Guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment

Richard Thomson, Helen McElroy, Mark Sudlow

Abstract

Objective: To describe the content of guidelines on the use of anticoagulant treatment in patients with atrial fibrillation and the impact of variations in guidelines on treatment.

Design: Postal survey of guidelines, semistructured interview with lead developers of guidelines, and application of guidelines to patient sample.

Subjects: 15 lead developers of the 20 guidelines identified in the postal survey were interviewed. 100 patients over 65 with atrial fibrillation to whom the guidelines were applied.

Main outcome measures: Evaluation of guidelines and the methods of dissemination, implementation, review, and evaluation; proportion of patients recommended for anticoagulant treatment by each guideline; and level of agreement between guidelines.

Results: There was considerable variation in whether anticoagulant treatment was recommended for subjects (range 13% to 100%, k = 0.12). Guidelines varied greatly in advice on treatment by age, the use of echocardiography, and the target value or range of the international normalised ratio (8 of the 20 guidelines included values unlikely to be effective). Development was unsystematic; evidence based approaches were rarely used. 9 of the 15 lead developers had developed the guidelines themselves, and the 6 guidelines developed by groups relied on informal consensus. Methods to support effective dissemination, implementation, and evaluation were limited.

Conclusion: The widespread non-systematic production of guidelines has led to considerable variation with implications for the quality of care and clinical decision making. There is a need for a central, well funded programme of guideline development to ensure that valid guidelines are produced and disseminated.

Introduction

Clinical guidelines are an effective method for improving both process and outcome in health care.1-7 They have been promoted as an important tool in evidence based practice and may reduce inappropriate variations in treatment. However, the results of some surveys have created concerns about the quality of guidelines.8-10 Unless guidelines are produced using appropriate methods they may replace normal clinician variation with consistently inappropriate practice.

The use of anticoagulant treatment to prevent stroke in patients with atrial fibrillation is supported by randomised controlled trials and pooled analysis of their results.11-12 None the less treatment varies,13-20 thus providing conditions where valid clinical guidelines may be useful.

We performed a survey of guidelines in Great Britain to explore variation in content; we interviewed the lead developers of the guidelines to assess the reasons for variation. We then applied these guidelines to a community sample of patients with atrial fibrillation to determine whether the advice given in the guidelines would support consistent clinical decision making.

Subjects and methods

Clinical guidelines on the use of anticoagulant treatment in England, Wales, and Scotland were identified. Organisations that produced guidelines were contacted by telephone, and 440 people were sent a questionnaire seeking information on and copies of...
their guidelines and asking for details of other organisations that might also use guidelines. The sample comprised district directors of public health and public health representatives of the regional and national NHS Executive; chairpeople of the Medical Audit Advisory Group; national professional and charitable organisations with an interest in clinical guidelines, audit, cardiovascular and cerebrovascular disease; and members of the mailing list of the national medical audit conference. Non-respondents were sent an additional questionnaire. Further participants were sought through announcements at conferences on the quality of health care, personal contacts, and queries on relevant email discussion lists. An additional 94 contacts were identified this way and sent the questionnaire. Participants were chosen to represent purchasers and providers of health care who were likely to be aware of appropriate guidelines and also to represent relevant national organisations.

Guidelines were assessed independently for inclusion in the study by two investigators (RT and MS). A guideline was defined as a document produced to help clinicians decide which patients should be given anticoagulant drugs. Draft documents, documents designed for use only in a single specialised unit, and documents designed to provide guidance on the use of warfarin only once treatment had been decided on were excluded.

Between July and September 1996 the lead developer for each guideline was invited to participate in a semistructured telephone interview, which was recorded and transcribed. All interviews were done by a single interviewer (HM). Questions were asked about the development of the guideline—because of the recognised importance of development procedures in ensuring guideline validity—and the format, purpose, dissemination, implementation, and review of the guideline.

