National Stroke Foundation response to Review of Anticoagulation Therapies in Atrial Fibrillation

strokefoundation

Executive Summary

Estimates suggest 240,000-400,000 people have atrial fibriallation (AF) in Australia with many of these people being undiagnosed. People with non-valvular atrial fibriallation (NVAF) make up approximately 90% of those with AF and are five times more likely to develop stroke. Approximately one third of people with stroke have AF and have more disabling and fatal strokes and poorer outcomes. Those with AF are also at higher risk of heart failure, overall mortality and reduced quality of life. The estimated annual cost of AF in Australia is $1.25billion with 64% of this due to major events such as stroke and heart failure which would be reduced with appropriate detection and prevention. The prevalence incidence of NVAF increases with age and is higher in men compared with women. With an ageing population NVAF will become increasingly important to manage effectively to minimise the risk of stroke. AF is an important, deadly and increasingly prevalent disease that requires further attention.

Unfortunately current proven treatments are underutilised with recent estimates suggesting anywhere from 40 to 60% of patients at risk are not taking recommended therapies. The reasons behind this are many and include lack of knowledge and understanding of available therapies, their associated benefits and risks by consumers and health professionals.

The NSF welcomes the current review of therapy for AF along with the interest in the newer agents to manage AF. Clearly improvements are needed to better protect those with, or who are at risk of, AF. The NSF strongly supports greater attention on improving anticoagulation therapy to prevent stroke in Australia. We believe this will occur by:

1. Improved detection of NVAF
2. Greater awareness of the need to improve management of AF (with a wider range of treatment options becoming available). A new Australian clinical guideline specifically for AF should be considered a priority based on the outcomes of this review. Current treatment algorithms urgently need updating based on recent data and newer agents. This work should be considered as a priority by the National Lead Clinicians Group and be commissioned by the Australian Commission for Quality and Safety in Health Care (ACQSHC). Key stakeholders such as the NSF should be included in this process.
3. Ensuring the right patients are offered the right agent by increasing treatment choice. Approving the new agents is warranted based on clear benefits with reducing ICH. Providing education and support for health professionals and consumers regarding management choices and most appropriate therapy in different situations is crucial and can build on current NPS programs.
4. Develop a systematic, comprehensive and multifaceted program (i.e. developing guidelines, setting standards and targets, ongoing monitoring and quality improvement activities across multiple levels) to increase overall and safe use of anticoagulation (both old and new). This would importantly involve patients in all aspects of development and delivery and a clear focus on patient-centered care.

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About the National Stroke Foundation

The National Stroke Foundation (NSF) is the peak national non-for-profit organisation that focuses on reducing the impact of stroke by preventing stroke, improving treatment and support for those with stroke. The NSF promotes evidence-based practice by developing and coordinating the National *Clinical Guidelines for Stroke Management 2010*.[1] Significant advances in treatment over the last 20 years now means the provision of evidence-based stroke care (as outlined in the guidelines) can significantly reduce death and disability and is cost effective.

The NSF has provided significant leadership to improve the quality of stroke care in Australia. The NSF promotes a range of activities aimed at improving stroke prevention; improving adherence to evidenced based care and improving support to stroke survivors and carers. These activities include:

- Production of the national *Clinical Guidelines for Stroke Management*[1] (approved by the National Health and Medical Research Council in 2010)
- Coordination of the National Stroke Audit Program which is offers a snap shot of quality of stroke care across Australia.
- Provision of the only national stroke-specific quality improvement program Strokelink to stroke care institutions nationally.
- Production of national advocacy and policy documents such as the Australian Stroke Services Framework.
- Sole national organisation dedicated to supporting stroke survivors and carers. The NSF is dedicated to ensuring consumers receive high quality care that achieves excellent clinical outcomes and at the same time responds to the needs and experience of survivors and carers. The NSF provides support to consumers through the provision of programs including StrokeConnect, aimed at stroke survivors and carers at discharge, connecting them with information, advice and support; StrokeLine, a health information and advice line; Peer support - online, phone and groups; evidence based written information; and a stroke specific self management program
- Coordination of National Stroke Week and a national FAST social marketing campaign to increase knowledge of stroke and stroke warning signs and thereby help reduce treatment delay
- Coordination of the 'Know your numbers' health check campaign to raise community awareness of blood pressure and other leading risk factors for cardiovascular disease
- Production of *Guidelines for the Management of Absolute Cardiovascular Disease Risk* on behalf of the National Vascular Disease Prevention Alliance (NVDPA).

