service delivery may be made and savings or efficiencies achieved whilst maintaining or improving patient outcomes.

8 Further information

Other useful sources of information for developing local anticoagulation services may include:

- NHS Improvement [heart](#) and [stroke](#)
- [British Society for Haematology](#) and [British Committee for Standards in Haematology](#), including [Guidelines on oral anticoagulation with warfarin](#)

-
- [Atrial Fibrillation Association](#)
 - [Anticoagulation Europe](#).

Policy documents

- Department of Health (2013) [Improving cardiovascular outcomes: strategy](#).
- Department of Health (2011) [Innovation Health and wealth: accelerating adoption and diffusion in the NHS](#).
- Department of Health (2010) [Venous thromboembolism \(VTE\) risk assessment](#).
- Department of Health (2009) [Venous thromboembolism prevention: a patient safety priority](#).
- Department of Health (2008) [Using the commissioning for quality and innovation \(CQUIN\) payment framework](#) (see guidance on national goals for 2011/12).
- Department of Health (2007) [Report of the independent expert working group on the prevention of venous thromboembolism \(VTE\) in hospitalised patients](#).

NICE implementation support

- Baseline assessment tool, audit support, clinical case scenarios, costing report, education resources and slide sets for [NICE clinical guideline on venous thromboembolic diseases](#).
- Costing report, costing template, slide set, and implementation advice for the [NICE clinical guideline on AF](#).

9 Topic Advisory Group: anticoagulation

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

Vanessa Brown

National Improvement Lead – AF, NHS Improvement

Christian Clark

Lay member

Campbell Cowan

Consultant Cardiologist, Leeds General Infirmary

Dr Matt Fay

GP, Shipley Medical Centre

David Fitzmaurice

GP and Professor of Primary Care, University of Birmingham

Hayley Flavell

Anticoagulant and Thrombosis Consultant Nurse, Royal Bournemouth and Christchurch Hospitals NH Trust

Hugh Janes

Head of Strategy and Service Redesign, Fareham and Gosport Clinical Commissioning Group

Dr Peter Rose

Consultant Haematologist, South Warwickshire NHS Foundation Trust

Dr Gerard Stansby

Professor of Vascular Surgery, Freeman Hospital, Newcastle upon Tyne NHS Foundation Trust

Peter Walton

Lay member

The following people contributed by email:

Sarah Clarke

Medicine Management Pharmacist, Coastal West Sussex Clinical Commissioning Group

Dr Richard Day

Consultant Geriatrician, Poole Hospital NHS Foundation Trust

Professor Huon Grey

Interim National Clinical Director for Cardiovascular Disease, Department of Health

Jo Jerrome

Deputy Chief Executive Office, AF Association

Professor Beverley Hunt

Professor of Thrombosis and Haemostasis, Kings College, London

Consultant in Departments of Haematology, Lupus and Pathology, Guys and St Thomas NHS Foundation Trust

Nick Rutherford

Medicine Management Technician, Coastal West Sussex Clinical Commissioning Group

The following members of the NICE Implementation Collaborative (NIC) subgroup for the novel oral anticoagulants also commented by email:

Dr Frances Akinwunmi

Consultant Pharmacist Anticoagulation, Imperial College Healthcare NHS Trust

Dan Beety

Government and Industry Affairs Manager, Bayer PLC

Eve Knight

Chief Executive, AntiCoagulation Europe

Tom Sunderland

Senior Health Economist, Boehringer Ingelheim Ltd