Interviews were analysed qualitatively using Glaser and Strauss's work to identify emergent themes. Initial analysis of the transcripts was undertaken independently by two observers (RT and HM). Themes and concepts identified by each observer were confirmed or modified following discussion between the researchers and re-examination of transcripts.

All guidelines selected for inclusion were then applied to 100 consecutive patients with atrial fibrillation aged 65 years or older who were identified in a community survey. Details of risk factors for stroke and of contraindications to treatment with anticoagulants were obtained. A single observer (MS) determined whether each guideline recommended anticoagulation or another course of action (no treatment, aspirin, further investigation, or referral) for every patient. Intraobserver (test-retest) reliability was assessed by repeating this method 3 months later on a random sample of 20 of the patients using five guidelines. Interobserver reliability was assessed by comparing the decisions derived from the guidelines with the decisions of another observer (RT). The degree of agreement was quantified using \( \kappa \).

We also compared the guidelines on three selected topics (recommendations on the use of echocardiography, implication of the patient's age on treatment, and the recommended target value or range of the international normalised ratio).

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**Overview of clinical guideline development process based on interviews with 15 lead developers of guidelines on use of anticoagulant treatment in patients with atrial fibrillation**

<table>
<thead>
<tr>
<th>Lead developer</th>
<th>Method of development</th>
<th>Outside consultation</th>
<th>External review</th>
<th>Distribution</th>
<th>Type of educational meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Guideline developed by group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General practitioner</td>
<td>Informal consensus</td>
<td>Yes: cardiologist, haematologist, elderly care physician</td>
<td>Yes: cardiologist, haematologist, elderly care physician</td>
<td>Sent to general practitioners and others who requested guidelines</td>
<td>To introduce guidelines</td>
</tr>
<tr>
<td>Consultant physician</td>
<td>Informal consensus</td>
<td>No</td>
<td>No</td>
<td>Sent to general practitioners, clinicians, and junior doctors</td>
<td>None</td>
</tr>
<tr>
<td>General practitioner</td>
<td>Informal consensus</td>
<td>Yes: general practitioners</td>
<td>Yes: relevant parties in district</td>
<td>Handed out at educational meeting</td>
<td>Series on use of guidelines in general practice</td>
</tr>
<tr>
<td>General practitioner</td>
<td>Informal consensus</td>
<td>Yes: cardiologist, haematologist</td>
<td>Yes: cardiologist, haematologist</td>
<td>Sent to group members</td>
<td>None</td>
</tr>
<tr>
<td>Medical adviser to health authority</td>
<td>Evidence based</td>
<td>Yes: health economist, public health doctor</td>
<td>Yes: circulated to full health authority, plus 3 month consultation exercise with all practices, consultants, and others with known interest</td>
<td>Sent to all involved in consultation exercise</td>
<td>To discuss guidelines</td>
</tr>
<tr>
<td>Director of public health</td>
<td>Informal consensus</td>
<td>No</td>
<td>No</td>
<td>Sent to general practitioners</td>
<td>To launch guidelines</td>
</tr>
</tbody>
</table>

| **Guideline developed by one person** | | | | | |
| Consultant cardiologist | NA | No | Yes: general practitioners, committee set up to establish guidelines | Handed out at initial launch | Meetings during development and initial launch |
| General practitioner | NA | Yes: cardiologist | Yes: physiotherapists, consultants, other health professionals | Sent to general practitioners | Workshops in 10 areas within district |
| Consultant cardiologist | NA | No | Yes: specialty audit meeting | Handed out to senior house officers, sent on request to general practitioners | None |
| General practitioner | NA | Yes: cardiologist | No | Handed to practice members | None |
| General practitioner | NA | Yes: cardiologist | Yes: partners in practice | Handed to practice members | None |
| Consultant cardiologist | NA | No | Yes: physicians | Sent to junior staff | Incorporated in seminars on atrial fibrillation |
| Consultant haematologist | NA | Yes: cardiologist | Yes: cardiologist, general practitioners | Sent to general practitioners | None |
| Consultant in elderly care | NA | Yes: staff grade doctor | No | No | None |
| Consultant geriatrician | NA | No | Yes: cardiologist | Sent to general practitioners | Discussed at community based clinical audit committee |