The NSF is also a major partner in the development of the Australian Stroke Clinical Registry (AuSCR); co-chairs and provides the secretariat for the Australian Stroke Coalition (ASC) and is a partner in the Australian Chronic Disease Prevention Alliance (ACDPA) and the NVDPA (current chair).

The NSF welcomes the current review of therapy for AF along with the interest in the newer agents to manage AF and presents the following information to inform this review.

Background

Estimates suggest 240,000-400,000 people have atrial fibrillation (AF) in Australia, 70% of whom are on some form of treatment with a further 10-30% undiagnosed (Pricewaterhouse Coopers 2010; Deloitte 2011). The estimated annual costs of AF is $1.25billion (2008/9) with 64% of this due to major events such as stroke and heart failure (Pricewaterhouse Coopers 2010) which would be reduced with appropriate detection and prevention. People with non-valvular atrial fibrillation (NVAF) make up approximately 90% of those with AF and are five times more likely to develop stroke. Approximately one third of people with stroke have AF and these patients with AF have more disabling and fatal strokes, with poorer outcomes (Gattellari et al 2011). Those with AF are also at higher risk of heart failure and overall mortality. There is a reduced quality of life, which is lower in women than men and in younger patients. UK data suggests the majority of those with NVAF are at high risk of stroke (CHADS2 >1) (Rietbrock et al 2008). The prevalence and incidence of NVAF increases with age and is higher in men compared with women. In an aging population it is increasingly important to manage NVAF effectively, to reduce the risk and burden of stroke.

Australian sample of 321 GPs and 14,750 patients over 30 years (Sturm et al 2002)

	<50	50-59	60-69	70-79	80+
Men	~<1%	~<2%	~6%	~14%	~16%
Women	~<1%	~<1%	~3%	~9%	~13%

BEACH study (Britt et al 2008)

The prevalence of atrial fibrillation is increasing in Australia
1998-99 NVAF managed at a rate of 0.6 per 100 encounters
2007-08 NVAF managed at a rate of 1.0 per 100 encounters

AF is an important, deadly and increasingly prevalent disease that requires further attention.

Assessment of NVAF

Unfortunately many people who have NVAF are not aware of it in the first place and under-treatment of those who are aware is well recognised. The National Stroke Audit (2011) Clinical Report for Acute Services includes 3548 audited cases of people admitted to hospital with stroke. On admission there were 995 cases of people with stroke who had AF and only 298 (30%) were found to be taking medication prior to admission (NSF 2011). While the NSF welcomes a discussion on new treatment options, further attention is required to improved AF detection –particularly in those at greatest risk of stroke - before new management options are considered. The NSF suggests that this Commonwealth review provides a great opportunity to consider wider issues and opportunities, such as existing health check and GP education programs.

Key message 1: Increasing available therapy options will have limited benefit unless there are better ways to detect AF in those at greatest risk and there is an increase in the uptake of evidence–based treatment.

Reducing the burden/management – evidence for interventions – what will make a difference

There is robust evidence for the use of warfarin for both primary and secondary stroke prevention. (Agulilar & Hart 2005; Agulilar et al 2007; Hart et al 2007; Saxena & Koudstaal 2004; Saxena & Koudstaal 2004)

The numbers needed to treat to prevent 1 stroke over 1 year are (Hart et al 2007):

- 37 (primary prevention) and 12 (secondary prevention) for adjusted dose warfarin compared to placebo/control
- 125 (primary prevention) and 40 (secondary prevention) for aspirin compared to placebo/control
- Anticoagulation (warfarin) reduces event rates by over 1/3 compared to antiplatelet agents (aspirin and dual therapies).

