Genesis of medical thromboprophylaxis guidelines in Australia: a need for transparency and standardisation in guideline development

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ABSTRACT

- Clinical guidelines are recommendations based on systematic identification and synthesis of the best available scientific evidence. The National Health and Medical Research Council (NHMRC) has published standards for guideline development.
- According to the NHMRC standards, guideline development must be a transparent and independent process, with full disclosure of any potential competing interests.
- Australian guidelines for prevention of venous thromboembolism have been published by an autonomous group. Several features of the processes used to produce and distribute these guidelines, such as pharmaceutical sponsorship, do not meet NHMRC endorsement standards.
- The guidelines may overstate the need for thromboprophylaxis in medical patients, and thus expose some patients to an unnecessary risk of bleeding complications.
- Despite this, these guidelines have been taken up avidly by national and state bodies responsible for safety and quality in health care, and mandated national application has been proposed.

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In a recent article in the Journal, I questioned the scientific and clinical basis for routine medical thromboprophylaxis using low molecular weight heparin (LMWH) or unfractionated heparin.[1] Such a policy risks a benefit–hazard (major bleeding) ratio that is less than unity.[2] In this article, I discuss how *Prevention of venous thromboembolism: best practice guidelines for Australia and New Zealand*, fourth edition (henceforth, the *Guidelines*),[3] have achieved widespread dissemination and acceptance in Australia despite being produced by an autonomous group and not having been peer-reviewed. Two major factors appear likely here — first, the *Guidelines* are sponsored by a global pharmaceutical company and are professionally marketed; second, clinical quality and safety bodies appear to have adopted them "on trust", without further independent assessment. I believe there needs to be greater transparency of all aspects of guideline production, and that current standards need to be more closely adhered to.

Genesis and status of the *Guidelines*

The *Guidelines* are written by the Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism.[3] The Working Party comprises 14 eminent and appropriately qualified haematologists, physicians and surgeons from Australia and New Zealand, although how they came together as a group or whether the Working Party belongs to any parent organisation is not stated. The *Guidelines* are published as a booklet and can also be found on third-party websites,[4,5] but neither the *Guidelines* nor the Working Party have a specific website. Unlike similar overseas guidelines on the prevention of venous thromboembolism (VTE)[6,7] which have been published in peer-reviewed journals, these *Guidelines* have only been published in independent booklet form. Examples of other guidelines published in peer-reviewed journals include a position statement on warfarin reversal (which includes several members of the current Working Party as authors),[8] and guidelines in other areas of clinical medicine.[9-11]

There are three main methods by which clinical guidelines can achieve status within the medical community. First, the National Health and Medical Research Council (NHMRC) has produced a guide for the development of guidelines,[12] and will consider endorsing any externally produced guidelines according to its standards of scientific merit, sponsorship and conflicts of interest. The *Guidelines* have not been so endorsed. Second, guidelines can be submitted for assessment and publication in a peer-reviewed journal. This has not occurred with the *Guidelines* to date. Third, guidelines can be endorsed by a recognised medical authority, often in the form of a position statement of the relevant learned society, which may also be disseminated by publication in a peer-reviewed journal. This has not happened with the *Guidelines*.

The Working Party states that it is "proud" to be affiliated with the International Union of Angiology and the Australasian Society of Thrombosis and Haemostasis,[3] but it does not claim endorsement by any organisation. The nature of the affiliation is not described, and the public websites of these organisations do not refer to the *Guidelines* or the Working Party.[13,14]

Sponsorship

The current (fourth) edition of the *Guidelines* acknowledges commercial sponsorship by a "non directed" grant from Sanofi-Aventis, the manufacturer of the LMWH enoxaparin.[3] This implies that the Working Party receives funds from the sponsor but retains editorial discretion, although the precise funding mechanism is uncertain. Some of the Working Party members have disclosed additional financial associations with Sanofi-Aventis in an editorial previously published in this Journal.[15] No acknowledgement of sponsorship was present in the third edition of the *Guidelines*, so the sponsorship is either new or previously unannounced. The provisions for medical prophylaxis are the same in both editions.

