Developing hospital accreditation in Europe

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ABSTRACT

This brief guide is addressed to governments of Member States in the WHO/European Region, which are considering or implementing a programme of accreditation, particularly for hospitals. It is also addressed to funding agencies in order to assist in the specification, monitoring and evaluation of contracts for health care development funding. It is not intended to be a comprehensive document but it includes references to more detailed guidance.

Keywords

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HOSPITALS – standards
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I Introduction: certification, licensing, accreditation

1.1 Purpose and scope of this guide

This brief guide is addressed to governments of Member States in the WHO/European Region, which are considering or implementing a programme of accreditation, particularly for hospitals. It is also addressed to funding agencies in order to assist in the specification, monitoring and evaluation of contracts for health care development funding. It is not intended to be a comprehensive document but it includes references to more detailed guidance.

The aim is to provide an overview of the practical issues involved in order to help governments to:
- assess the effectiveness of existing mechanisms for stewardship and regulation of their health system
- identify the objectives, added value, options and resource implications of institutional accreditation
- integrate the development of accreditation with related programmes of health reform, such as decentralisation of management, health care funding, performance management, professional development and hospital information systems
- procure and monitor technical assistance to design and implement a programme of hospital accreditation.

The documents provides for the key issues in developing accreditation a checklist of issues that need to be considered by national/regional authorities,

1.2 Definitions

There are three main systems to define standards, assess compliance and award formal recognition to successful institutions (see box). These are increasingly used worldwide to regulate, improve and market health care providers, especially hospitals.

<table>
<thead>
<tr>
<th>Accreditation</th>
<th>Public recognition by a national healthcare accreditation body of the achievement of accreditation standards by a healthcare organization, demonstrated through an independent external peer assessment of that organization’s level of performance in relation to the standards.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification</td>
<td>Formal recognition of compliance with set standards (e.g. ISO 9000 series for quality systems) validated by external evaluation by an authorized auditor.</td>
</tr>
</tbody>
</table>
| Licensure     | Process by which a government authority grants permission, usually following inspection against minimal statutory standards, to an individual practitioner or healthcare organization to operate or to engage in an occupation or profession. |}

Each of these systems is being adapted to meet the changing demands for public accountability, clinical effectiveness and improvement of quality and safety, but the most rapid development is in accreditation.
1.3 Links to WHO policy and publications

WHO has supported the development of accreditation at many levels, such as through:
Publications e.g. monographs on using standards in health care (1), and on measuring performance in hospitals (2) and in health systems (3,4),
Workshops and discussions e.g. on the impact of accreditation on health systems (5)
Commissioned research e.g. into accreditation and quality systems around the world (6)

Most recently, WHO endorsed the international ISQua toolkit for accreditation programmes, which was sponsored by the World Bank (7) and which underlined the ALPHA principles (8) and standards (9) for external assessment systems.

At regional level, accreditation has been supported through workshops and reports, such as Cyprus (10), Saudi Arabia (11), Myanmar (12) and Thailand (13). In the document by the WHO Regional Office for WHO/Europe (WHO/WHO/Europe) summarizing national quality policies in the Region, accreditation is identified as a key strategy in many countries.

1.4 Current trends in external assessment

Accreditation of health care, especially of hospitals, is spreading across WHO/Europe. The first regional programme started in Catalonia, Spain in the 1980s, and two independent national programmes began in the UK in 1990. Since the mid-1990s there has been a steady growth of programmes in the EU, as well as in the Balkan states and eastwards into the former Soviet republics. This growth of programmes is faster in WHO/Europe than in any other region of the world.

Many countries, inside and outside Europe, will be watching with interest to see how these new models of accreditation develop and what impact they have on hospitals. There is no set formula for how to start an accreditation programme, but the combined experience of many countries (described in the World Bank toolkit (7)) suggests that there are some general specifications on which programmes could be designed and evaluated (defined in the ISQua principles and standards).

1.5 Structure of this guide

The next chapters of this guide to accreditation outline some of the activities and steps, which lead to a sustainable programme. These steps are an amalgam of the discussions, activities and results of many countries; no one country has followed them all, and many have embarked on chapter 3 before chapter 2. The most painful experiences are in countries, which began with chapter 4 or 5.

The following stages therefore act only as a guide:

Chapter 2: Analysing the national context - take stock of values and mechanisms relating to quality and safety in health care; develop government policy framework for regulation and reform of the health care system
Chapter 3: Defining the guiding principles - choose a national strategy for accreditation; establish a working group to define and recommend options for adopting or adapting a model of accreditation; design and enable a national accreditation agency

Chapter 4: Establishing a national agency – authorize agency and terms of reference working group enables establishment and hands over to new agency

Chapter 5: Developing and launching accreditation systems - develop standards and assessment process, surveyor selection and training, pilot testing and education, revision of standards and methods; first “live” surveys, first accreditation decisions; performance measures; sustainability
II Analysing the national context

Take stock of values and mechanisms relating to quality and safety in health care; develop government policy framework for regulation and reform of the health care system

2.1 Make values and visions explicit

Identify the multiple dimensions of quality in health care, recognize the various customers and their values; acknowledge the differences.

Values: define the values of quality in health care provision (e.g. that services should be accessible, appropriate, capable, continuous, effective, efficient, responsive, safe and sustainable).

Aims: define key aims for quality improvement in the health care system (e.g. public accountability, protection of patients and staff, equity of service standards, promotion of patients’ rights, adoption of evidence-based clinical practice, reduction of waste and inefficiency, professional self-regulation – and improvement of performance of individuals, organizations and the overall health care system).

Stakeholders: define the principal stakeholders and their representative organizations that have a direct interest in purchasing, providing and consuming health services.

Quality culture: assess the social and organizational factors, which encourage or discourage people and organizations to change and to improve; in many countries, staff are working within an environment, which makes systematic improvement difficult for individuals, teams and organizations. Without clear policies, structures, methods and basic resources (e.g. clinical data and protected time) there can be no effective systems for internal self-regulation – a key requirement of accreditation standards worldwide.

2.2 Catalogue existing mechanisms, constraints and alternatives

Use the WHO self-assessment tool (14) as a framework for mapping the current position, identifying the options and restrictions, and comparing with other countries.

Mechanisms: define the scope and (actual or potential) contribution to quality improvement of existing national mechanisms (e.g. licensing of institutions, professionals, medical devices, pharmaceuticals; statutory certification of environmental safety including fire, radiation, toxic chemicals, hygiene; professional recognition of institutions suitable for the training of clinical personnel).

Legislation and related policies: identify existing policies and laws at local, national and international (e.g. WHO, European Union (EU)) level, which relate to quality and safety (e.g. employment law, public rights, medical laboratories, pharmaceuticals).
Alternatives: identify and review alternative additional mechanisms or institutions at national level for improving quality throughout the health care system (e.g. expanding statutory licensing, mandatory establishment and demonstration of internal quality systems, ISO certification of institutional quality systems, procuring accreditation services from established external programme, or developing a Jordanian national accreditation programme).

2.3. Draft a national quality policy

Use the WHO background document (14) to summarize the current position, to outline strategic objectives, to options and to consult with stakeholders.

The criteria and principles, which underlie four possible headings of such a policy, are given below.

2.3.1 Values and priorities for quality

Principle: The government’s values, vision and strategies for quality improvement are comprehensive, consistent and based on evidence and consultation with stakeholders.

They are explicitly stated and disseminated to the public, providers and purchasers. The policy is comprehensive, accessible and consistent with other policies and legislation. It identifies key roles and incentives for quality improvement.

2.3.2 Organization and institutionalisation of quality

Principle: There are effective mechanisms to integrate and implement the national policy within national and local government, and between all stakeholders and sectors of health care provision.

Coordination of quality improvement is clearly defined within the ministry of health; there are effective communications with other agencies e.g. health insurance, public health, finance, information and international.

Accountability and mechanisms for implementing quality improvement are defined throughout the health system.

Support structures, such as agencies, boards, committees and networks (including non-governmental organizations, patients’ complaints, training and research institutions, professional groups) are established, publicised and accessible nationally.

2.3.3 Methods, techniques and tools for development of quality

Principle: Effective methods for quality improvement are systematically promoted at national and local level, consistent with experience and scientific evidence. Adoption of demonstrated quality methods is recognized and rewarded in organizations and individuals.
Statutory mechanisms to ensure the safety of public, patients and staff are established and evaluated. Their regulations, standards, assessment processes and results are accessible to the public.

Voluntary external quality assessment and improvement programmes are recognized by and consistent with statutory investigation and inspection. Their standards, assessment processes and operations comply with international criteria.

There are formal mechanisms to define and protect the rights of patients and their families to health services.

Local quality programmes are systematically planned and co-ordinated to meet national priorities and the needs of local stakeholders. They use standards, measures and improvement techniques, which are explicit and known to be effective in that setting.

### 2.3.4 Resources for quality improvement

The national programme identifies responsibility for funding and providing the basic knowledge, skills and information required for quality improvement.

Personnel are trained to evaluate and improve the performance of their own work and of their health care organization.