Subsequent trials have confirmed benefits of therapy both with warfarin (eg. Mant et al 2007) and antiplatelet therapy (e.g. Active Investigators 2009) and the newer anticoagulants (Re-LY; ROCKET-AF; AVERROES; and ARISTOTLE).

Different therapy options have slightly different risk profiles (warfarin / antiplatelet therapy / newer oral anticoagulants) particularly bleeding risks. This has led to treatment recommendations based on risk levels (via CHADS2 risk tool –see below and CHADS Vasc). It is clear from all trials that overall benefit far outweighs risk.

Unfortunately current treatment is underutilised. Recent estimates suggest only ~30% of moderate and high risk patients are taking warfarin and alarmingly 40% are receiving no treatment (Deloitte 2011) Similarly the National Stroke Audit found 70% of those with NVAF related stroke were not reported to be taking warfarin, prior to admission (NSF 2011).This is similar to a Canadian experience which reported approximately 60% of the 597 patients with a first-ever stroke were not receiving warfarin at the time of admission and of those receiving warfarin, approximately three-quarters had a subtherapeutic INR recorded on admission(Gladstone et al 2009). Other Australian studies have also found low rates of warfarin use prior to stroke in those with NVAF ranging from 20-53% (National Institute for Clinical Studies 2008; Fahridin et al 2007). The intention to prescribe warfarin in high risk patients 75 years and over ranges from 14-74% depending on patient profile (Gattellari et al 2008). Despite recommendations in various clinical guidelines, including Australian national clinical guidelines shown below, health professionals perceive various non-evidence based barriers to anti-coagulation. Such perceived barriers will require more attention, irrespective of the introduction of newer agents.

<u>The NSF Clinical Guidelines for Stroke Management (NSF 2010)</u>

The NSF Clinical Guidelines for Stroke Management 2010 were endorsed by NHMRC in September 2010. These guidelines cover anticoagulation therapy for those after stroke (secondary prevention section 5.5).

Recommendations made include:

Anticoagulation therapy

a) Anticoagulation therapy for secondary prevention for people with ischaemic stroke or TIA from presumed arterial origin should NOT be routinely used. (Grade A)
b) Anticoagulation therapy for long-term secondary prevention should be used in people with ischaemic stroke or TIA who have atrial fibrillation or cardioembolic stroke. (Grade A)
c) In stroke patients, the decision to begin anticoagulation therapy can be delayed for up to two weeks but should be made prior to discharge. (Grade C)
d) In patients with TIA, anticoagulation therapy should begin once CT or MRI has excluded intracranial haemorrhage as the cause of the current event. (GPP)

The current guidelines do not specify which anticoagulation therapy should be used (and in whom). New published evidence, including published trials of new anticoagulant agents will need to be considered with any future revision of the existing guidelines.

<u>Position Statement on NVAF (Hankey et al, 2001)</u>

The position statement on NVAF is now more than 10 years old and there is no comprehensive Australian guideline specifically currently covering AF management. In this position statement warfarin and aspirin were the only considered treatments and selection was based on an assessment of risk-benefit.

Box 1: Risk stratification and prophylaxis in atrial fibrillation (Hankey 2001)

High risk (6%-12% per year risk of stroke)
- Age >65 years and hypertension or diabetes
- Previous transient ischaemic attack (TIA) or stroke
- Valvular heart disease or Heart failure
- Recent myocardial infarction
- Impaired left ventricular function on echocardiography
- Thyroid disease or Left atrial thrombus or left atrial spontaneous echo contrast (TOE done on basis of clinical suspicion)

Treatment: Warfarin (target INR 2.0-3.0) if possible and not contraindicated.

Moderate risk (2%-5% per year risk of stroke)
- Age 65 years and hypertension or diabetes
-Age >65 years and not in high risk group

Treatment: Warfarin (target INR 2.0-3.0) or aspirin 75-300mg daily, depending on individual case and echocardiography findings.

Low risk (Less than or equal to1% per year risk of stroke)

- Age 65 and no hypertension, diabetes, TIA, stroke, or other clinical risk factors

Treatment: None, or aspirin 75-300mg daily.

A reassessment of the risk stratification used in Australian and international guidelines (e.g Eur Heart J 2010; 19: 2369–2429; NICE 2006) is obviously required in respect of newer agents and for those under 65 years of age (Gattellari et al 2011).