NA—not applicable.
Results
The survey response rate was 350/534 (66%) and yielded 48 documents, of which 20 fulfilled the study definition for clinical guidelines. Guidelines were produced in a variety of formats—from single page algorithms to a 29 page report with an algorithm—were primarily for general practitioners, and were intended to be used in populations ranging from 12 000 to 500 000. The production of only two guidelines had been funded (by a pharmaceutical company and a health authority).

Interviews
Altogether 15 of the 20 people who developed the guidelines agreed to be interviewed (table). Six of them were general practitioners, seven were consultant physicians, one was a director of public health, and one was an independent medical adviser to a health authority.

Only 6 of the 15 guidelines were developed by groups. Each development group included at least one general practitioner and one consultant physician; half included a public health doctor. The roles required within development groups (subject expert, facilitator, literature searcher, evidence evaluator, chairperson, and guideline methodologist) were commonly recognised by the developer, but often one person performed several roles. Six of the nine lead developers who had sole responsibility for guideline development had sought views from another health professional (five from cardiologists), while 7 had sought an external review before finalising the guidelines. Five of the 15 guidelines were developed by the end users (internal development), 3 were developed externally by a local organisation (usually a hospital consultant producing guidelines for local general practitioners), and 7 were produced by a combination of methods (intermediate development).

The main reasons given for the development of guidelines were the need to clarify the management of atrial fibrillation and to reduce the incidence of stroke. Other reasons for developing guidelines included the perception that atrial fibrillation was a common and important condition and the lack of satisfactory alternative guidelines. According to those interviewed, the main objectives in developing guidelines were to improve clinical management and to produce uniform practice (7/15), to reduce the incidence of stroke (5/15), and to improve clinical knowledge (2/15). Only one of the guidelines included written objectives.

Literature searches were used in the development of all guidelines, but the extent and detail of the searches and the appraisal of the literature varied considerably. Only 5 of the 15 lead developers had undertaken a literature search; six had used only literature of which they were already aware. Review articles were used by 11 and articles on original trials by five. Altogether five lead developers had reviewed other guidelines, but four had tried and failed to identify any. Some form of grading of the evidence was used by four of the lead developers.

Those who had developed guidelines within a group believed that the guidelines were evidence based. However, most groups had not undertaken systematic literature searches, had not involved anyone with specific expertise, had no formal method of evaluating the evidence, and had not attempted to link the recommendations specifically to the evidence. On the basis of Wool’s classification of guideline development, only one guideline developed by a group could be categorised as evidence based. However, none of the guidelines developed by individuals were evidence based using this definition, and it is difficult to understand how such a group dependent process could be undertaken by an individual.

The method and extent of distribution of the guidelines also varied considerably. Seven of the 15 guidelines were promoted further in local educational...
Table 1: Numbers of patients with atrial fibrillation for whom anticoagulant treatment would have been recommended according to each guideline evaluated

<table>
<thead>
<tr>
<th>Guideline</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>10</td>
<td>17</td>
<td>18</td>
<td>20</td>
<td>33</td>
<td>33</td>
<td>35</td>
<td>46</td>
</tr>
<tr>
<td>B</td>
<td>16</td>
<td>20</td>
<td>66</td>
<td>66</td>
<td>79</td>
<td>81</td>
<td>88</td>
<td>91</td>
</tr>
<tr>
<td>C</td>
<td>66</td>
<td>66</td>
<td>88</td>
<td>91</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Discussion

This study has shown that there are large variations in the advice included in guidelines on the use of anticoagulants in patients with atrial fibrillation. We found that these differences would affect treatment decisions by applying the guidelines to a sample of patients with atrial fibrillation in the community. The good interobserver and intraobserver agreement suggests that variation in treatment is largely due to variations in the advice offered by guidelines. These differences could have a profound effect on the process and outcome of care and on the incidence of stroke and bleeding complications; they might also lead to substantial differences in the use of resources, particularly anticoagulation services. Our results support a similar finding on the use of different guidelines to treat hypertension in general practice.