Personnel have protected time to participate in formal, systematic quality improvement programmes.

Health facilities provide staff with accurate, complete and timely data by which clinical and organizational performance can be measured.

Authoritative information on the theory and practice of standards, measurements and improvement is accessible to all health personnel.

The direct financial costs of the quality programme are realistically identified in advance and allocated to agreed budgets, especially for training, research and information.

The selection of accreditation as the mainstay of or supplement to a national quality strategy should be based on a systematic analysis of the available options (by the government, by potential investors and by technical advisers). Several countries have set up a national programme without this preparation and have then found unexpected delays and conflicts later on, such as:

- Unclear scope and purpose of accreditation programme
- Gaps and overlaps of standards and regulatory mechanisms e.g. professional development and licensing; institutional regulation and inspection
- Conflicts between statutory control, accountability and self-regulation
- Fragmentation of health reform initiatives e.g. decentralisation of control, empowerment of managers; health care financing and performance management; development of primary care and preventive services
• Donor agencies and successor governments are not convinced that the decision to pursue accreditation was soundly based or worthy of further support
III Defining the guiding principles

Choose a national strategy for accreditation; establish a working group to define and recommend options for adopting or adapting a model of accreditation; design and enable a national accreditation agency

Once the decision is made to explore accreditation, many countries set up a working group or committee to research and design the principles of the programme, to define and establish a governance structure for the accreditation agency and then to monitor and evaluate its progress in development. This process may take from 3 to 5 years before the accreditation agency is formally launched; many countries have regretted starting too early with drafting and piloting standards without a process of political, professional and social preparation.

However the accreditation design is managed, it needs to address fundamental questions before detailed technical issues, in particular the ten points from the World Bank toolkit (7).

3.1 Values, aims and stakeholders

Clarify what accreditation is expected to achieve and for whom.

What should be the mission of the programme?
How would that relate in general to plans for health reform, and in particular to the national quality strategy?
Who should be the stakeholders, and how should they be involved?
Should the programme include private and public (civilian and military) hospitals?
Should it be voluntary or mandatory?
Should it aim at organizational development and self-regulation, or at central control?
Can the programme fulfil the government responsibility for regulation and public accountability?

3.2 Choosing the appropriate tools

Confirm that accreditation is appropriate and achievable in the national context

Is accreditation the best option for achieving the objectives?
What alternatives e.g. licensing, inspection, certification, have been considered?
What gaps or weaknesses in statutory systems would accreditation be expected to resolve?
If hospital budgets, human resources and planning are managed centrally, should accreditation be assessing the civil service rather than hospitals?

3.3 Developing a receptive environment

Anticipate potential conflicts and challenges; develop opportunities to reinforce and sustain the accreditation programme.
Do hospitals have the authority, structures and skills to regulate themselves e.g. medical staff structure, capacity to improve quality and performance, continuing education and in-service training?
Is government willing:
To lead quality improvement by example?
To make policies, procedures and decision criteria explicit and public?
To decentralize management to hospitals and delegate authority to staff?
To share data and information with providers, professions and public?
To support local initiatives with national action e.g. technical advice, training?
Are managers and professionals willing, trained and organized to accept responsibility for their own performance?

3.4 Offering incentives

Provide positive incentives for hospitals to participate voluntarily.

Why would hospitals want to join an accreditation programme voluntarily?
Is personal and institutional funding based on historical expenditure or on demonstrated performance?
What market advantage would an accredited hospital gain?
Should accreditation be a requirement for all teaching and training hospitals?
Would improved risk management reduce liability to litigation and compensation?
Would an accredited hospital be exempted from statutory relicensing?
How are innovation and improvement in staff and hospitals recognized, documented and rewarded?
Are managers allowed financial discretion e.g. deciding where to re-allocate efficiency savings?

3.5 Defining relationship to government

Review the advantages and disadvantages of a governmental programme; identify legal, ethical and social constraints and opportunities for establishing an independent but accountable governing body for the accreditation programme.

Would the government be able and willing to accept an independent accreditation agency (the Agency)?
Could a governing body be established which is representative of the principal stakeholders but is dominated by none of them?
Would enabling legislation be needed to authorize the activity of the programme?

3.6 Scope of responsibilities

Define what will and will not be the responsibilities of the accreditation programme.
The Agency should become the principal national centre for the definition, measurement and improvement of standards of service management; to what extent should it also be responsible for:

Resource centre for quality improvement standards, methods and experience.
Training in quality improvement.
Research into clinical practice guidelines, health technology assessment and evidence-based medicine.
Collection, analysis, comparison, publication and active feedback of data on performance of providers (e.g. quality, quantity, cost and value for money)?
Licensing (organizational or individual), specialty certification.
Patients’ rights and complaints management.
If the accreditation programme does not take these on, who does?
If the programme focuses initially on public hospitals, how could it be extended later to other sectors, particularly to polyclinics and primary care?

3.7 Defining relationship to other agencies

Define communications and relationships with other departments and agencies to harmonize the setting and assessment of health care standards, to avoid waste and conflict between systems, and to minimise the “burden of inspection” on health care organizations.

Should a new programme seek to integrate and build upon existing systems of standards and inspections, or merely add a comprehensive but separate layer?
Could the procedures for exchange of information between organizations (public and private) be improved to support existing assessment bodies, and the accreditation programme?
How would the standards and assessments of the accreditation agency integrate with:

- Regulatory inspectorates and other external agencies e.g. fire, radiation, medical devices, safety, hygiene, health data collection agencies and independent assessors e.g. laboratory external quality assurance programmes.
- Public health institutes e.g. sharing data on population health and on the performance of providers and the health care delivery system.
- Consumer groups e.g. as a means of making health services more transparent and accessible to the public.
- Professional institutes e.g. development of clinical standards and practice through medical academies and professional chambers.
- Health Insurance Funds e.g. offering financial levers to encourage improved quality, such as could be demonstrated by the achievement of accreditation?
How could training in quality and performance management be shared with other agencies?
Table 1: Mapping responsibilities for quality training

| Universities and authorized training centres for clinicians should systematically analyse basic training with respect to the knowledge attitudes and skills, which will be required to implement a national quality programme and sustain hospital accreditation. They should ask to what extent the existing arrangements for curriculum, teaching and examinations fulfil the quality agenda. Professional chambers and specialty training programmes should similarly analyse current and potential future opportunities to ensure that trainees are equipped to apply general quality principles to specialist practice. Responsibility should be identified among universities and other institutions for coordinating the development of intramural and extramural programmes for continuing professional development, including continuing medical education (CME). The Agency, together with academic coordinators, should identify the special needs of key staff groups for continuing training and career development, including quality/risk managers, internal and external auditors, health inspectors, Agency staff, developers of practice guidelines and trainers in the field of health care quality. |

3.8 Ensuring transparency and objectivity

*Develop a fair transparent and valid system in which the public, professions and hospitals can trust.*

Would the members of the governing body effectively represent the stakeholders? Would the sole criterion for the award of accreditation be compliance with the standards? Would the governance, standards, assessment processes and criteria for accreditation awards be made publicly available? How much of the survey reports on individual hospitals should be made public? What principles should the Agency follow to ensure valid and reliable assessment and evaluation? Would the international ALPHA principles and standards be adopted for the design and operation of the programme?

3.9 Planning for a sustainable programme

*Make realistic projections of the time, human resources and money required; identify potential sources of funding for the development and operational phases.*

What are the likely infrastructure, research and development costs in the first three years? Could these be linked to an existing programme of health reform? Who might fund the development costs? In which year would development funding begin to taper off? How soon would the programme generate partial or full funding? How many hospitals would be expected to participate in the first, second and third year of full operation? What would be the expected costs of operating the programme divided by the number of hospitals surveyed during each year? Would these costs be expected to be covered by product sales (e.g. user fees charged to hospitals, publications, training), by subsidy from health insurance funds, by direct government grant, or by a combination of sources?
Who will buy accreditation services – hospital managers, insurers or ministries? Who will therefore own the survey reports?

Reliable data on time and money spent on developing accreditation in different countries are not available for comparison. But figures from Zambia suggest it took four years and US$787,000 to get 12 of the total 79 hospitals through a full accreditation cycle to the point of accreditation decisions (15). The costs per full cycle ($10,000 per hospital) included start up costs and were projected to reduce to $7000 if the programme reached a steady state.

This figure is consistent with the experience of many other countries. Excluding North America, and programmes less than 3 years old (when unit costs are inevitably high), the expenditure per survey in 1999 ranged from $3000 per hospital in Argentina to $34,000 in the UK (6). Much of this difference may be attributed to differences in staffing costs and level of services provided to hospitals, but the mid-range is $9-12,000 per hospital. The figures only include the costs to the accreditation programme (including on-going development costs), not the internal costs to the hospitals of preparation and staff time.