Strategies to overcome known barriers to prescribing warfarin

Strategies are needed to overcome known barriers to prescribing warfarin. Perceived barriers have been described in the literature and are listed in Box 2. Unfortunately GP's are more fearful of sins of commission than sins of omission even though those risks are not equal. GPs report feeling a greater sense of responsibility for a patient experiencing a bleed on anticoagulation than a stroke while NOT on anticoagulation (Gattellari et al 2008; Choudhry et al 2006).

Box 2. Perceived barriers to prescribing warfarin in survey of NVAF in ~600 GPs across Aust.

Item	% Sometimes Usually/Always
Patient reluctance to take warfarin	15.4% (n=92)
Patient refusal to take warfarin	22.3% (n=133)
Regular INR monitoring will be too inconvenient	10.1% (n=60)
Risk of adverse events unacceptably high	32.7% (n=195)
Patient unable to comply with regular follow-up	21.3% (n=127)
Patient has contraindications to warfarin	40.6% (n=242)
Patient is at risk of falls	24.0% (n=143)

(Gattellari et al 2008)

The NSF believes unmet need accounts for a large proportion of all avoidable fatal and disabling strokes in Australia. The mortality and major bleeding risks of anti-coagulants are dwarfed by the benefits of existing and emerging agents. However, if new agents only replace current warfarin usage the gains will be modest (and the cost greater). For real and substantial benefits to be realised both doctors and patients will need to increase appropriate evidence-based use of anticoagulants in NVAF.

Key message 2: Greater effort and new strategies are needed if consumers and health professionals are to better understand the serious risks of severely disabling stroke in NVAF and the benefit of evidence-based anticoagulant treatment. New measures should seek to overcome an excessive perception of anticoagulant risk, improve the detection of atrial fibrillation and include a revision of the existing Australian guidelines for detection and management of AF.

Treatment of NVAF is challenging. Anticoagulation remains the cornerstone of preventative therapy, before and after stroke. There are risks with any medication and the safe and appropriate use of anticoagulants is paramount. America research has found that most emergency hospitalisations for recognised adverse drug events, in older adults, result from a few commonly used medications, including warfarin used for stroke prevention (Budnitz et al 2011). Balancing the benefits and risk of individual agents needs careful consideration in individual patients. There are salient differences in metabolism, efficacy and reported complications for all proposed anti-coagulants. The Commonwealth may consider a programme of education, monitoring and feed-back for any approved anticoagulants.

Factors to consider include:

Factor	**Comments**
Age –highest prevalence of AF is >75	BAFTA trial demonstrates safe use of warfarin for the elderly. Dabigatran had higher major bleeding rates > 75 years, but retains a lower ICH rate than warfarin. Dabigatran also has a relatively high rate of lower GIT bleeding which can be a complex management problem. Apixaban may have the better safety profile in the elderly.
Burden of frequent INR monitoring	Monitoring can significantly impact on quality of life, including travel limitation. Patient often have out-of-pocket travel costs to/from the clinic, productivity losses for the time to undergo tests and the inconvenience of regular testing. For some the frequent monitoring may be useful to assess compliance and manage ongoing complex health issues (see below).
Co-morbidities and need for close medical review	While frequent monitoring can be a burden for some (eg. younger, stable patients) more frequent contact with health professional may be beneficial, particularly for elderly patient with complex medical conditions. Warfarin may best be used in those at extremes of weight and in those with renal impairment.
Food and medications interaction	These are significant factors with warfarin use. Newer agents have less impact on diet but have some medication interactions.
Pharmacology	Unlike warfarin, new agents have a more predictable dosage profile, a wider therapeutic window and more rapid onset of action than warfarin. However, for newer agents the measurement of anticoagulation and its interpretation is complex and the drug exposure varies significantly by gender, age and weight. Pradaxa particularly relies on renal function for clearance and use of some new agents are restricted in the presence of different levels of renal insufficiency. Monitoring of renal function has been recently suggested for some patients.

