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External quality mechanisms for health care: summary of the ExPeRT project on *visitatie*, accreditation, EFQM and ISO assessment in European Union countries

CHARLES D. SHAW

CASPE Research, London, UK

Abstract

This paper is a summary of the operation, findings and conclusions of a European Union project on external peer review techniques, termed 'ExPeRT', to research the scope, mechanisms and use of external quality mechanisms in the improvement of health care. Many of the themes outlined are described in detail in other papers that have been prepared specifically for this issue of *The International Journal for Quality in Health Care*. Although the emphasis of this project and of this issue of the *Journal* is on Europe, the conclusions are more widely relevant.

Keywords: accreditation, Europe, European Foundation for Quality Management, International Organization for Standardization, peer review, quality in healthcare

The ExPeRT Project was funded by the European Commission for 3 years from August 1996 as part of the BIOMED 2 research programme. It had three aims:

- To exchange experience of external quality improvement in the European Union (EU) by identifying existing organizations actively pursuing such systems, by cataloguing achievements, and by networking.
- To establish mechanisms for collection and dissemination of concepts, implementation and training, and to support integration of external systems with internal quality improvement.
- To define a common framework and criteria for health service standards, surveyor training and programme operation.

We defined an external mechanism as 'a regional or (potentially) national process voluntarily entered by service provider organizations for the improvement of organization and delivery of health services assessed against explicit, published standards by peer group teams moderated by a non-partisan authority involving (but impartial to) users, providers, purchasers and government'. This excludes programmes aimed primarily at the recognition of speciality training (e.g. certification) or assessment of clinical practice (e.g. clinical audit).

Methods

The principal partners represented the Instituto Superiore di Sanita (Italy), The Netherlands Institute for Healthcare Improvement/CBO (The Netherlands), Fundacio Avedis Donabedian (Spain), National Board of Health and Welfare (Sweden) and CASPE Research (UK). Under reciprocal research agreements with the EU, this project also included associate partners representing national accrediting bodies in Australia, Canada, Israel, South Africa and the USA. A full-time project manager was appointed.

Published and grey literature was searched and catalogued to identify organizations and individuals active or interested in the subject, and to identify factors to be included in a data-set for external systems. This bibliography is accessible by Internet at the ExPeRT website [1]. Each of the 15 European states was allocated to one partner to profile, using a semi-structured questionnaire to describe national positions. This was completed by direct interview or by telephone with key personnel in government, professional and independent organizations to form the 'baseline' report in November 1997 [1].

Six staff exchanges allowed individuals to visit other countries, subject to receiving a report, for their own development or to pursue specific enquiries requested by the partner team.

Address reprint requests to C. D. Shaw, CASPE Research, 11–13 Cavendish Square, London W1M 0AN, UK. E-mail: cshaw@kehf.org.uk

Invitational seminars were held for identified representatives of each country, and other experts, about 50 in all. Each seminar had a theme: initial 'baseline' findings (London), political context (Scheveningen), operational issues (Budapest) and summary framework (Stockholm). A database was set up of activities, contacts, project working papers, standards and bibliography. Progress was disseminated through regular newsletters to the participant network, and through a dedicated website.

In addition to the partnership organizations, contact was also made with representatives of pan-European and international bodies including the European Organization for Quality, European Societies for Quality in Health Care, European Accreditation, the European Commission Hospitals Committee, the Joint Commission International (JCI) standards task force and the ALPHA project of The International Society for Quality in Health Care (ISQua).

Observations

Social context

The uptake and success of external quality systems in individual countries are closely connected to the social, political and economic climate that determines incentives and disincentives for participation. The variety of national pictures reflects this diversity [2].

In principle, the delivery of health services in EU countries remains the unique responsibility of individual states (Treaty of Amsterdam: article 152/5); the European Commission has competence in the co-ordination of activities relating to public health (health determinants, response to health threats, systems information) and policy on pharmaceuticals, medical devices and blood products. It also has authority in parallel fields, such as freedom of trade, consumer policy, mobility of professional staff and research and occupational hazards, which demand some harmonization of national services [3].