<table>
<thead>
<tr>
<th>Year first survey</th>
<th>Expenditure 1999, $thousand</th>
<th>Number of surveys 1999</th>
<th>Expenditure per survey $thousand 1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (ACHS)</td>
<td>1974</td>
<td>2750</td>
<td>272</td>
</tr>
<tr>
<td>New Zealand</td>
<td>1989</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>UK (HAP)*</td>
<td>1990</td>
<td>225</td>
<td>19</td>
</tr>
<tr>
<td>UK (HQS)*</td>
<td>1990</td>
<td>2945</td>
<td>86</td>
</tr>
<tr>
<td>Switzerland*</td>
<td>1998</td>
<td>135</td>
<td>15</td>
</tr>
<tr>
<td>South Africa</td>
<td>1994</td>
<td>539</td>
<td>92</td>
</tr>
<tr>
<td>Argentina*</td>
<td>1996</td>
<td>60</td>
<td>22</td>
</tr>
<tr>
<td>Japan**</td>
<td>1997</td>
<td>2600</td>
<td>189</td>
</tr>
</tbody>
</table>

Most countries take at least two years to the first pilot survey and would need much longer to build sufficient capacity to survey and reach accreditation decisions on the majority of hospitals in the country. This also depends on the rate of uptake: to reach accreditation decisions on the first 10% of eligible hospitals took 2 years in Zambia, 3 years in The Netherlands and 5 years in France (16).

### 3.10 Finding technical assistance

*Download and refer to the World Bank toolkit and the ISQua principles and standards; take stock of the existing national policies, personnel, skills and structures that could contribute to the development of accreditation; then identify where specialist technical advice is needed, and where it may be found.*

What are the existing internal skills and experience (including the private sector) which could support the national accreditation programme e.g. quality “champions”, academics and trained quality coordinators?
On what general issues is external technical assistance required e.g. for option appraisal, policy development, programme design, training, evaluation?
What short-term support (e.g. for situation analysis, option appraisal, consultancy contracting) could be obtained e.g. from neighbouring countries, current health reform programmes, WHO?
What long-term support is needed (e.g. for training, development of standards, assessment processes and internal management)?
On what criteria should consultant advice be selected (see table below)?

**Table 3: Some criteria for consultant selection**

<table>
<thead>
<tr>
<th>Consultants should have following experience and qualifications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Proven track of record in field of accreditation and quality improvement in the health sector</td>
</tr>
<tr>
<td>• Experience in implementation of national health care accreditation programmes, including the development of criteria for accreditation programmes, and advising accreditation programmes on requirements</td>
</tr>
<tr>
<td>• Evidence of technical qualifications in the underlying disciplines of medicine, health care quality improvement, health care accreditation and health service management.</td>
</tr>
<tr>
<td>• In particular:</td>
</tr>
<tr>
<td>o Implementation of strategic and business plans for accreditation bodies</td>
</tr>
<tr>
<td>o Implementation of training programmes for quality improvement through undergraduate, specialty and continuing education</td>
</tr>
<tr>
<td>o Developing clinical and organizational standards and monitoring of clinical practice guidelines development, including the knowledge of its dissemination and monitoring use</td>
</tr>
</tbody>
</table>

Developing clinical and organizational performance indicators
IV. Establishing a national agency

From this point, at which a country has decided what accreditation is expected to achieve and how it would fit into the future healthcare system, the steering committee establishes and hands over to new Agency. Expert external technical assistance, if not already involved, should be sought. The next step is to establish an organization (referred to here as the Agency).

From here the ISQua ALPHA standards offer guidance on how to implement a programme, particularly:

STANDARD 1: GOVERNANCE AND STRATEGIC DIRECTIONS
The external evaluation body is effectively governed to meet its mission, strategic direction and objectives, with a set of values underpinning all its activities.

STANDARD 2: ORGANIZATION AND MANAGEMENT PERFORMANCE
The external evaluation body has in place clear management arrangements and operational systems to effectively deliver strategies, goals and objectives, to manage performance, and to continuously improve the services provided to its clients.

4.1 Legislation

Draft and ratify enabling legislation, if necessary.

One third of 34 programmes responding to the WHO survey in 2000 were enabled by legislation, and most of these began in the late 1990s. Some countries have made participation by hospitals legally compulsory, but most merely authorize the functions of the accreditation agency, such as by authorising the Agency to set and recognize the standards against which hospitals would be granted or refused accreditation; these standards would not be set by government and would not be written into the law. But some governments have chosen to embed organizational standards into legal instruments which them difficult to update frequently enough to keep pace with the advancement of science.

4.2 Governance of the Agency

Draft the constitution of the governing body; oversee initial appointments.

The first standard requires the Agency, which runs the programme to be governed by a formally organized body:

- The Agency is a legal entity (e.g. a non-governmental organization), or part of one (e.g. a division of the ministry);
- The governing body has a written constitution or articles of association;
- Members of the governing body:
  - are chosen to provide a balance of interests, with no single interest predominating, in order to ensure impartiality;
  - are required to declare their interests in matters relating to both policy and external evaluation decisions in order to avoid conflict of interest;
have their authority and duties clearly defined and documented in a position description;
are oriented through a planned induction programme to ensure they understand their responsibilities and duties.

4.3 Management of the Agency

*Establish policies, procedures, planning, staffing and facilities to fulfil the agreed responsibilities of the Agency.*

Building on the principles set out by the steering committee, the Agency must set up a functioning organization, including:

- Strategic plan to define the mission and long-term objectives of the accreditation programme.
- Business Plan to define activities, costs and milestones of the development phase and transition towards financial self-sufficiency.
- Projections of long-term operating costs, sales and income from various sources (see Table 4 below).
- Operational programme for developing accreditation standards and clinical practice guidelines.
- Administrative policies and procedures e.g. committee functions, financial procedures, procurement and employment policies.
- Information system e.g. to collect, aggregate and compare data over time within and between participating organizations, standards and surveyors, such as compliance profiles of individual standards, profiles of participating facilities, aggregated results for comparison in time, function and place, and measures of the overall impact of the programme.

<table>
<thead>
<tr>
<th>Table 4: Factors in the cost of accreditation surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>Although the number of health care organizations in the country may be a key determinant of programme costs, it is the policy decisions about the configuration, development and operation of the programme, which have greater impact. In general, the more institutions that are covered by the programme, the cheaper are the unit costs. Other key factors are:</td>
</tr>
<tr>
<td>Programme configuration</td>
</tr>
<tr>
<td>Single national programme, or multiple sub-national ones</td>
</tr>
<tr>
<td>Limited priority focus e.g. hospitals, policlincs or entire health system</td>
</tr>
<tr>
<td>To supplement or to replace existing external assessments</td>
</tr>
<tr>
<td>To inspect and regulate, or to teach and develop</td>
</tr>
<tr>
<td>Development</td>
</tr>
<tr>
<td>Standards off the peg or made to measure</td>
</tr>
<tr>
<td>Thoroughness of system design and testing</td>
</tr>
<tr>
<td>Cost of specialist expertise</td>
</tr>
<tr>
<td>Operation</td>
</tr>
<tr>
<td>Surveyor payment, workload, wastage</td>
</tr>
<tr>
<td>Length and depth of surveys</td>
</tr>
<tr>
<td>Length of survey cycle</td>
</tr>
<tr>
<td>Efficiency of scheduling, transport, survey logistics etc</td>
</tr>
<tr>
<td>Investment in communications, publicity, information</td>
</tr>
<tr>
<td>Efficiency of report handling, accreditation adjudication</td>
</tr>
</tbody>
</table>
V Developing the accreditation system

Develop standards and assessment process, surveyor selection and training, pilot testing and education, revision of standards and methods.

At this stage it is useful to set up a number of working groups to develop standards and procedures in detail. All of these have already been defined in other countries and many of them are in the public domain, but local working groups are important:

- to review and modify external examples to local laws, organization and expectations;
- to demonstrate a commitment to consultation, transparency and inclusion;
- to harness the enthusiasm of potential quality leaders;
- to identify and involve pilot hospitals in developing and testing standards;
- to develop a cadre of informed representatives;
- to identify people who would be able and willing assessors.

5.1 Standards development

Here the best guidance is in the ISQua Principles, which describe key steps in the design, drafting, consultation, testing, authorisation and revision of the standards and criteria, which will be used by the Agency for assessing hospitals. Using these, the Agency should define its own principles for developing standards e.g.

- to map the scope of the hospital standards and define the boundaries;
- to adopt a patient-focused (horizontal) or management-focused (vertical) structure of chapters (see guidance on structure below);
- to exclude standards which are not relevant, understandable, measurable and achievable (see guidance on selection below);
- to introduce each group of standards with an overarching principle or statement of intent
- to follow each standard with criteria or measurable elements;
- to integrate or to separate the standards, the criteria, the self-assessment, the external assessment and the report format.

5.1.1 Guidance on structure of accreditation standards

Chapters
The outline structure might reflect a hierarchy of chapters, sections, headings, principles, standards and criteria. A “vertical” structure may include:

- Corporate and clinical management
- General management
- Hospital facilities
- Professional clinical services
- Specialist patient services
- Support services
- Sections
Each chapter may contain a number of sections, which cover related elements of the hospital. These are often assigned to a specified manager, such as under support services:

- Catering
- Housekeeping
- Estates department
- Laundry
- Mortuary
- Sterile supplies
- Voluntary services
- Transport services.