Reversibility	Currently only warfarin can be reversed rapidly for emergency surgery, acute bleeding or the delivery of thrombolysis in the setting of ischaemic stroke. The current lack of acute reversibility is likely to become a perceived barrier to anticoagulation with newer agents.
Financial incentives	Some GPs express concern that the management of AF/stroke risk and monitoring of warfarin is not adequately compensated or supported with resources in kind. At present the checking of INR levels and 'calling-through' of the suggested warfarin dose is not financially compensated. Point-of-care testing of INR has proved attractive with a face-to-face review and fee-for- service compensation. POC has not been shown to improve INR control and is not suitable for all patients. However, follow-up consultation may have tangible benefits in an older, complex cohort.
Geography	Remoteness with limited access to INR testing facilities and health professionals generally
Cognitive issues	May impact medication compliance (on warfarin and new agents)
Other	• Warfarin has a poor brand image with some consumers and health professionals. • While compliance may be an issue for both warfarin and the newer agents (especially in the case of twice daily dosing). Dabigatran appears unsuitable for Webster packaging and confirming compliance with testing is an issue with the newer agents. • People with phobia of needles may benefit from new agents rather than warfarin. • Blood pressure control (or lack of) is important for ICH risk on all anticoagulants.

As this table demonstrates, various factors will determine the most appropriate treatment choice, not only for the health professionals but for patient outcomes and quality of life. Having greater choice will add complexity but also allow greater tailoring to patient need. Future directions in the management of NVAF, if well implemented, can reduce the burden of stroke and heart failure in the community and reduce the impact of AF on individuals.

Although different rates for efficacy, major bleeding and ICH are reported for warfarin and the newer agents the absolute differences are not great and are likely to be have been influenced by quality of INR control and a high concomitant use of aspirin (20-40%). Concomitant aspirin use is known to increase bleeding, including ICH, on warfarin. The high concomitant use in recent trials is unusual and probably important. In the reported trial data INR control in Australia was of relatively high quality which significantly impacts on the relative efficacy of warfarin.

Experience of all bleeding events is known to impact on clinician perception and practice. The NSF would emphasise that not all bleeding events are clinically equivalent and that clinicians may be most concerned with the small but important incidence of intracranial haemorrhage (ICH). ICH should be regarded as a 'catastrophic outcome'. Setting aside concerns over high aspirin use, each of the recently published trials of new oral anticoagulation agents (Dabigatran, Rivaroxaban and Apixaban) consistently report a statistically significant reduction in ICH rates (although absolute numbers are small).

Long term safety for Dabigatran has been questioned with the number of national product warnings. The Therapeutic Goods Administration issued Safety Advisory Alerts on 5 October and 3 November 2011. One was a bleeding -related adverse event report and the other an advisory on renal function monitoring requirements. A recent meta-analysis of Dabigatran studies confirmed a small but significantly increased in risk of myocardial infarction (MI) (Uchino 2012), and MI is identified as a possible adverse event in the Dabigatran product insert. Patient safety is paramount to the NSF and strict criteria for patient selection and support should be combined in a multifaceted implementation program that includes new guidelines, data collection processes and quality improvement support.

The NSF strongly supports a process in which new anticoagulant agents are available to patients who may not be eligible or suitable for warfarin as part of well planned and coordinated program to increase the uptake of anti-coagulants in general and ensure their safe use.

Key message 3: Ensuring the right patients are offered the right agent is critical in achieving the best patient and community outcomes. Whilst warfarin will continue to be the treatment of choice for many patients, a choice of newer agents may overcome some patient and professional barriers to greater anticoagulant uptake, as well as offering tangible clinical benefits such as lower overall ICH rates and greater efficacy and safety, for some patients.

What are the things that will bring about change?