Although copyright to the *Guidelines* is held by the Working Party, the booklets are distributed free of charge by Sanofi-Aventis representatives at meetings sponsored by the company, and are not readily available via other sales outlets. Within the *Guidelines*, the sponsor's product is consistently mentioned as the first of the two LMWHs currently available in Australia. This may reflect the unique registration with the Therapeutic Goods Administration for medical prophylaxis enjoyed by enoxaparin in Australia. Sanofi-Aventis is

also a major sponsor of the "affiliated"[3] International Union of Angiology, listed as such on the Union's website.[13]

The *Guidelines* are published by Health Education and Management Innovations (HEMI) Australia Pty Ltd, which is incorporated in New South Wales. In a shared website,[16] HEMI describes itself as providing "a 'broker' service between clinicians and the healthcare industry". At the time of writing, the company had no telephone number listed in the White Pages, no easily accessible public address, no dedicated website detected by Google, and used a generic email address (hemiaustralia@aol.com). HEMI's company details, available from the Australian Securities and Investments Commission, reveal that a member of the Working Party is a HEMI director and shareholder. The above relationships suggest that, in effect, the Working Party publishes its own *Guidelines* via a company that is part-owned by a member, with essential costs met by the acknowledged "non directed" grant from Sanofi-Aventis.

HEMI has published several booklets in the field of thrombosis and thromboprophylaxis.[3,17,18] One of these is subtitled "best practice international guidelines" for the prevention of VTE.[17] It has no named authors, has very similar content to the Working Party's *Guidelines,* claims endorsement by the International Union of Angiology and is also sponsored by Sanofi-Aventis.[17] Readers of this publication are referred to HEMI for details of authorship and copyright, but, as yet, I have received no response to a request for information on these points.

In addition to direct sponsorship of the Working Party, Sanofi-Aventis has funded the public relations company Fleishman-Hillard to help market enoxaparin.[19] This marketing process has been reported to include "the release of hospital guidelines, the publication of a research study in *Lancet*, and a summit in Sydney".[19]

Promotion of the *Guidelines* and "ACTION on VTE"

The need for thromboprophylaxis has received ready coverage in the media. For example, in an article in the *Sydney Morning Herald* entitled "Simple jab can cut blood clot deaths", a member of the Working Party claimed "All patients should be given the prophylaxis. It's very cheap, it's very safe and it's very effective".[20] The same article states that the injection should be "mandatory" and claims that 10 000 deaths per year will be "combat[ed]" by prophylaxis. Similar articles[21,22] followed a recent research article[23] and invited editorial[15] in this Journal.

In furtherance of its aims, the Working Party organised a "summit" at the Westin Hotel, Sydney, on 2 May 2008 on behalf of itself and another group called "ACTION on VTE" (Australian Coalition on Thrombosis for Improving Outcomes Nation-wide on VTE). A report of the summit was published the following day in major daily newspapers, again under dramatic headlines such as "Blood clots cost Australia $1.72 billion".[24-27] Invitations to the summit (which did not feature any provision for presentation of independently submitted papers) did not state whether the meeting was sponsored, but the Coalition's secretariat was HEMI, and acknowledgements of registration were sent under the letterhead of and "on behalf of" Sanofi-Aventis. The genesis of the concept of an Australian "Coalition" is uncertain, but a "Coalition to Prevent Deep-Vein Thrombosis", sponsored by Sanofi-Aventis, exists in the United States.[28] This group also conducts meetings in hotels and has involved special interest groups, the public, and politicians.