- **Headings**
  Each section needs an internal structure, such as:
  - Scope and management
  - Policies and procedures
  - Facilities and equipment
  - Human resources
  - Evaluation and quality improvement.

- **Principles**
  Each heading may have one or more principles, which describe the values and overall intention of the standards, which follow. These principles are generally consistent with quality policies internationally and tend to be similar in many countries.

- **Standards**
  These describe key elements of a hospital function, which should contribute to fulfilling the intent of the principal.

- **Criteria**
  These “measurable elements” are the points, which can be observed by an assessor and used as objective measure of whether the hospital complies with the standards. Many of these may not be transferable to hospitals in another country, state or health system.

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**5.1.2 Guidance on selection**

Principles and standards need to be:
- Relevant to hospitals nationally;
- Understandable by staff and by assessors (internal or external);
- Behavioural, referring to what people do and how activity is organized;
- Achievable now or within the near future.

Criteria, by definition, must also be measurable (giving the acronym RUMBA); any assessor should be able to test the criterion by direct observation, by interviewing staff or by reading documented evidence. “Documented evidence” might include inspection of Standard Operating Procedures (SOPs), which give detailed specifications for routine work, but compliance with SOPs is not directly audited by assessors; having written SOPs does not itself prove compliance with standards – assessors must also find evidence that they are disseminated, understood, applied and effective.

For the purpose of developing a first draft manual of standards, these guidelines should be applied first to the principles, then to the standards and finally to the criteria.

The Agency should:
• Review available options for adapting existing international standards
• Define and publish the process and timetable for the development of standards, consultation, testing, and evaluation
• Develop a policy and procedures for reviewing and updating standards, weightings, ratings/scoring and supporting guidance

Table 5: countries can draw on a variety of sources of standards
Consensus e.g. between professions, stakeholders, and districts on “best practice” is a basic but legitimate source
Normative targets of process and outcome e.g. immunisation rates, population health
Legislation, government directives, and professional guidance
Aggregation of empirical descriptions of how organizations operate and what they achieve e.g. benchmarking performance
Accreditation standards of other countries
Qualitative studies and randomised controlled trials (RCTs) of clinical interventions and pathways

5.2 Surveyors

The effective recruitment, selection, development, deployment and performance management of surveyors assist the Agency to deliver a high quality service to its clients in accordance with its scope and operational processes. Standard 4.

This requires several policies, documents and activities to ensure that surveyors are trained and retrained to minimise inter-observer variation and that survey teams are selected to avoid personal conflicts of interest:

Recruitment criteria: role specification and a defined set of competencies for surveyors, to ensure that the most appropriate people are selected and trained; assessment and selection process.

Review criteria: policy and procedure for reviewing surveyors continuation every 3 to 4 years, to ensure that they are undertaking sufficient surveys and maintaining skills, knowledge and experience; policy and procedure to deal with the suspension or dismissal of surveyors who consistently fail to meet the required standards or who through their actions bring the Agency into disrepute.

Training: development of a training programme to introduce surveyors to the standards and annual re-training to reinforce best practice and to introduce new procedures; a surveyor manual for the training programme and for use as a reference document when preparing for or taking part in a survey.

Evaluation and feedback: development of an evaluation tool to provide surveyors with feedback on their performance during surveys and help them to identify opportunities for improvement.

5.3 Assessment procedures

The preparation of clients for survey, the survey, and the follow-up meet the needs of clients, facilitate objective and consistent decision-making, and are delivered in accordance with
documented policies and procedures which have been communicated to and are understood by clients. Standard 7.

Unlike statutory licensing which centres almost exclusively on site inspection, accreditation emphasizes preparation through self-assessment, and independent validation and adjudication, as well as the survey report itself. Before any of these begin, most agencies draw up a written contract with the hospital to define obligations on both sides, and many also require part-payment in advance.

Pre-survey assessment: hospitals will need to have the standards, self-assessment tool and guidance notes – as well as time (up to one year) to prepare. The Agency will also need each hospital to submit basic data (e.g. number of beds, staff, specialties, locations) in order to match the size and composition of the visiting team and the length of survey to the complexity of the hospital. This requires the Agency to define general policies and procedures for determining the size and skill mix of the survey team and in which circumstances surveyors should not be selected to avoid potential conflicts of interest.

On-site survey: hospitals and surveyors appreciate clear arrangements in advance concerning, for example, team leadership, logistics, scheduling, listing and location of required documents, access to staff, patients, records and secure areas. Information is gathered by interview, observation and access to documents in order to validate the internal self-assessment (noting and explaining any discrepancies which may be found). Hospitals should be encouraged to rate their experience of the standards, the survey process and the survey team. All these procedures need to be written down, formally authorized and available to all concerned.

Report management and validation: the Agency must define systems to ensure that reports are written promptly and comply with defined rules to avoid judgments which are subjective, unsubstantiated, internally inconsistent or irrelevant to the published standards and criteria. Survey reports may be validated through internal administrative checking and through confirmation of drafts by the hospital concerned. These procedures must be documented in general, and recorded when followed for individual reports.

5.4 Accreditation process

The external evaluation body maintains a system for the determination, awarding and maintenance of accreditation or certification that ensures the integrity of the processes. Standard 8.

The main aim here is to be able to design, operate and document a system, which ensures fair and reliable assessment of a hospital’s compliance with standards (see). All decisions must be based on traceable evidence and follow the published procedures without political, professional, commercial or other bias. Individual surveyors or programme staff should not make final decisions on accreditation awards.

The difficulty lies in deciding several principles:
- Should accreditation be awarded for demonstrated improvement, or for having reached a set level of compliance with standards?
Should the “set level” be the same for small public hospitals as for academic centres and private hospitals?
Which standards mark the “bottom line”?
How is compliance measured?
What proportion of hospitals should fail?

If, for example, all public hospitals might “fail” for non-compliance with a specific requirement for radiation protection which was systematically left out of the X-ray departments when they were designed and constructed by the ministry of health:

Should the standard have been approved in the first place?
Should compliance with the standard be regarded as essential?
Should the threshold for “compliance” be lowered to allow hospitals to be accredited?
Should the hospital be penalised for failures, which are beyond its control?
Should the Ministry close down a service which has been declared unsafe?

One practical solution is to adopt empirical criteria; avoid setting any “essential” criteria, weightings or threshold values until the standards, assessments, surveyors, reporting and the accreditation decision committee have been tested in at least a dozen hospitals. Thereafter, some programmes have developed sophisticated systems of criterion weighting and compliance scoring in order to provide a mathematical solution; some only use these decision criteria in the event of close calls.

These systems are not usually available to hospitals or even to the surveyors in case they encourage “gaming”.

Table 6: other ways of checking objectivity and reliability
Surveyors are selected, trained and evaluated against explicit published criteria.
Survey teams are tailored to each individual hospital, according to published criteria, to avoid any conflict of interest.
The survey team reports initial findings back to hospital management before leaving the site, especially any observations which are likely to generate recommendations for improvement, in order to check for accuracy and to ensure there are no surprises later.
Team reports are prepared and agreed jointly and in compliance with procedures, which are often defined in the surveyors’ handbook.
Team reports are independently checked within the agency for content, consistency and compliance with procedures.
Final draft reports are referred to the client hospital for verification before accreditation decision.
Accreditation awards are made by an independent panel, based on the team’s report, not by the surveyors themselves.

However an individual programme chooses to move, it will be necessary to design and publish procedures for contracting, facilitation, assessment, reporting and accreditation decisions which promote confidence and avoid improper influence by any individuals or factions, including:
The basis for awarding accreditation.
The grades or duration of awards.
Requirements for follow-up and reporting.
Policy, procedure and rules for dealing with appeals.
Circumstances under which accreditation awards may be withdrawn or suspended.
5.5 Training programmes

Many countries choose to introduce accreditation as a vehicle for quality management at national and at local level. In this case, there are unlikely to be enough teachers and courses already available, so the accreditation programme takes on the role of teaching not only about accreditation, but also about internal quality systems e.g.:

- Induction and development of core staff.
- Orientation of members of the governing council or board.
- Initial and continuing training of surveyors.
- General preparation of participating institutions and their staff.
- Specific methods of internal quality improvement required to meet accreditation standards, such as infection control, risk management, performance measurement, patient surveys.

The Agency thus has to develop a core curriculum, teaching materials and skills in many directions including:

- Training for hospital accreditation.
  The Agency should identify the additional training needs of personnel in relevant organizations, and options for meeting these needs:
    - By consulting with the ministry on the adaptation and teaching of inspection standards and procedures, to be consist with the accreditation programme.
    - By offering training to selected staff of Health Insurance Funds, Public Health Institutes on standardisation of minimum data sets, data quality, performance indicators.
- Training for members of professional chambers: assessment of competences, credentialing, clinical practice, licensing of practitioners.
- Providing management and technical training for quality to local coordinators, leaders, and teachers.
- Training in standards development: research, evidence, structure, implementation and review of clinical and organizational standards.
- Training for internal quality systems.

