Beyond Conventional Stroke Guidelines

Setting Priorities

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Background and Purpose—Priorities in the care of stroke patients are often intuitive. An open and translucent priority-setting procedure would benefit patients, professionals, and decision-makers. Prioritization is an innovative part of the new Swedish national stroke guidelines.

Methods—Working groups identified diagnostic procedures, interventions and therapies in stroke care, assessed each one according to severity (needs), effect of action, level of scientific evidence and cost-effectiveness. The items were then ranked into priority groups from 1 (highest) to 10 (lowest). Procedures lacking evidence for routine clinical use were also identified (and entered a do-not-do list), as well as procedures in research and development. Resource allocations resulting from the priority-setting process were identified.

Results—Of 102 core procedures identified, 50 were assigned to high-priority groups (1–3), 29 to moderate priority groups (4–7) and 23 to low priority groups (8–10). Almost a quarter were graded 8 to 10, indicating that they may not necessarily be applied if resources are scarce. Twenty-eight procedures were assigned to the do-not-do list and 16 to the research and development list.

Conclusions—In stroke services, it is possible to identify not only diagnostic procedures and interventions with high priority, but also a considerable number of items used today that have low priority or should not be used at all. Strict adherence to the guidelines would result in a substantial reallocation of resources from low-priority to high-priority areas. (Stroke. 2007;38:2185-2190.)

Key Words: cost analysis ■ health priorities ■ needs assessment ■ practice guidelines ■ stroke services

A dherence to stroke guidelines has been shown to improve outcome1 and reduce healthcare costs.2 Conventional clinical guidelines, including those on stroke, are usually produced by a group of physicians and have a limited scope, focusing on prevention or diagnostic and therapeutic procedures. Many guidelines produced today systematically evaluate the strength of scientific evidence that their recommendations are based on. This has also been used in most of the stroke guidelines published in recent years.3–12

Grading of scientific evidence cannot, however, be used as the sole basis for guiding clinical stroke practice. First, needs must also be considered. A widely accepted ethical principle is that patients with great needs should have a greater share of common resources than those with less need.13 Second, the effect size of an intervention is a decisive factor when weighing different interventions against each other. Third, it is inevitable that limitations of resources, human or financial, must be taken in account when priorities are set in stroke management.

All these elements are probably incorporated in the intuitive priority setting that constitutes the daily life of stroke physicians and the stroke team. They form, together with other values, also the basis for decision-makers at the administrative level of health care.

An open and translucent priority-setting procedure would benefit patients, professionals, and decision-makers. It could reduce the frustration of clinicians when challenged with difficult decisions (eg, whether to refer a patient to neurosurgery for lobar hematoma) and promote patient empowerment (eg, support a patient’s demand for carotid surgery for tight stenosis to be performed with short delay). It could also relieve healthcare administrators and politicians of being forced to make decisions that are not evidence-based (eg, allocating resources to memory training or acupuncture treatment after stroke).

Previous reports on priority-setting procedures in stroke care have been restricted to single institutions14,15 or the choice between a few interventions.16
An overall aim of the series of national clinical guidelines produced the Swedish National Board of Health and Welfare is to use resources efficiently and that they are shared according to patients’ needs, irrespective of geographical location within the country. In the present article, we describe features specific to the new comprehensive national guidelines on stroke management in Sweden. Special attention is paid to a unique and potentially controversial feature of the Swedish national stroke guidelines, namely open and transparent prioritization of diagnostic procedures and interventions and the economic consequences of this.

Methods

Organization of the Guideline Work

The work with new national stroke guidelines was coordinated by the National Board of Health and Welfare. An aim was to broadly involve the Swedish stroke community and to make the guideline work itself a first part of the implementation process. Therefore, the participation of representatives of all potential stakeholders was ensured. The different perspectives considered were (1) laymen, professionals and decision-makers, (2) all levels of the stroke care—primary care, local and tertiary hospitals and social care in the community, and (3) fair geographical distribution of participants across the country.

A Steering Group decided on the final documents of the project, basing its decisions on the work of 3 subcommittees (Prioritization, Medical Facts, Health Economics). The subcommittees represented a wide spectrum of physicians (specialists in neurology, internal medicine, rehabilitation medicine, general practice, geriatric medicine, neurosurgery, vascular surgery, intensive care, cardiology and clinical physiology), other healthcare professionals (stroke nurses, community nurses, physiotherapists, occupational therapists, speech therapist, neuropsychologist, social worker, dentist and dieticians), an expert in medical ethics, healthcare administrators, patient representatives and staff of the National Board of Health and Welfare. In all, 62 people were involved in producing the national stroke guidelines.

The stroke guidelines were produced in 2 different versions: 1 for decision-makers (with emphasis on priority-setting) and 1 containing the medical and health economic facts background, mainly targeted at professionals in stroke care. A third version with patients/laymen as target group is underway. A reference group reviewed all documents. It included representatives appointed by 21 professional and patient organizations and healthcare providers.