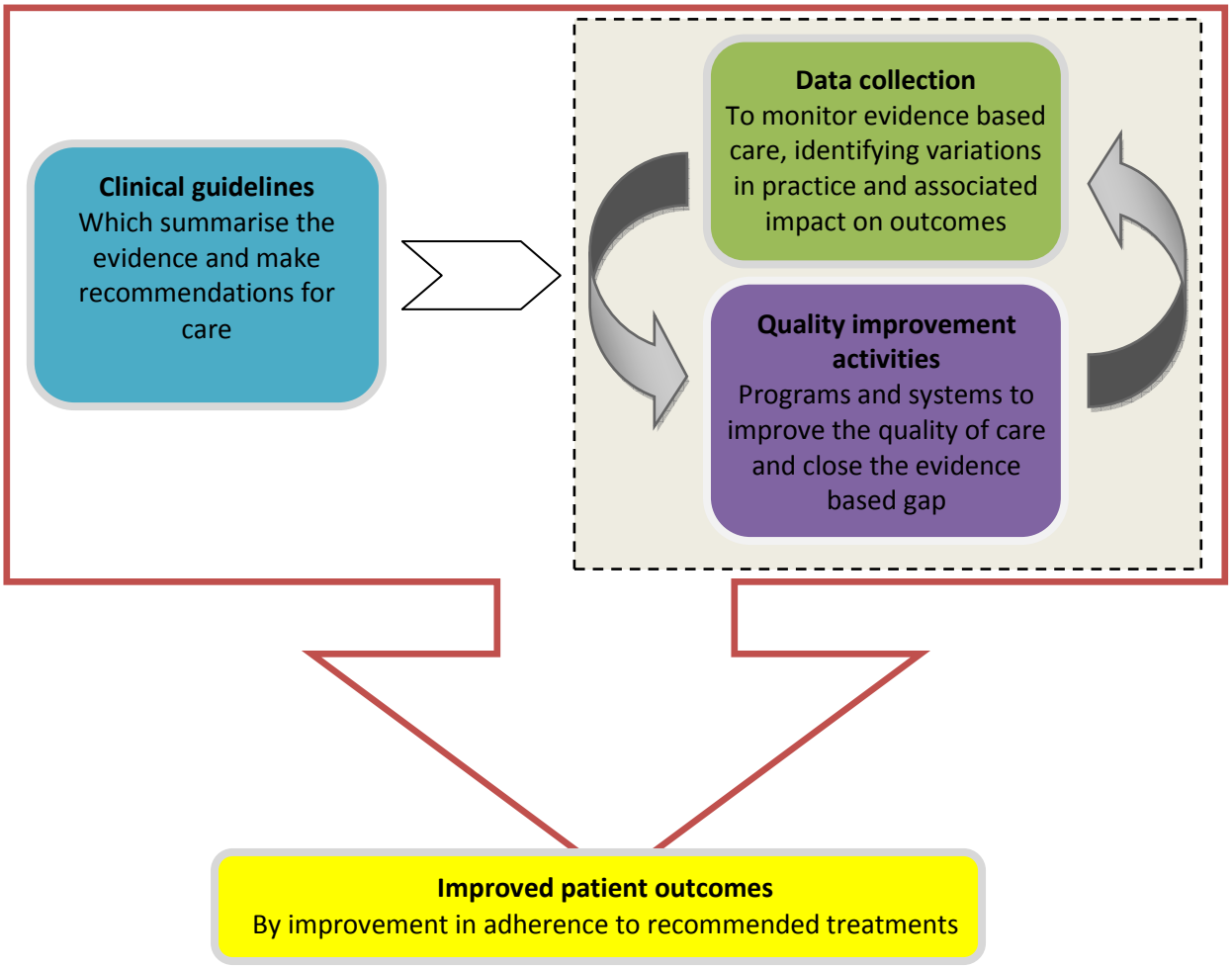
Changing clinician behaviour in line with evidence-based practice is challenging. (Grimshaw et al 2006) It is suggested that attempts to implement evidence-based practice are most effective when concrete plans use tailored and specific strategies, based on an analysis of local factors (including identified barriers and enablers), to foster clinical behavior change. (Baker et al. 2010) More than one approach is usually needed to overcome barriers to evidence-based practice, as barriers can occur at different operational levels within the health system. Levels which may need to be targeted include:

1. *Professional level*: with strategies supporting health professionals in adoption of guidelines. Strategies include: dissemination/distribution of information; education and training; audit and feedback, reminders, decisional support tools and the use of local consensus processes.
2. *Organisational (systems) level*: with strategies to support organisational change to facilitate adoption of guidelines. Strategies may include quality improvement systems, accreditation processes and the adoption of new policies and protocols.