The Agency should provide assistance to hospitals in developing their own policy, organizational structures and methods of quality improvement, in particular:

- Development of organizational and clinical standards.
- Arrangements for dissemination, application and monitoring of the use of clinical practice guidelines.
- Identifying relevant existing information and advising on systems requirements to provide numerical measures of clinical and organizational performance.

5.6 Information centre

The Agency will need to become the main national focus for information on standards and assessment of quality and safety in health care in hospitals. This function is likely to extend, if there is no other provider, into information on all aspects of quality, both clinical and managerial, in all sectors of the health care system. Given the common state of hospital libraries in many countries (non-existent, vandalised, unfunded or obsolete), it is not surprising that people turn to the Internet (if they can) or to a national reference centre (if there is one) for advice on many of the issues which are highlighted by hospital accreditation but are primarily
about hospital management, such as: clinical effectiveness, cost/usage/waste, risk/safety, patients' rights, accessibility, management, organization, information/data, operating policies, personnel management, equipment management, environmental control.

The Agency must decide whether it has resources or responsibility for managing an external reference library, whether all its documents will be in the public domain and whether they would be free of charge. But, at least the Agency should establish and maintain a resource including:

- Guidance documents developed by Agency.
- Accreditation standards.
- Surveyors’ manual.
- Hospital guidance and preparation manual.
- Management guidance on implementing quality systems.
- Technical manual on the principles and practice of quality management.
- Guidance and teaching materials on effective methods for quality improvement.

**External documents**

- Key international texts on quality and safety
- Bibliography of quality in health care
- Examples of hospitals’ operational policies and procedures

**Data**

- Links to national and international networks to source data and information relevant to standards
- Data routinely collected by participating hospitals and development of a plan for utilising the data to measure performance, provide comparisons, benchmarking and trend analysis
VI Conclusions

6.1 Putting the programme into action

No matter how much research, preparation and technical assistance goes into designing the system, the first time the individual elements are put together and tested in real hospitals is a great lesson for everyone concerned. It is vital for the Agency to get immediate feedback from, and to provide immediate support to surveyors and to hospitals.

One way to ensure this communication is to attach a staff member to each preparing hospital and to each survey team as a facilitator who helps the hospital with project management, interpretation of standards, drafting of procedures, collection of data, and helps the surveyors with logistics, coordination, documents and report writing. These facilitators rapidly learn the common problems and solutions in the field, and soon become the experts who recommend changes in the standards, criteria, assessment, surveyor training, report writing and so forth. But the Agency must decide from the beginning whether facilitators will become a permanent feature (and cost) of the accreditation programme, or whether they should be withdrawn at the end of the pilot surveys.

Some people recommend taking a sample of ten percent of all eligible hospitals as pilot sites; others would say a “reasonable” number like 12 – 15, depending on the total number and the resources (time and money) available for the pilot phase. If there is reason to think that many hospitals are unable to meet certain key standards, or that there are wide gaps between the rich and poor, the private and public or the North and South, then the pilot sites cannot be limited to the self-selected enthusiasts who have already had the advantage of helping to develop the standards. It is important to know what an average hospital is and how relevant and achievable are the standards in that setting.

Whether hospital volunteer or are “chosen” as pilot sites, it is important to emphasize – especially to ministers and funding agencies who tend to be impatient for results – that these early assessments are testing the standards, procedures and surveyors rather than the performance of the hospitals. Premature interpretation of pilot test results will almost certainly be unfair to hospitals, lead to misleading comparisons, undermine trust in the system and discourage any further voluntary participation.

Piloting and consequent revisions to documents and procedures is likely to occupy twelve months.

6.2 Key messages and cautions

Not all accreditation programmes survive; pilot schemes in several countries had expert technical assistance but never became embedded in the national health system. Any country contemplating a new programme should research the global experience. Much of this is gathered into the Toolkit for Healthcare Accreditation (7), which identified ten factors that may compromise new programmes.
1. Clarity of purpose: failure to balance organizational development with regulatory control.
2. Appropriate technology: confusion of accreditation and licensing.
3. Quality culture: unwillingness to share information, authority and responsibility with stakeholders.
5. Independence: government domination of programme direction, leading to conflict of interest in assessment of public services.
6. Scope of responsibility: unrealistic expectations that the accreditation programme would resolve issues for which it was not designed.
7. Clear relationships: lack of mechanisms to cooperate and communicate with related professional, academic, independent and governmental bodies.
8. Objectivity and probity: lack of defined and transparent procedures for the assessment of facilities and decisions on accreditation awards.
9. Sustainable resourcing: underestimation or under funding of the time, personnel and skills needed to establish a new programme.
10. External technical assistance: failure to learn from the experience of accreditation in other countries.

6.3 Perspectives on accreditation in Europe

Currently there is wide variation between European states in the governance, standards and assessment methods applied both to regulatory and to developmental processes in health care. Each state has a responsibility for stewardship of its own health system, and for adopting mechanisms, which are based on evidence of what is most likely to be effective in achieving explicit objectives in that environment. Individual states have their own particular circumstances, which will moderate which methods of regulation or quality improvement to adopt, but there are general principles which are based on global experience and which are universally relevant – in much the same way as evidence-based clinical guidelines are relevant to individual patients.

If independent accreditation programmes are to survive, they must adapt to the needs not only of stakeholders (public, providers, professions and purchasers) but also of regulators. In London, the Cabinet Office recognized that provider institutions suffer a “burden of inspection” from regulatory, professional and independent agencies; if these systems could be more standardised there would be less duplication and disruption for providers, and if they shared information with the regulators there would be less need for inspection. The new United Kingdom (UK) watchdog, the Healthcare Commission, is developing a “concordat” between regulators (and some independent programmes) to define common methods, exchange information and reduce overlap; the ALPHA standards could provide a basis for that harmonization between UK assessors, and the Commission may itself volunteer to be externally assessed against those international standards.

Similar pressures for harmonization within countries apply also between countries, especially in the European Union. The mobility of patients and trained staff, cross-border purchasing, freedom of trade, protection of public safety and patients’ rights within the Union imply the need for a common approach to the definition, assessment and improvement of standards in health care.
This overrides the principles of subsidiarity but could be approached by voluntary standardisation between agencies in member and accession states.

Increasingly, inspection, accreditation and peer review are converging into a network of standards-based assessment for public and professional accountability; any further surveys should not be confined to traditional labels and borders, but aim to map and support the wealth of such mechanisms across Europe.
References

Annex 1: National self-assessment questionnaire

1 Policy: The government’s values, vision and strategies for quality improvement are comprehensive, consistent and based on evidence and consultation. They are explicitly stated and disseminated to purchasers, providers and the public.

<table>
<thead>
<tr>
<th>The policy is explicit and accessible</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>is formally published</td>
<td></td>
<td></td>
</tr>
<tr>
<td>is systematically disseminated to providers, purchasers, public</td>
<td></td>
<td></td>
</tr>
<tr>
<td>is accessible free of charge</td>
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</table>

<table>
<thead>
<tr>
<th>The policy is consistent</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>with existing and proposed legislation which it identifies</td>
<td></td>
<td></td>
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<tr>
<td>with public health policy and priorities</td>
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<td></td>
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<tr>
<td>with WHO Health for All policy</td>
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</table>

<table>
<thead>
<tr>
<th>The policy is comprehensive</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>defines the scope of quality (e.g. technical, social, economic) and factors which affect it</td>
<td></td>
<td></td>
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<tr>
<td>identifies and reflects the differing viewpoints of stakeholders</td>
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<td></td>
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<tr>
<td>actively involves consumers in defining and assessing quality</td>
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<td></td>
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<tr>
<td>relates to independent, voluntary and social care, as well as the public sector</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>The policy identifies key roles in quality improvement</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>commits Government to lead quality improvement by example and to ensure that quality remains visible on every management agenda</td>
<td></td>
<td></td>
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<tr>
<td>identifies the responsibilities and accountabilities of public, private and professional bodies (e.g. for training, monitoring)</td>
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</table>

<table>
<thead>
<tr>
<th>The policy identifies incentives for quality</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>requires evidence of quality improvement systems as a condition for funding contracts with practitioners, hospitals and health care organizations</td>
<td></td>
<td></td>
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<tr>
<td>identifies incentives to motivate staff to participate in quality improvement</td>
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</tr>
</tbody>
</table>

2 Organization: There are effective mechanisms to integrate and implement the national policy within national and local government, and between all stakeholders and sectors of health care provision

<table>
<thead>
<tr>
<th>2.1 Coordination of quality improvement is clearly defined within the Ministry of Health</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>there is an identified quality unit and a named accountable officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>an organizational chart identifies sections within the ministry which contribute to quality improvement, and shows relationships between them</td>
<td></td>
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<tr>
<td>a published annual report identifies quality activities and quantified improvements in performance of the health care system</td>
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</table>