ACTION on VTE plans include mandatory reporting of VTE risk assessment, incidence and readmission rates under the Australian Health Care Agreement. Thus, like its American counterpart, the Coalition seeks to mandate a discretionary element of medical practice by deployment of political authority. In promotional material for the summit, it was claimed that "a delay in ACTION on VTE until the next round of Healthcare Agreements in five years time could contribute to up to 50,000 preventable deaths [a repeat of the 10 000 per year quoted above] from pulmonary embolism in Australia". This high figure was not referenced and would seem more likely to be an estimate of the total annual deaths from VTE in Australia.[23] A report by Access Economics, commissioned by the Working Party and released at the Sydney summit provides VTE incidence data based on Australian Institute of Health and Welfare coding statistics that include cerebral infarction due to embolism of precerebral and cerebral arteries, arterial embolism, and thrombosis.[29] As these non-venous phenomena account for 26% of the total VTE,[29] the report may overestimate VTE incidence by up to 35%. The report does not state its funding source, but an article in the *BMJ* reported that "the summit and the report were both part-funded by Sanofi-Aventis", and that the summit was "organised with help from Fleishman-Hillard".[19]

NSW Health resolved to distribute the fourth edition of the *Guidelines* to NSW medical practitioners in a form that erases the reference to the commercial sponsorship.[30] This arrangement was formally announced in September 2008.[31] NSW Health was reported as seeing no problem with obscuring the fact of commercial sponsorship because in its view, the *Guidelines* have been produced by experts.[30]

Role of clinical safety and quality assurance bodies

The *Guidelines* have been reproduced or cited on the websites of various national and state bodies responsible for quality assurance in health care. These include the National Institute of Clinical Studies (NICS; an institute of the NHMRC),[32] and the Australian Commission on Safety and Quality in Health Care.[33] The Commission has indirectly supported the *Guidelines* by virtue of its "Stop the Clot" campaign in residential aged care facilities, which has received the support of the federal government. On the NICS website, the main evidence for emphasising thromboprophylaxis is given in three "commissioned" papers[34] that used an investigative tool (analysis of coded hospital morbidity data) that is subject to admitted bias[35] and is known to be unreliable in related research.[36] Like the *Guidelines*, these reports have not been published in a peer-reviewed journal. Similarly, the NSW Therapeutic Advisory Group[37] and the Office of Safety and Quality in Healthcare[38] in Western Australia advocate adoption of and cite the *Guidelines*, as a clinical indicator and clinical quality assurance standard respectively.

As far as I am aware, no group justifies its choice, but the most likely explanation is that the *Guidelines* have been accepted without question by virtue of the presumed unimpeachability of the members of the Working Party, similar to the reasoning offered by NSW Health to justify distributing the *Guidelines* with the sponsorship details removed. Alternatively, the lead of one such organisation may simply have been copied by the others. Commendably, NICS is reviewing and continuing to develop its thromboprophylaxis guidelines.[39] The reviewing committee includes two members of the Working Party in a representative capacity.[40]

Scientific considerations

I am concerned that the *Guidelines* overstate the need for pharmacological prophylaxis in medical patients, and that patients at low risk

Selection and exclusion criteria from two trials of LMWH thromboprophylaxis in medical patients compared with the eligibility criteria for thromboprophylaxis according to the Australia and New Zealand Working Party *Guidelines*[3]