3. *Consumer level*: with strategies supporting behavior change among consumers in relation to evidence-based practice guidelines.
4. *Regulatory or financial level*: with strategies targeting regulatory systems to support and encourage practice change. This may include changes to reimbursement items for GPs, practice-based incentives, altered approval processes and costs of medicines.

A systematic approach to improving care should include components which define the care that should be delivered, measure rates at which this care is delivered and develop systems to improve adherence to best practice care, proven to improve outcomes. See Figure 1 (below).

Figure 1. Processes required to ensure delivery of evidence based clinical care



While approaches could be grouped into system or regulatory level strategies or individual consumer or professional level strategies and another important distinction is between approaches aimed at initiation of anticoagulation and those aimed at quality of ongoing management. Irrespective, the NSF suggests that multifaceted approach is needed targeting several levels and includes initiation and quality of ongoing anticoagulation therapy regardless of whether current or new agents are used.

Multifaceted approach

Evidence suggests multifaceted interventions to improve stroke prevention guidelines can improve care and prevent stroke. One UK study involving of 76 primary care practices found a multifaceted approach including evidence-based recommendations, audit and feedback, interactive educational sessions, patient prompts and outreach visits led to a 36% increase in diagnosis of AF and 46% increase in compliance with recommended care (for AF and transient ischaemic attack combined) (Wright et al 2007). Key components of the model include contextual analysis, strong professional support, clear recommendations based on robust evidence, simplicity of adoption, good communication and use of established networks and opinion leaders (Wright et al 2007).

Other multifaceted approaches reported in the literature, however, have provided less clear results and further strategies are needed particularly around initiation of therapy (Thomson et al 2007; Holbrook et al 2007).

While educational programs are the foundation for multifaceted strategies reported in the literature education alone has only a limited effect (Mandryk et al, 2008).

Ongoing Australian studies of stroke prevention in general practice should add to our knowledge of successful strategies (e.g. Gattellari et al.2011).

Detection

Incidental diagnosis of AF often occurs during hospitalisation. Pharmacist screening has been found to improve detection and change management strategies.(Jackson et al 2005; Jackson 2010; Bajorek 2005) However, the greatest potential impact on overall detection of AF would be improve detection in primary care. One UK study found the preferred method of screening in patients aged 65 or over, in primary care, is opportunistic pulse taking with follow-up electrocardiography.(Fitzmaurice et al 2007) (Wright 2007) Simple new technology, such the measurement of using finger-tip pulsation may also prove useful in detecting AF. (Lewis et al 2011)

As well as detection, there needs to better recognition of the significance of short paroxysms of AF. These are themselves a sufficient indication of heightened stroke risk, equal to the presence of chronic atrial fibrillation. There significance is often confused with provoked AF and delays in treatment, waiting for detection of a second elusive paroxysm, often accounts for avoidable stroke. Interrogation of pacemakers suggests that brief paroxysms are rarely isolated.

Ongoing compliance and quality use of medicines

AF is most prominent in those over 75 years of age. They are often on multiple mediations and many will be stroke survivors. Adherence with medication is challenging. Drug trials commonly report high discontinuation rates (e.g. the RE-LY study reported discontinuation of dabigatran in 21% and 16% on warfarin; ARISTOTLE reported 25% discontinuing Apixaban Vs 27.5% on warfarin). Discontinuation often relates to symptoms but measures such as Webster packaging, supervised administration and Home Medicine Review are useful tools to improve compliance and quality of medication use, in the elderly AF cohort.

The published benefits of warfarin are realised if patients spend approximately 70% of the time with an INR in the target therapeutic range of 2-3. There may be benefits from setting a specifc INR target of 2.5 (BAFTA) but it remains a challenge to maintain an appropriate time in the therapeutic range (TTR). Quality use of warfarin medication requires close attention to the quality of INR control, which is almost uniquely nfluenced by diet and medication interactions. Meta-analysis shows that improved warfarin control could decrease the likelihood of almost half of all anticoagulant-associated adverse events (Oake et al 2007). For this reason, a substantial number of programs have aimed at increasing the TTR for warfarin, including a recent programme from the National Prescribing Service (NPS).