Some states (such as The Netherlands, Germany, Portugal, Spain) have comprehensive legislation on the management of health care quality, others mandate specific mechanisms (such as for infection control, transfusions, prescribing). Italy and France have legislation for governmental accreditation schemes [4,5].

Incentives and sanctions within health care delivery systems also determine the nature of quality, and the uptake of external peer review mechanisms. Both insurance-based systems (such as in Germany) and tax-based systems (such as in the UK) have moved in the 1980s and 1990s towards contract models between providers and financiers at regional level. The demands for accountability, access and transparency are common throughout the various countries and have been an important force for initiatives in the field of accreditation and certification [6].

In addition to patients and the public at large, many corporate bodies were found to promote external quality mechanisms at the national level (Table 1).

Table 1 Corporate stakeholders and their concerns in external quality mechanisms

Stakeholder	Primary concern
Government	Health policy
Statutory bodies	Registration
Health care providers	Management
Insurers	Funding
Membership societies	Quality improvement
Professions	Education, self-regulation
Consumer organizations	Public information

Four models

Classification

Methods of developing and assessing organizational standards range from the medical speciality-driven 'visitation' in The Netherlands, through traditional accreditation (as in North America and Australia) and European Quality Awards (and national variants) to industrial certification using ISO standards. Much of the project was devoted to analysing their differences and similarities in purpose, scope, methods and impact [5].

Visitatie

Although used widely in the selection and monitoring of speciality medical training, external peer review (visitation, *visitatie* in Dutch) has also been developed to focus on clinical practice, professional development and service quality. Visiting teams are mostly clinical and often unidisciplinary. Standards tend to be derived implicitly from practice guidelines and personal experience. Reports are not available to the public [7].

Accreditation

The term 'accreditation' (applied to organizations rather than to speciality clinical training) reflects the origins of systematic assessment of hospitals against explicit standards; it developed in the USA from 1917 as a mechanism for recognition of training posts in surgery. That model was the beginning of the Joint Commission on the Accreditation of Healthcare Organizations, was exported via Canada to Australia in the 1970s and arrived in Europe in the 1980s. It is most evident in the UK, Spain, Portugal, The Netherlands, Finland and, by statute, in Italy and France; it is being developed in Switzerland (by the Swiss Society for Quality in Health Care) and Germany (jointly by the Medical Chamber and insurance companies). Assessment is by a multi-disciplinary team of health professionals against published standards. 'Accreditation', having acquired three different meanings, causes some confusion. Each meaning is correct in its own context; users need to be aware of the difference between contexts (Table 2).

In most countries where accreditation has flourished, health care is licensed or managed by regional, state or provincial – rather than national – government; devolved,

Table 2 Meanings of 'accreditation' as used by different professional groups and constituencies

Used by	Intended meaning	Since
Professional bodies	Recognition of specialty training	19th century
Consortia of clinicians and managers	Recognition of service delivery	c1920
International Organization for Standardization	Recognition of agency competent to certificate health care providers	1946

statutory regulation is associated with national, voluntary accreditation.

European Foundation for Quality Management (EFQM)

The Baldrige Awards, developed in the USA for improvement of quality in production industries, inspired the EFQM and the 'business excellence' model [8]. Health care providers who seek voluntary development or a European Quality Award are assessed against performance standards for service industries in specific areas such as clinical results, patient satisfaction, administration and staff management. The EFQM model is characterized by a graphic conceptual framework that was revised for 1999. Several countries, particularly in Scandinavia, have introduced their own national awards based on the European framework.

International Organization for Standardization (ISO)

The ISO developed standards for quality systems (ISO 9000 series) which have been used to assess specific aspects of health services – particularly in Germany and Switzerland. Because the standards relate to administrative procedures rather than to clinical results, ISO has been used mostly in more mechanical departments such as laboratories (EN 45001), radiology and transport, but has also been applied to whole hospitals and clinics.

In each country, a national body tests and recognizes ('accredits') independent agencies as competent to certificate organizations that comply with the standards. The audit process tests compliance with standards and is not intended in itself for organizational development. A revised version of the ISO series, to be issued in 2000, is moving closer to the development model of EFQM and accreditation [8].