Trial	General selection criteria	Disease criteria for trial entry (trials) or for drug prophylaxis (*Guidelines*)	Additional risk factors	Exclusion criteria
MEDENOX study[41] (enoxaparin)	Age > 40 years; projected LOS > 5 days; prior immobility < 4 days	CCF (NYHA grade III or IV); acute respiratory failure	No	Pregnancy, lactating women, women not using contraception; stroke or major surgery within 3 months; iodine sensitivity; thrombophilia; creatinine > 150 μmol/L; intubation; HIV infection; blood pressure > 200/120 mmHg; active peptic ulcer; bacterial endocarditis; increased haemorrhagic risk, including a requirement for anticoagulants or use of anticoagulants for > 48 hours.
		Acute infection with septic shock; acute rheumatic disorder including acute lumbar pain or sciatica or vertebral compression; acute arthritis or rheumatoid arthritis of the legs; or inflammatory bowel disease	Yes — one of: age > 75 years; cancer; previous VTE; obesity (BMI > 30 kg/m^2); varicose veins; HRT; chronic heart or respiratory failure	
PREVENT study[42] (dalteparin)	Age > 40 years; projected LOS > 3 days; prior immobility < 4 days	Acute CCF, acute respiratory failure not requiring ventilatory support	No	Acute coronary syndrome within 1 month; surgery or invasive procedure within 1 month or planned within 2 weeks; bacterial endocarditis; immobilised lower limb because of cast or fracture; stroke within 3 months; high bleeding risk; platelet count < 100 × 10^9; heparin or LMWH given for > 48 hours before randomisation; contraindication to heparin; creatinine > 200 μmol/L; hepatic insufficiency or active hepatitis; pregnancy or breastfeeding; life expectancy < 1 month.
		Infection without septic shock; acute rheumatological disorders or inflammatory bowel disease.	Yes — one of: age > 75 years; cancer; previous VTE; obesity; varicose veins or chronic venous insufficiency; HRT; chronic heart or respiratory failure; myeloproliferative syndrome	
Working Party *Guidelines*[3]	Age > 60 years	Ischaemic stroke; history of VTE; active cancer; decompensated heart failure; acute or chronic lung disease; acute inflammatory disease	No	None.* All patients with the indications are at "high risk" and are eligible for prophylaxis. Other patients are at "low risk" and are not eligible.

LMWH = low molecular weight heparin. MEDENOX = Prophylaxis in Medical Patients with Enoxaparin. LOS = length of stay. CCF = congestive cardiac failure. NYHA = New York Heart Association. VTE = venous thromboembolism. BMI = body mass index. HRT = hormone replacement therapy. PREVENT = Prevention of Recurrent Venous Thromboembolism. * Exclusion criteria related to bleeding have been added to the version of the *Guidelines* distributed in New South Wales.[33] ◆

of VTE will be exposed unnecessarily to the risk of bleeding complications. The Working Party's dichotomous system for defining medical patients for VTE risk is problematic because the absolute risk threshold between low risk and high risk is not stated. In the *Guidelines*, patients are deemed to be at "high" risk and requiring anticoagulant prophylaxis if they have any of seven features (six specified disease states, or age > 60 years).

The two large trials of LMWH — MEDENOX (Prophylaxis in Medical Patients with Enoxaparin)[41] and PREVENT (Prevention of Recurrent Venous Thromboembolism)[42] had more stringent trial selection criteria for medical thromboprophylaxis than the *Guidelines* (Box). One of the conditions listed in the *Guidelines* as a high-risk condition (ischaemic stroke) was an exclusion criterion in the trials. These trials included patients who had an additional risk factor for VTE unless they had congestive heart failure or severe respiratory disease. The omission of these factors from the *Guidelines* means that they apply to a larger subpopulation of medical patients than was entered into the trials, and thus define a medical patient population for prophylaxis that is at lower average risk of VTE than the trial populations. This decreases the benefit–hazard ratio and degrades cost-effectiveness. No justification for the dichotomous grouping, or for deviating from the trial evidence base, is provided. The *Guidelines* state that "the relative risks for bleeding versus VTE must be considered when commencing anticoagulation", but neither the likely bleeding risk nor guidance on how it should be "considered" is provided.

Comment

This article describes commercial and working links between various parties in the field of thromboprophylaxis in Australia. In summary, the *Guidelines* were written by a Working Party of experts, but sponsored by the manufacturer of a drug advocated in the guidelines. They were not externally reviewed or published in a peer-reviewed journal, and appear to have become widely accepted and found their way into secondary guidelines promoted by national and state bodies responsible for clinical safety and quality without further assessment by these bodies. There is a business link between one of the members of the Working Party and the publisher of the *Guidelines*. Promotional activities associated with the dissemination of the *Guidelines* have been funded by the sponsor and resemble similarly funded activities by the same sponsor overseas. The *Guidelines* were initially only available from the sponsor, although they have subsequently been made available on third-party websites. I believe that some scientific aspects of the *Guidelines* need further clarification.