The variation found in the guidelines is likely to be caused by their non-systematic development. Only one guideline could be classified as evidence based—that is, incorporating explicit links between recommendations and the quality of supporting evidence. In most cases literature review and appraisal were non-systematic. Though expert opinions and external reviews were sought, the methods of incorporating evidence and opinion into the guidelines were unstructured. Even in cases in which guidelines had been developed as a group process, access to the range of necessary skills was limited and group members often took on several roles.

Those developing guidelines on anticoagulant treatment were apparently unaware of the literature on development and validity; several participants thought that their guidelines were evidence based and that they had graded the evidence, although after the interview and on review of the guidelines this was not the case.

Although the interviews with the lead developers of the guidelines concentrated on the development process, shortcomings in dissemination, implementation, and review of the guidelines were also identified. Almost half of those who developed guidelines used educational initiatives, such as seminars for medical staff, to support dissemination, but strategies for implementation were absent. Planned review and evaluation were rare.

Though we undertook an extensive survey, we will have failed to identify some guidelines. However, those who responded voluntarily are likely to have provided higher quality guidelines than those who declined to provide guidelines. Thus, our conclusions are unlikely to be weakened by the inclusion of guidelines that we initially failed to identify. This is equally true of any potential non-response bias from the interviews.
It is not our intention to criticise those who produced these guidelines. They have contributed considerable time and effort with the explicit intention of improving patient care. However, the resources required to develop valid guidelines are substantial. Production of most of these guidelines was inadequately funded. Many of the guidelines suggest courses of action that are not ideal, presumably as a result of errors in interpretation or presentation of the evidence. Many of the respondents identified the shortcomings of their approaches but, in the absence of alternatives, recognised a need to produce guidelines for local use. These results confirm that guidelines developed non-systematically are likely to be variable in content and impact. Hence, those considering developing guidelines should first explore whether evidence based guidelines already exist and can be adapted for local use. If they do not exist advice should be sought from experts on guideline development and literature appraisal. We suggest that a centralised organisation could develop clinical guidelines in a more cost effective manner than the current system and would be more likely to produce reliable and valid guidelines. The organisation would need to apply rigorous and transparent methods to the development of guidelines, and the guidelines produced would need to be readily accessible. This organisational role could be taken by the NHS Research and Development Organisation or professional organisations such as the royal colleges or specialist associations. Critical appraisal of available guidelines, such as that commissioned by the Clinical Outcomes Group of the Department of Health, would lend further support to this approach. Such centrally produced, validated, evidence based guidelines could then be adapted to local circumstances.

We thank all those who responded to our postal survey, and Phil Adams, Malcolm Aylett, Françoise Cluzeau, Martin Eccles, Denise Howel, and Rose Anne Kenny for their help and advice.

Contributors: RT initiated and coordinated the formulation of the study idea and its design; contributed to the assessment of the guidelines, including their application to patients; contributed and advised on the qualitative analysis of the interviews; participated in the interpretation of the results; and led the writing of the paper. MS contributed to the design of the study and to the assessment of the guidelines, participated in data collection, led the analysis of the quantitative application of the guidelines to the series of community based patients, participated in the interpretation of results, and contributed to the writing of the paper. HM contributed to the design of the study, undertook the interviews, led the qualitative assessment of the guidelines, participated in the interpretation of the results, and contributed to the writing of the paper. Carol Fraser helped with management of the postal survey. RT and MS are guarantors for this paper.

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Conflict of interest: MS and RT are now involved in developing evidence based guidelines on the use of anticoagulant treatment in atrial fibrillation using decision analysis.

7 Implementing clinical practice guidelines. Effective Health Care 1994; No.8.

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