The stroke guideline work was initiated in January 2003. The guidelines were officially approved by the National Board of Health and Welfare in December 2005 and published in February 2006. An English translation of the key chapters is available.

Procedures for Priority Setting

The ethical principles of priority setting were those adopted by the Swedish parliament in 1997 on a proposal by a parliamentary committee. Three principles constitute this ethical platform: (1) human dignity (all humans being should be treated equally, irrespective of their social position, age, mental handicap, etc), (2) needs and solidarity (those in greatest need should get the greatest support) and (3) cost-effectiveness (rational use of common resources).

The priority-setting process followed the main principles of the Importance (Priority/Relevance) dimension of the Policy Delphi process. Different working groups were used to identify clinical questions and to collect background information. A separate group was then deciding on priorities in a reiterative process involving many different stakeholders.

The first step of the priority-setting process was that the Prioritization subcommittee preformulated key clinical conditions that should be addressed in the priority rankings and possible actions to be taken. Usually, these were diagnosis-treatment pairs (eg, severe carotid stenosis-thrombendarterectomy) but they could also describe other clinical problems (eg, risk of falling-specific training).

As a second step, the Medical Facts subcommittee reviewed the literature for scientific evidence in support of each intervention. The strength of scientific evidence obtained from systematic reviews was graded into Levels of Evidence from 1 to 4 using a slight modification of the system used by SIGN, the Scottish Intercollegiate Guidelines Network. When a systematic review was not available (for instance, for many nursing interventions), the scientific evidence was graded as very good/good/limited, or described in free text according to prespecified criteria. In prevention, risk assessment was based on the long-term risk for death from any cardiovascular event according to the SCORE system. When applicable, the scientific strength of the cost-effectiveness results was also assessed.

For each condition-action pair, the background data were summarized by the Medical Facts subcommittee in 4 items: (1) severity of stroke and of stroke complications, (2) effect of action, (3) strength of scientific evidence for effects and (4) cost-effectiveness assessments expressed as cost-per-year or cost-per-quality-adjusted life-year gained.

The third step of the process was that priorities were rated from 1 (highest) to 10 (lowest) by the Steering Committee and the Reference Group together, thus ensuring that all of stakeholders (patients, professionals and decision-makers) were represented in the process. The contributions of laymen were mainly to assess severity of stroke and its sequelae and to safeguard that outcomes relevant to patients (eg, life satisfaction and impact on family members) were included in the assessments when available.

In the priority setting, the 4 background information items for each condition/action pair provided by the Medical Facts subcommittee were the main deciding factors. A formal scoring system to weigh the components was not used. Instead, they were discussed an iterative Delphi-like process and compared with those of other items to “calibrate” the priorities in different areas of stroke management (such as prevention, acute treatment, nursing and rehabilitation).

As a fourth step, a preliminary version of the priority list was presented and discussed at regional seminars with local key healthcare decision-makers, patient representatives and professionals. Participants were asked to comment on the documents and analyze the consequences for local stroke services. There was, in general, broad support for the principles underlying the priority setting and for the rankings in the preliminary version. However, some new facts and arguments emerged at the regional seminars and they were taken into account when a final decision on priority grades for all condition-action pairs was taken by the Steering Committee.

Diagnostic procedures and interventions that should not be used in routine clinical practice were identified and listed separately. The criteria for deferring items to this do-not-do list were: (1) not supported by scientific data or by consensus, (2) good evidence that there are similarly effective alternative methods with a more favorable safety profile, and (3) proven effectiveness only on some intermediate outcome(s) but not affecting outcome in terms of survival, function or quality of life.

Diagnostic procedures and interventions that were deemed to be interesting and promising but not yet sufficiently well supported by scientific evidence were assigned to a research and development list with the intention to review the forthcoming evidence to possibly include the methods when the scientific evidence becomes stronger.

Economic Ramifications

The organizational and economic consequences of the national guidelines were analyzed to identify possible needs for reallocation of resources. The focus was on possible reallocation of resources within the stroke care sector. Therefore, only direct costs (and not indirect costs by loss of production) were included in the assessments. The economic consequences were calculated at the national level (=per 9 million inhabitants).

Because of limited availability of health economics data for many interventions, a limited number of key diagnostic procedures and therapies were analyzed in more depth. The consequences for several
other diagnostic procedures and interventions were assessed based on absolute risk reductions and crude estimates of associated economical effects on changes in outcomes and costs of interventions.