While some studies report Australian patients are within their therapeutic INR range only 50-60% of the time (van Walraven et al 2006) recent experiences from the newer trials suggest mean TTR is good in Australia (e.g. RE-LY mean TTR in Australia was 74% -equal second best country [Wallentin et al 2010]). The NSF endorses continued and greater effort to increase the TTR for those on warfarin and efforts to reduce discontinuation rates.

The management of anticoagulation around the time of procedures can account for avoidable stroke. Guidelines are available (Gallo et al MJA) but anticoagulants continue to be ceased for excessively long periods or inappropriately. As a cause of avoidable stroke, for those already on anticoagulants, a quality use of medicines program is needed to address this problem.

Although outcomes are mixed, there are a range of models and strategies (in addition to consumer and professional education) proven to improve compliance with warfarin including:

- Anticoagulation clinics and Point-of-Care testing
- compliance monitoring
- self monitoring and self management (particularly for younger patients)
- continuum of care arrangements
- pharmacogenetic testing and collaborative (shared care) arrangements
- pharmacist led care/reviews (eg: HMR)
- use of decision support tools

(see Connock et al 2007; Heneghan et al 2012; Fitzmaurice et al 2007; Murray et al 2008; Bloomfield et al 2011; Jackson et al 2005; Jackson 2010; Bajorek 2005 etc). Using some of these strategies, in a multifaceted approach, is likely to improve the quality of INR control and directly improve the safety and efficacy of warfarin.

Monitoring and reporting processes are strongly recommended as part of a multifaceted approach to anticoagulant use. An anticoagulant or even AF disease register could be considered. Existing and effective primary care arrangements for diabetic care provides a proven model for the Commonwealth's consideration. Monitoring current performance to drive improvements in quality of care is consistent with the current health reform agenda.

Shared decision making can lead to improved patient centred care and patient satisfaction (Lewin et al 2001) however it is unclear which are the best interventions to promote this. (Légaré et al 2010) It is noted that shared decision making will require specific training for healthcare professionals. (ACSQHC 2011) The NSF advocates for a greater focus on patient centred care in line with recent standards by the Australian Commission for Safety and Quality in Health Care.(ACSQHC 2011) Patient groups should be included in any multifaceted approach and education and support are clearly required to increase health literacy and outcomes.

Key message 4: There is need for a multifaceted and systematic approach to improve the use of anticoagulation in at risk groups, increasing anticoagulant uptake, maintaining compliance and reducing adverse events. This should include care provider and consumer education and organisational and regulatory commitment to support the systems required to monitor (and report) quality of care.

Solutions and recommendations

The NSF welcomes the current review of therapy for AF along with the interest in the newer anticoagulant agents for management of AF. A national /Commonwealth approach is needed to improve the outcomes and quality of life of those with, or who are at risk of, atrial fibrillation. The NSF strongly supports the Commonwealth's focus on improved anticoagulation therapy and better stroke prevention. We believe this can be achieved through:

1. Improved detection of NVAF
2. Greater awareness of the need to improve management of AF (with a wider range of treatment options becoming available). A new Australian clinical guideline specifically for AF should be considered a priority based on the outcomes of this review. Current treatment algorithms urgently need updating based on recent data and newer agents. This work should be considered as a priority by the National Lead Clinicians Group and be commissioned by the Australian Commission for Quality and Safety in Health Care (ACQSHC). Key stakeholders such as the NSF should obviously be included in this process.
3. Ensuring the right patients are offered the right agent by increasing treatment choice. Approving the new agents is warranted based on clear benefits with reducing ICH. Providing education and support for health professionals and consumers regarding management choices and most appropriate therapy in different situations is crucial and can build on current NPS programs.
4. Develop a systematic, comprehensive and multifaceted program (i.e. developing guidelines, setting standards and targets, ongoing monitoring and quality improvement activities across multiple levels) to increase overall and safe use of anticoagulation (both old and new). This would importantly involve patients in all aspects of development and delivery and a clear focus on patient-centered care.

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