<table>
<thead>
<tr>
<th>2.2 Accountability and mechanisms for implementing quality improvement are defined throughout the health care system</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>quality improvement is explicitly incorporated into national health programmes</td>
<td></td>
<td></td>
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<tr>
<td>implementation of national guidance (e.g. reports, enquiries and ministry/health department advice) is systematically followed up through performance management or independent review in primary, secondary and tertiary services</td>
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<tr>
<td>there is designated leadership, accountability, supervision, monitoring and communication of quality at</td>
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</table>
sub district, district, regional and national levels
quality management structures and mechanisms are integrated within each provider and commissioning organization (e.g. clinical governance, clinical, patient and public satisfaction, audit, performance measurement, risk management)
accountability for the quality of clinical practice is clearly defined within each provider organization

2.3 Support structures, such as agencies, boards, committees and networks (including non-governmental organizations, teaching and research institutions and professional groups) are established, publicized and accessible nationally
- there is a national quality policy group representing consumers, providers, insurers, and professions
- there is a national resource centre for technology assessment
- the dissemination of clinical standards is co-ordinated nationally to avoid duplication and to ensure they are coherent, affordable and cost-effective
- there is a resource centre for collecting and developing clinical practice guidelines
- there is a national society for quality in health care
- there is a national resource centre for quality improvement
- there is a national resource centre for technology assessment
- there is a national resource centre for the collation and dissemination of comprehensive comparative information on health system performance
- there are active quality improvement structures identified within each self-regulating clinical profession and specialty
- there is a national information and resource centre for quality improvement
- there is a national information and resource centre for patient and public satisfaction with health care

3 Methodology: Effective methods for quality improvement are systematically promoted at national and local level, consistent with experience and scientific evidence. Adoption of demonstrated quality methods is recognized and rewarded in organizations and individuals

<table>
<thead>
<tr>
<th>3.1 Statutory mechanisms to ensure the safety of public, patients and staff are established and evaluated. Their regulations, standards, assessment processes and results are accessible to the public.</th>
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<tbody>
<tr>
<td>Licensing of public health care facilities</td>
</tr>
<tr>
<td>licensing of private health care facilities</td>
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<tr>
<td>licensing of doctors, dentists, nurses and allied practitioners</td>
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<tr>
<td>periodic re-licensing of facilities</td>
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<tr>
<td>periodic re-licensing of practitioners</td>
</tr>
<tr>
<td>certification of radiation safety</td>
</tr>
<tr>
<td>certification of fire safety</td>
</tr>
<tr>
<td>certification of environmental and occupational safety</td>
</tr>
<tr>
<td>licensing of medical equipment and drugs</td>
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<tr>
<th>3.2 Voluntary external quality assessment and improvement programmes are recognized by and consistent with statutory investigation and inspection. Their standards, assessment processes and operations comply with international criteria.</th>
</tr>
</thead>
<tbody>
<tr>
<td>there is a formal mechanism by which voluntary and statutory programmes collaborate towards convergence of standards, assessment, quality improvement and public accountability</td>
</tr>
<tr>
<td>the uptake of ISO certification and EFQM assessment in health care, regulated by their formal national bodies, is actively monitored and supported</td>
</tr>
<tr>
<td>accreditation programmes are supported in primary, secondary and tertiary care</td>
</tr>
<tr>
<td>accreditation programmes meet international ALPHA standards</td>
</tr>
<tr>
<td>there is a national external quality assurance system for clinical laboratories</td>
</tr>
<tr>
<td>there are systematic, confidential national enquiries into the occurrence of adverse events and outcomes in health care</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>3.3 There are formal mechanisms to define and protect the rights of patients and their families to health services</th>
</tr>
</thead>
<tbody>
<tr>
<td>patients’ rights to high quality health care are explicitly stated, widely disseminated, and in the language of ethnic minorities</td>
</tr>
<tr>
<td>the results of national sample surveys of patient experience and satisfaction with health care have been</td>
</tr>
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</table>
made public

there is a well-publicized national programme for receiving and analysing complaints about health services

3.4 Local quality programmes are systematically planned and co-ordinated to meet national priorities and the needs of local stakeholders. They use standards, measures and improvement techniques, which are explicit and known to be effective in that setting.

Population access and system responsiveness to community needs
Consumers’, users’ and clients’ views and experience
Staff welfare, morale, development
Staff competence, knowledge, attitudes, skills, accountability
Clinical practice, guidelines, care pathways
Service delivery, co-ordination, continuity, management
Risk, health and safety
Resource management, efficiency, cost-benefit, rationing
Communications, records, information

4 Resources: The national programme identifies responsibility for funding and providing the basic knowledge, skills and information required for quality improvement

<table>
<thead>
<tr>
<th>Personnel are trained to evaluate and improve the performance of their own work and of their health care organization</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>relevant techniques of quality improvement are incorporated in the curriculum, teaching and examination of all clinical undergraduates</td>
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<tr>
<td>performance analysis and improvement are included in the continuing professional development programme provided by all health facilities</td>
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<tr>
<td>professional colleges, academic centres and research institutions have an agreed and specified role in supporting the skills and knowledge of personnel in hospitals, clinics and health centres</td>
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<tr>
<td>a national curriculum is defined for staff who specialize in the co-ordination of quality programmes</td>
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<tr>
<td>responsibility is identified for national integration and provision of training in quality management in all health disciplines</td>
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<table>
<thead>
<tr>
<th>Personnel have protected time to participate in formal, systematic quality improvement programmes</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>time for quality improvement activity is specified in contracts with employees and with health care purchasers</td>
<td></td>
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<tr>
<td>participation in clinical and organizational peer review is a condition of employment or staff privileges in all health facilities</td>
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</table>

<table>
<thead>
<tr>
<th>Health facilities provide staff with accurate, complete and timely data by which clinical and organizational performance can be measured</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>there is a nationally agreed minimum patient data set</td>
<td></td>
<td></td>
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<tr>
<td>this includes in-patient, ambulatory, primary and preventive care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>national standards for data quality are defined and monitored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient administration systems in all facilities are designed to generate indicators, indices and data for clinical and administrative review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>data systems are accessible to clinicians and managers for routine or ad hoc analysis</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Information on the theory and practice of standards, measurements and improvement is accessible to all health personnel</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>staff have access to a database of quality experience in their own organization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>staff have access through publications, library services or Internet to national and international resource centres</td>
<td></td>
<td></td>
</tr>
<tr>
<td>national quality resources, reference centres and publications are actively catalogued, signposted and accessible to intended users across all borders of the nation</td>
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</tbody>
</table>
The direct financial costs of the quality programme are realistically identified in advance and allocated to agreed budgets, especially for training, research and information.

direct costs of agreed quality programmes are identified in purchaser-provider contracts

service level agreements identify agreed quality targets as well as price and volume of clinical activity

local resource allocation mechanisms respond to deficits demonstrated by quality management programmes

central funding of quality initiatives is based on an agreed programme which is publicly accountable

priority is given to research and development to identify and implement incentives and mechanisms which are shown to effect behavioural change.

Principle
Providers of health care in hospital should have and be able to demonstrate systems for quality management, which improve services to patients, develop staff skills and maintain a safe environment.

A Policy
There should be a written, approved and disseminated policy on quality management, and documented plans for its implementation and review

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>The hospital has a written strategy for quality management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>- which integrates patient, clinical and managerial approaches</td>
<td></td>
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<tr>
<td>1.2</td>
<td>- which has been formally adopted by the hospital Board</td>
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<tr>
<td>1.3</td>
<td>- which has been agreed by principal purchasers</td>
<td></td>
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<tr>
<td>1.4</td>
<td>- which is disseminated through the organization</td>
<td></td>
<td></td>
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<tr>
<td>1.5</td>
<td>- which specifies the nature and purpose of performance</td>
<td></td>
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<tr>
<td>1.6</td>
<td>- which has been updated within the past two years</td>
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</tbody>
</table>

B Organization
Responsibility and mechanisms for quality management should be defined within the organizational structure and in relation to external agencies

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>A member of the senior management has defined responsibility and authority for the co-ordination of quality support throughout the Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>- who manages all quality/audit support staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>- who manages a defined budget for quality support</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>Responsibility for quality is defined in management job descriptions</td>
<td></td>
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<tr>
<td>3</td>
<td>There is a defined group which has formal, regular and documented meetings to monitor, support and advise on quality management</td>
<td></td>
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<tr>
<td>4</td>
<td>There is an identified lead clinician to co-ordinate clinical audit within each clinical department</td>
<td></td>
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<tr>
<td>5</td>
<td>There is a recognized mechanism by which national guidelines on best practice are incorporated into each department</td>
<td></td>
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<tr>
<td>6</td>
<td>There is a central record of recent and current quality improvement projects</td>
<td></td>
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<tr>
<td>7</td>
<td>An annual programme of quality improvement (including clinical topics) is incorporated in the current business plan</td>
<td></td>
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<tr>
<td>8</td>
<td>There is a current annual report of quality improvement activity and achievement in the previous year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.1</td>
<td>- which is formally received by the Hospital Board</td>
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<tr>
<td>8.2</td>
<td>- which is available throughout the Hospital</td>
<td></td>
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<tr>
<td>8.3</td>
<td>- which identifies methods, lessons learned and quantified benefits</td>
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</table>
C Methods