Results

Priority-Setting

One hundred and two condition-action pairs were identified and graded in priority groups 1 to 10. Fifty of the actions were allocated to high priority groups 1 to 3, 29 to intermediate priority groups 4 to 7, whereas 23 were graded 8 to 10 (low). In addition, there were 28 situations (7 diagnostic and 21 interventional) in which specified actions used in Swedish stroke care today fulfilled the criteria for not being recommended for routine clinical practice, i.e., they were assigned to the do-not-do list. One diagnostic procedure and 15 interventions were assigned to the research and development list.

Two detailed examples of the components of the priority-setting procedure, 1 resulting in a high priority rank and 1 in a low rank, are given in Table 1. Other examples of priority grading, do-not-do procedures and items on the research and development list are given in Tables 2 and 3. Complete lists are available in references 17 and 18.

Economic Ramifications

As a result of the priority setting, resources liberated by not applying the lowest-ranked or do-not-do diagnostic procedures and interventions should be diverted toward underfunded areas. By adhering to the priority recommendations, the resources currently spent on expensive drugs used in stroke prevention could be reduced considerably. It is estimated that, in the country (population 9 million) the annual cost for antihypertensive drug treatment could be reduced by €20 million, if the use of angiotensin receptor blockers (listed as a do-not-do procedure in primary prevention) is minimized.

Among statins, simvastatin is the preferred choice in primary and secondary prevention (rank 5 in high-risk and 8 in low-risk individuals) because its cost-effectiveness profile is considerably better than that of other statins (rank 7 in high-risk and do-not-do in low-risk individuals). If these recommendations are adhered to, €25 million per annum will be saved in Sweden for use in other, higher prioritized areas of stroke care.

Additional resources can be mobilized by abandoning, in routine clinical practice, specified diagnostic procedures and interventions that are deemed to be outdated, too hazardous, too cost-ineffective or lacking scientific support (rank 8 to 10 in the priority list plus items on the do-not-do list).

According to the priority list, investments are primarily needed in (1) increased detection of hypertension and its treatment with drugs other than angiotensin receptor blockers, especially in people at high total risk of a cardiovascular event, (2) increased use of anticoagulants for the prevention of embolic stroke in patients with atrial fibrillation. This would cost an additional €28 million, but money saved in later links of the stroke care chain makes this intervention cost-neutral for the healthcare system, (3) access to stroke unit care for all acute stroke patients in the country (additional cost €20 to 25 million), (4) structural changes to improve the proportion of patients being treated by early thrombolysis (most extra costs counterbalanced by saving in rehabilitation and long-term care, resulting in net additional cost of €2 million only) and (5) some of the methods available for stroke rehabilitation (no specific sum given). The modest additional investment in stroke units that was calculated to be required is because stroke unit care is already widely available in Sweden with 79% of all acute stroke patients being admitted to a stroke unit in 2005. The prioritization of rehabilitation is because the scientific evidence is reasonably strong for some of the methods used, the effect size is considerable and both patient representatives and professionals considered persistent stroke sequelae to be a severe problem (one of the priority criteria).

Discussion

This work is the first in which open and translucent priority setting has been applied to stroke management on a national level. The process to produce national guidelines was tedious and resource consuming. The work shows, however, that open and translucent priority setting with consensus among a broad spectrum of stakeholders (professionals, decision-makers and patients) is feasible also within the area of stroke. Whereas it is not difficult to reach agreement on diagnostic procedures and interventions with high priority, our guideline process shows that agreement can also be reached as regards procedures in stroke care that should have low priority, not be used at all or await further scientific documentation before being applied in routine clinical practice.
About half of the diagnostic procedures and interventions were assigned to priority groups 1 to 3. This indicates that a large share of what is used today in stroke prevention and care remains essential even after careful scrutiny of needs, effects, cost-effectiveness and scientific support. A different finding would have been surprising.

A few comments to the prioritization process are warranted. The strength of scientific evidence varies systematically between different areas of intervention (in general, pharmacotherapy, surgery, rehabilitation, and nursing, in that order), and this may favor drug treatments over many other parts of care. A few organizational changes, such as stroke unit care or early supported discharge with home rehabilitation, have been researched quite extensively, whereas others have not. The great variations in scientific background between different aspects of stroke management were a challenge to the priority-setting team. Some deviations from a strict adoption of the principles of evidence-based medicine were unavoidable. For instance, in nursing of stroke patients, there is limited scientific evidence from clinical trials. Instead, most priority gradings of nursing interventions were based on either observational studies or consensus within the steering group and the reference group on what should constitute good clinical practice.

In prevention, the priority grading was highly dependent on whether an intervention was applied in a high-risk or a low-risk individual because needs as well as cost-effectiveness were different. Patients who have had a transient ischemic attack or stroke were usually in the high-risk groups, resulting in most secondary prevention measures being ranked higher than most primary prevention measures. In pharmacotherapy, cost-effectiveness became a deciding feature when several groups of drugs were available for identical or similar indications. For example, simvastatin was ranked higher than more expensive statins, and ARBs were assigned a lower priority than low-cost antihypertensive agents.