It is easy to see how national and state quality assurance bodies have become enthusiastic advocates of VTE prophylaxis, if they have received a potentially erroneous impression that tens of thousands of hospital patients will die unnecessarily each year without it. Quality and safety organisations are not primary medical bodies, and they may be inclined to accept clinical advice from external sources of "experts" without further critical assessment. In this case, the ready availability of apparently authoritative guidelines, and frequent

publicity of the topic in the lay press, appear to have created a "bandwagon" effect in favour of widespread adoption of the guidelines. However, such automatic adoption of non-peer-reviewed clinical guidelines intended for national application by taxpayer-funded bodies with a duty to improve the quality and safety of medical treatment may not be in the public interest.

Competing interests

I was a member of the Cardiovascular writing group for version 4 of *Therapeutic guidelines: cardiovascular* (Therapeutic Guidelines, Melbourne) in 2003. I have attended lunchtime meetings of my department that were sponsored, to the extent of provision of a light lunch, by Sanofi-Aventis and other pharmaceutical companies.

The views expressed in this article are solely my own and may not necessarily be held by my former or present institutions.

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COMMENT: The application of appropriate prophylaxis for venous thromboembolism (VTE) is recognised as an important patient safety measure. In a systematic review ranking 79 safety interventions, the Agency for Healthcare Research and Quality in the United States found that, based on the strength of overwhelming evidence that thromboprophylaxis reduces adverse patient outcomes and decreases overall costs, the highest-ranked safety practice was the appropriate use of prophylaxis to prevent VTE.[1] However, it has been shown that, worldwide, the application of appropriate VTE prophylaxis is underutilised.[2]

The Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism first convened in 1997. It comprises a group of specialists from medical and surgical disciplines actively involved in VTE management and representing all Australian states and New Zealand. Its objective was to produce a practical, pocket-sized booklet summarising published evidence-based guidelines, drawing on those of the American College of Chest Physicians (ACCP)[3] and the International Consensus Statement.[4] The Working Party has never attempted to produce a new set of guidelines.

The first edition of the *Guidelines* was published in 1998, with subsequent editions published in 2001, 2006 and 2008. Support from various companies in the medical industry was accepted to allay the cost of bringing Australian and New Zealand representatives to a meeting venue, usually an airport hotel meeting room on a Saturday. Members of the Working Party willingly gave of their time for these meetings, and none received payment. In return for their support and their assistance in distribution of the *Guidelines*, it was agreed that the companies could place their logo on the back cover of the booklets. It is erroneous to state that "the *Guidelines* are sponsored by a global pharmaceutical company and are professionally marketed". The statement that "the current (fourth) edition of the *Guidelines* acknowledges commercial sponsorship by a 'non directed' grant from Sanofi-Aventis, the manufacturer of the LMWH enoxaparin" is incorrect. It is clearly stated in the *Guidelines* that "The Working Party members wish to acknowledge the support of the medical industry through their provision of non-directed educational grants. The opinions expressed in this booklet are entirely those of the expert clinicians on the Working Party".

The concern expressed in the article that "the *Guidelines* overstate the need for pharmacological prophylaxis in medical patients, and that patients at low risk of VTE will be exposed unnecessarily to the risk of bleeding complications" is at variance with the recommendation from the latest ACCP guidelines, which advocate low molecular weight heparin (Grade 1A recommendation), low-dose unfractionated heparin (Grade 1A), or fondaparinux (Grade 1A) for acutely ill medical patients admitted to hospital.[5]

The Working Party advocates that VTE risk assessment should become standard practice for all surgical and medical patients on admission to hospital. From experience since publication of the first edition of the *Guidelines*, it is anticipated that there will be an ongoing demand for a pocket-sized booklet that summarises current best practice in VTE prevention, and we will endeavour to continue to meet this need.

Competing interests: I have received speaker fees and travel assistance from Sanofi-Aventis and GlaxoSmithKline, and a speaker fee from Bayer Schering Pharma.

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