There should be evidence that relevant standards are defined, systematically measured, and improved with respect to safety, user satisfaction, staff skills, clinical practice, machine performance and service delivery

1 Health and safety

<table>
<thead>
<tr>
<th></th>
<th>There is current documented preventive maintenance programme</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1.1</td>
<td>electromechanical patient equipment</td>
<td></td>
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<tr>
<td>1.2</td>
<td>calibration of blood pressure measurement</td>
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<tr>
<td>1.3</td>
<td>patient hoists</td>
<td></td>
<td></td>
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<tr>
<td>1.4</td>
<td>fire extinguishers</td>
<td></td>
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<tr>
<td>1.5</td>
<td>lifts</td>
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<thead>
<tr>
<th></th>
<th>Safety assessments and reports dated within previous two years are available for all sites</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>2.1</td>
<td>radiation protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>environmental health and hygiene (e.g. kitchens)</td>
<td></td>
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</tr>
<tr>
<td>2.3</td>
<td>fire control</td>
<td></td>
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<tr>
<td>2.4</td>
<td>infection control</td>
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</table>

2 Safety assessments and reports dated within previous two years are available for all sites

<table>
<thead>
<tr>
<th></th>
<th>There is documented evidence of appropriate response to these</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>4.1</td>
<td>in manual handling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>in fire safety</td>
<td></td>
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<tr>
<td>4.3</td>
<td>in departmental procedures e.g. food-handling</td>
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3 There is documented evidence of appropriate response to these

4 Records are kept of individual participation in staff training

5 There is evidence of action on non-participants

6 There is an effective mechanism for incident reporting

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<tr>
<th></th>
<th>There is an effective mechanism for incident reporting</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>6.1</td>
<td>all departments contribute</td>
<td></td>
<td></td>
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<tr>
<td>6.2</td>
<td>collection and analysis are documented</td>
<td></td>
<td></td>
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<tr>
<td>6.3</td>
<td>there is evidence of resulting action</td>
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7 There is an effective mechanism for infection control

<table>
<thead>
<tr>
<th></th>
<th>There is an effective mechanism for infection control</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>7.1</td>
<td>reports are routinely monitored and documented</td>
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8 There is a hospital-wide antibiotic policy

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<tr>
<th></th>
<th>There is a hospital-wide antibiotic policy</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>8.1</td>
<td>updated/reviewed within the past two years</td>
<td></td>
<td></td>
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<tr>
<td>8.2</td>
<td>adherence is regularly monitored and enforced</td>
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2 **User satisfaction**
The rights of patients are freely available in writing satisfaction surveys systematically assess the experience of patients information leaflets about the hospital are available to patients Complaints and resulting actions are recorded systematically

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<tr>
<th>Yes</th>
<th>No</th>
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3 **Staff skills**
induction programme for all staff
- generic
- departmental
credentialling
performance review
continuing development
training budget

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4 **Clinical practice**

1. General methods recorded in current annual report
1.1. - adverse event/occurrence screening
1.2. - routine indicator monitoring
1.3. - criterion-based topic audit
1.4. - care/recovery pathways
2. Documented evidence of each clinical audit project includes
2.1. - quantified performance before and after the review
2.2. - definition and origins of standards and criteria used
2.3. - what conclusions were reported to whom
2.4. - resulting actions taken

5 **Machine performance**
Lab calibration, Xray, sphygmos, defibrillators

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6 **Service delivery**

General methods adopted include
- Investors in People
- ISO 9000 certification
- Accreditation/organizational audit (see reports)

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D  Resources

There should be identifiable resources available to enable staff to implement the agreed quality management programme

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<tr>
<th></th>
<th></th>
<th>yes</th>
<th>no</th>
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<tbody>
<tr>
<td><strong>Time</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1</td>
<td>There is an allocation of time agreed with management and defined in contracts for participation in formal quality improvement activity</td>
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<tr>
<td><strong>Support staff</strong></td>
<td></td>
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<tr>
<td>2</td>
<td>Trained clinical audit support staff are available to all clinical staff</td>
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<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>Records of staff training in quality improvement are maintained</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Data</strong></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>Aggregated data on diagnosis, interventional procedures and diagnostic tests are complete, accurate, and available for analysis</td>
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<tr>
<td><strong>Information</strong></td>
<td></td>
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<tr>
<td>5</td>
<td>Staff have access to information on relevant standards, methods and results of projects completed within the hospital</td>
<td></td>
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<tr>
<td>6</td>
<td>Current relevant periodicals are available in libraries for staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Outcomes briefing</td>
<td></td>
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<tr>
<td><strong>Budget</strong></td>
<td></td>
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<tr>
<td>8</td>
<td>There is a training budget identified for audit and quality improvement</td>
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Annex 3: Case study on hospital accreditation implementation in Poland

Rafal Nizankowski (National Center for Quality Assessment in Health Care, Poland)

I Description of the environmental context
In 1994, the Polish Minister of Health decided, upon proposal from experts from the Ministry of Health and from the field, to establish an organization devoted to quality issues, the National Center for Quality Assessment in Health Care (NCQA). Four areas of work had been defined for the NCQA: (i) develop an accreditation system for hospitals, (ii) develop training in continuous quality improvement, (iii) develop quality indicators for hospitals, and (iv) develop practice guidelines.

At that time, quality was considered as an important issue. It was decided to start setting up an accreditation system for hospitals. Other alternatives like ISO or the EFQM model were not considered, as accreditation proved to be working in other countries and Poland was willing to take this direction. In 1995, during the ISQUA conference, the possibility that the Joint Commission International (JCAHO, USA) would assist the NCQA in developing the hospital accreditation process was discussed for the first time. The NCQA applied for a USAID grant, which was approved and supported the joint work between the NCQA and the JCAHO for two years. The JCAHO provided the NCQA with technical support in Poland and in the training of Polish experts in the USA.

Developing a quality policy has proven to be a complicated issue and it is still under development. No quality policy has been developed up to now.

II The guiding principles of the accreditation programme

2.1. What were the values of accreditation agreed upon?
Accreditation was based on major accreditation principles similar to those in the US or in Canada: voluntary participation to the accreditation programme, peer review exercise based on published explicit standards and on a survey carried out on site.

The NCQA made the choice of releasing only the positive results to the public and promoted a supportive rather than a blaming culture.

2.2. Why was accreditation chosen among other tools?
There was no real competition at that time with other quality improvement alternatives as ISO or the EFQM model, as the NCQA wanted to promote the most comprehensive model for quality improvement.

2.3. How was the national context worked upon to make it more favourable to the implementation of accreditation?
In order to make the national context more favourable to the implementation of accreditation, national conferences on quality improvement were organized at the School of Public Health in Krakow, with the participation of experts from the JCAHO.

2.4. Were incentives put in place for hospitals to participate in the accreditation programme?
Participation in the accreditation programme has always been voluntary in Poland. Nevertheless, it was believed by hospitals that accredited hospitals would get slightly better funding from the payers.
The lack of financial incentives has been a problem for a broader implementation of the accreditation programme in Poland, as financial difficulties arose in 1999 and hospitals shifted their accreditation from the accreditation programme introduced in 1997 to focus on the financial difficulties they were challenged with.

Nevertheless, 3 regions in Poland offered financial incentives to accredited hospitals. In Silesia, where this policy was the most developed, accredited hospitals received an increase of their overall budget comprised between 3 and 5% between 1999 and 2002.

2.5. What link was established between the accreditation agency and the government? What degree of independence could obtain the accreditation agency?

Formally, the NCQA has been linked to the Ministry of Health since the creation of the centre, as the Ministry of Health has always been paying for the core staff of the NCQA. But practically, the status of the NCQA confers certain autonomy to the centre in carrying out its accreditation role.

Hospitals have to pay to participate in the accreditation programme and surveyors are exclusively paid out of the accreditation fees. The diversity in the source of financing of the centre provides more autonomy to the centre. Moreover, the creation of a supervising body of the accreditation council allows the participation of representatives of the Physicians Chamber, of the Nurses Chamber and of the Hospital Managers Association to supervise the accreditation programme.

The Accreditation Council meets three times a year and is in charge of supervising the accreditation programme as well as all publications and work carried out by the core team. This system has ensured a real credibility of the NCQA towards the hospitals. The location of the NCQA in Krakow, outside of Warsaw, has also helped out to ensure the independence of the NCQA.

In 2004, the status of the NCQA changed to become a legal and independent entity. In 2005, these changes will allow the accreditation council to involve new stakeholders (stakeholders currently involved are the Chamber of Physicians, the Chamber of Nurses, the College of Family Doctors, and the Association for Quality Promotion).