Three common misconceptions about guidelines and priority setting should be addressed. First, guidelines do not replace clinical judgment. They still leave room for individualized therapy and the art of medicine. However, when practices in primary care, hospitals or other healthcare institutions are monitored, they should not deviate much from what has been agreed on in the national guidelines. Thus, the priority-setting applies to groups of patients rather than to individuals.

<table>
<thead>
<tr>
<th>Table 2. Examples From the 102 Items on the Priority List and From 28 Items on the Do-Not-Do List</th>
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<tbody>
<tr>
<td>Priority Condition–Action</td>
</tr>
<tr>
<td>Primary prevention</td>
</tr>
<tr>
<td>1 Smoking–brief antismoking advice including nicotine replacement</td>
</tr>
<tr>
<td>3 Hypertension in high-risk persons (5% risk for cardiovascular death in 10 y)–treatment with antihypertensive agents other than angiotensin receptor blockers</td>
</tr>
<tr>
<td>8 Hypercholesterolemia in low-risk person (&lt;5% risk for cardiovascular death in 10 y)–simvastatin</td>
</tr>
<tr>
<td>Do-not-do Hypercholesterolemia in low-risk person–statins other than simvastatin</td>
</tr>
<tr>
<td>Acute medical care</td>
</tr>
<tr>
<td>1 Acute stroke–admission to a nonintensive care stroke unit</td>
</tr>
<tr>
<td>1 Ischemic stroke &lt;3 hours–thrombolysis</td>
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<tr>
<td>10 Lobar intracerebral haemorrhage (supratentorial)–neurosurgery</td>
</tr>
<tr>
<td>Nursing</td>
</tr>
<tr>
<td>1 Urinary retention–scheduled bladder emptying</td>
</tr>
<tr>
<td>4 Risk of falling–training and other specific interventions</td>
</tr>
<tr>
<td>10 Risk of contractures in bedridden patients–resting positioning to prevent complications</td>
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<tr>
<td>Rehabilitation</td>
</tr>
<tr>
<td>3 Impaired motor function–task-specific training</td>
</tr>
<tr>
<td>6 Shoulder pain–TENS, acupuncture</td>
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<tr>
<td>Do-not-do Impaired motor function–acupuncture</td>
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<tr>
<td>Secondary prevention</td>
</tr>
<tr>
<td>2 Ischemic stroke in a patient with atrial fibrillation–warfarin</td>
</tr>
<tr>
<td>2 Symptomatic high-degree carotid stenosis–urgent carotid surgery</td>
</tr>
<tr>
<td>Do-not-do Intracranial stenosis–long-term treatment with warfarin</td>
</tr>
</tbody>
</table>

TENS indicates transcutaneous electrical nerve stimulation.

TABLE 3. Examples From the List of Interventions Awaiting Further Scientific Documentation Before Being Adopted in Routine Clinical Practice (Research and Development List)

- Homocystein-reducing therapy with vitamins in primary or secondary prevention of stroke
- Admission of all stroke patients to an intensive-care stroke unit
- Diffusion MRI to select patients for thrombolysis
- Constraint-induced movement therapy in the rehabilitation of stroke patients
- Pharmacotherapy to improve brain plasticity
- Stenting of carotid stenosis
Second, it must be emphasized that strength of scientific support does not equal priority ranking. It may well be that an intervention has support from a large and well conducted clinical trial but that the effect size, although statistically significant, is trivial and of little clinical significance. It may also have an unfavorable cost-effectiveness ratio or be directed toward groups of patients with modest needs. It is thus possible that an intervention with strong scientific support may end up being ranked low.

Third, the priority grading is not a fixed process. It is the result of a consensus procedure, and we realize that many individual items may be challenged. Although the procedure to rank the condition-action pairs was structured, there was inevitably an element of common sense in the final weighing of the various components contributing to the ranking. The lack of solid scientific documentation in many areas of stroke management contributed to this, as was a subjective component in the assessment of severity (needs). As stroke and health economics research progresses and cost-effectiveness ratios change because of cost reduction (or increase) of diagnostic procedures and interventions, there is a need for regular updating of the guidelines. Work on the next version of the national guidelines will start during 2008.

Because one of the bases for prioritization was cost-effectiveness, the scarcity of high-quality health economics data in the stroke research literature was disturbing. Making a crude estimate of the cost-effectiveness of a specific procedure usually solved the dilemma. This may have affected the precision in the cost-effectiveness estimates but did not, in practice, have a major influence on the priority ranking. The fact that most preventive actions (lifestyle interventions and drugs) have a very wide scope may lead to a significant, is trivial and of little clinical significance. It may also have an unfavorable cost-effectiveness ratio or be directed toward groups of patients with modest needs. It is thus possible that an intervention with strong scientific support may end up being ranked low.

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