2.6. What is the scope of responsibilities of the accreditation programme?

The responsibilities of the NCQA are in:
- training in quality improvement;
- hospital accreditation;
- development and implementation of quality indicators;
- patient safety.

Since the beginning of the accreditation programme, it was decided to split the work on quality standards (accreditation programme) and the work on quality indicators. Nevertheless, the NCQA aims to introduce quality indicators in the accreditation programme in the future.

2.7. What relationships have been developed between the accreditation agency and other agencies to avoid redundancy of functions?

There is no other agency working in the same field in Poland even though some associations develop their own clinical guidelines.

2.8. How was transparency introduced in the accreditation programme?

The quality standards used in the accreditation programme are public and available on the NCQA website.

2.9. How was the accreditation programme made sustainable (financially but also in terms of human resources)?
The core staff of the NCQA is made of 4 persons and one director, paid by the Ministry of Health. The accreditation surveyors are very active and promote accreditation, but are only paid out of the accreditation surveys fees.

2.10. What technical assistance was necessary to develop the accreditation programme?
The development of the accreditation programme was supported by the Joint Commission International through an USAID grant, as well as by different European organizations as the Donabedian’s Foundation in Spain and the UK’s King’s Fund. It was also supported by the development of the ALPHA programme and the participation to various ISQUA conferences.

III Development of the accreditation process

3.1. How were quality standards developed?
Small task forces were set up with experts in the different areas of standards development. The working group defined first the area of focus, then defined standards with the support of experts from the Joint Commission International and finally a review of the set of standards developed was made with the support of the JCI and of other national experts external to the standards development process.

3.2. How were surveyors recruited, trained and assessed?
The first surveyors came largely from hospitals voluntary to participate in the accreditation pilot test. The first surveyors selected had been proposed by the NCQA core staff.

A training/retraining programme was set up with the support of the JCI. A formal training of new surveyors with more experienced surveyors helps developing new surveyors’ capabilities.

At least a member from the NCQA core staff participates to the accreditation surveys. A formal assessment of the surveyors is carried out during each accreditation survey.

3.3. How are designed the assessment procedures?
There is no formal self-assessment required from the hospital. Nevertheless, there are pre-visits before the survey focusing on training of professionals and included in the accreditation fee paid by the hospitals.

3.4. How is the accreditation process run?
Hospitals apply voluntarily to the NCQA. They have to sign a formal agreement with the NCQA and to pay a fee, which entails staff training by the NCQA prior to the visit on site. A self-assessment has to be carried out before a formal visit by a team of surveyors encompassing peers and at least one of the NCQA core staff. After the visit, a report is sent to the hospital, which can respond to the surveyors’ recommendations. The process is finalized by a decision of the accreditation council. There are three different scenarios: the hospital can be accredited for three years, the hospital can be accredited for one year, or the hospital is not accredited. Only positive results are made available to the public.

Since 1998, 150 hospitals participated in the accreditation programme and around 100 achieved accreditation for one year or more.

Training is delivered on site prior to the accreditation survey, and can be delivered in the NCQA premises as well.
Annex 4: Case study on hospital accreditation implementation in France

Charles Bruneau (National Agency for the Development of Evaluation in Medicine, France)

I Description of the environmental context

Accreditation of all Health Care Organizations (HCOs) was compulsory by law in 1996. This requirement was preceded by a legal mandate formulated in 1990, establishing a formal evaluation process of quality of care in HCOs. A National Agency for the Development of Evaluation in Medicine (ANDEM) was created with the primary objectives of training and education of health care professionals, promoting demonstration projects in HCOs and providing tools such as guidelines and methods.

The accreditation programme was developed within the context of a “medicalized control of costs in health care” aiming to make the professionals accountable and responsible, in part, for cost control. This would be achieved by promoting evaluation, risk reduction and efficiency within the context of a new annual policy identifying national priority goals and financial objectives defined by the French Parliament.

The demands of evaluation and of quality improvement target physicians and private practice, since 1999, and all physicians and independent health care professionals since 2004.

II The guiding principles of the accreditation programme

2.1 What were the values of accreditation agreed upon?

The objective, as formulated in the law of 1996, is to improve quality and security of care. The emphasis is on inducing a cultural evolution and on generating change, and not merely on the formalization of organizational and clinical practices.

Professional participation in the elaboration and in the operation of the accreditation process is absolutely essential for appropriation by the HCOs and for credibility.

Increasing public trust is a key objective. This is done by promoting patient participation in all steps of the process and by informing the public both of the nature of the process and of the results by producing the reports of individual HCOs. The reports of about 1500 HCOs are now available on the website of the Haute Autorité en Santé.

While the report as a whole is public, the information gathered through the process that is not included in the report is privileged and protected by law, a confidentiality clause is necessary to obtain a thorough and honest self-assessment.

2.2 What is the scope of responsibilities of the accreditation programme?

The law of 1996 insisted on external evaluation against standards, incorporating practice guidelines and external recognition. The following decree defined that the review should be undertaken by peers who are health care professionals in actual practice and who cannot devote more than a third of their time to surveying activities.

The process is mandatory for all HCOs whether public or private, including short-term acute care, long term care, rehabilitation or home care facilities.
The results are communicated to the public and to the Regional Hospitalization Agencies (RHA). There are no direct links between the accreditation decisions. The decision is valid for four years. Conditional accreditation is issued with reservation and a mandate to follow up at a defined day.

The programme applies to all types of HCOs. It concerns the HCO as a whole and every sector of activity must be involved. It is centred on the patient, promoting patient participation at every step and evaluating primarily processes of care organized around the patient’s pathways.

2.3. What is the link between the accreditation agency and the government? How independent is the accreditation agency?

The accreditation process is operated by a national agency. The government, nevertheless, has kept an arm’s length relationship being aware of the need for a professional ownership of the process. The board of the agency is composed of 25 representatives from professional of hospital organizations and two representatives from the Ministry of Health. Financing is ensured partly by the government and partly by the HCOs. Support from government however has been essential for the rapid development of the process. At present, there are 800 surveyors trained and more than a 1000 HCOs have been surveyed. The hospitals first surveyed in 2000 and 2001 will be surveyed again as of May 2005.

2.4. What relationships have been developed between the accreditation agency and other agencies to avoid redundancy of functions?

Accreditation is seen as a process of quality improvement and of risk reduction. Safety is a major objective. The agency has worked closely with other inspection agencies also visiting HCOs to avoid redundancies. Surveyors are perfectly aware of the HCO status regarding safety topics that are primarily within the field of responsibility of the other agencies. Accreditation focuses specifically on safety issues related to care.

It is understood that conditional accreditation or non-accreditation decisions will lead to a close scrutiny of the HCO concerned by the Health Authorities.

2.5. What technical assistance was necessary to develop the accreditation programme?

ANAES has constantly turned to agencies in other countries experienced in the field of accreditation for the development of the programme. While the standards were in every way built with French health care professionals, advice from main American and Canadian accreditation agencies (JCAHO and CCHSA) was always sought.

The International Society for Quality in Health Care (ISQua), through its International Accreditation Programme, has also been a major source of help and support. The standards of the French accreditation programme have been accredited as abiding to the principles of ISQua in 2004.

III Development of the accreditation process

3.1. How were quality standards developed?

After a preliminary study of standards used by other accreditation organizations and after surveys of health care professionals and the public, standards were developed by groups of professionals representative of the various types of professions involved in health care and of the various types of HCOs. Standards were pilot tested in 40 HCOs. A second version of the standards has now been developed following similar steps.

3.2. How were surveyors recruited, trained and assessed?

They are experienced professionals in active practice who have also experience in health care management and in quality improvement activities. Initial training consists of two modules of about three
days and of a tutorial process. Surveyors participate in yearly continuous training activities. After each survey, surveyors are assessed through the HCO, their colleagues and the staff of the agency.

3.3. How are the assessment procedures designed?
Meetings with the surveyed HCO take place around 14 months before the survey and again 9 months before the survey. One staff of the agency is responsible for following up each organization undergoing the process.

Self-assessment is an essential step that will lead to a decision of non-compliance if not carried out properly. The self-assessment must be multidisciplinary, cover all sectors of activity of the organization and associate patients.

3.4. How is the accreditation process run?
Surveys are carried out by multidisciplinary teams of three to six surveyors for an average duration of five to six days. There is a formal presentation of the survey preliminary conclusions to the staff at the end of the survey. A report has to be sent to the HCO surveyed within two months, which the HCO may comment before the College of Accreditation, a body composed of professionals. This body makes the final decision regarding the accreditation status of the HCO. The agency strives to reduce significantly the time between the survey and the issuing of the final report.

The report is largely literary. Standards are scored. In the second version of the process as of May 2005, criteria will be scored and the report will be automated allowing for a more extensive analysis of data.

At present, there is a cumulative analysis of all decisions and recommendations made by the Accreditation College. Cumulated results are presented in the yearly report of the Accreditation College. Information about the compliance to specific standards was useful for the development of the second version of the accreditation manual.

Finally, to measure to many of the standards, hospitals must measure how they perform and use indicators. The indicators used are not standardized and the results obtained are not published.