Standards

Concept

Traditionally, the focus of standards reflects the original purpose of the four models: professional performance (*visitatie*), health service delivery (accreditation), management systems (EFQM) and quality systems (ISO). During the past 10 years, each has moved towards comprehensive standards for organization, management and clinical performance. For example the revised EFQM model identifies specific domains of results in terms of clinical outcome, and patient and staff satisfaction, and offers a conceptual framework to which standards in other models may be mapped.

Development

The development of ISO and EFQM are driven by existing users, most of whom are not related to health care. *Visitatie* and accreditation standards increasingly emphasize the clinician/management interface, evidence-based medicine and the continuum of care as seen by patients rather than managers. ISQua has developed general principles for standards based on analysis of existing accreditation programmes [9]. These offer a template for the development and content of health care standards and have been followed by the JCI in drafting standards for international accreditation [10].

Structure and content

Early accreditation programmes used standards based on legislation, expert advice, research, current practice and overseas experience, and expressed them in terms of headings within vertical management units. More recent standards tend to follow patient pathways and emphasize the interface between management units.

International compatibility of standards

Professional *visitatie* systems in The Netherlands have a common methodology due to their co-ordination by The Netherlands Institute for Health Improvement but in other countries have shown less consistency. The commonality of evidence-based practice and the harmonization of clinical training and mobility of professional staff across Europe may promote convergence in the future.

Although all accreditation programmes have common roots, their standards have developed in response to national legislation, economics, culture and demand; they therefore share common principles and values (summarized by ISQua) but are detailed and tested differently. Piloting of the new JCI accreditation programme will demonstrate the practicality of using a single set of international standards.

National versions of quality awards use standards and criteria directly based on the EFQM model. Detailed consistency between countries was not tested.

Because the use of the ISO 9000 series demands substantial and expert interpretation for application in health care, a separate study was commissioned of existing, published 'translations'. Two-thirds of the 34 national ISO accrediting bodies, which responded to an international enquiry about guidance on ISO health care, had no such documents. The six guidelines which were available showed major variation in the interpretation of key words (e.g. 'product', 'supplier' and 'design control') such that the standards (and thus any subsequent audit and certification) would not appear to be consistent between countries [11].

Assessment process

Self-assessment

All models require participants to provide preliminary information and to be able to present selected documents [12].

Some provide a self-assessment questionnaire (ranging from basic data on staff and activity, to a comprehensive checklist of criteria for compliance with standards), detailed guidance on preparation and external facilitation (typically over 6–12 months) to help the hospital or service towards compliance with the standards. In accreditation, the self-evaluation is commonly the starting point for the external survey team's assessment. With ISO, there is demarcation (absolute in theory, but vague in reality) between the audit and any prior consultancy.

Desk appraisal

Site visits are generally preceded by an external examination of a defined set of internal documents (e.g. resource and activity data, internal audits, policies and procedures). Indicators of performance are invited by EFQM but are prescribed by some accreditation programmes (e.g. the Health Quality Service in the UK) and by the Swiss variant of ISO as demonstration of a robust internal quality system. Performance indicators have been more widely applied in accreditation programmes in the USA, Canada and Australia [13].

Site visit

The formal external visit (*visitatie*), survey (accreditation), assessment (EFQM) or audit (ISO) lasts from 1 to 5 days depending on the size and complexity of the organization under review, and on the size of the visiting team. ISO focuses on documentation of management systems; other models include extensive interviews with staff (and sometimes patients), access to management, personnel and patient records, and systematic observation of clinical and support services. In large organizations, observations of topics, staff and sites are based on sampling, on the basis that it is not cost-effective to do otherwise; 'triangulation' (testing of specific issues from several angles or by different observers) is a practical proxy for perfect standards and perfect surveys.

Report and evaluation

Most models provide a verbal preliminary report, before leaving the site, to test validity of observations and to ensure that no surprises appear later in the formal written report, which generally includes commendations of positive features as well as noting non-compliance. Recommendations for action on improvement, in order to meet or exceed the standards, are usually provided.

In some external review systems, the process ends at this point. In other models, the report is then subject to checks for internal consistency and compliance with report-writing protocols, to numerical scoring of achievement and to independent scrutiny in order to verify the award (and, in accreditation, its duration).

Assessing organizations do not generally make their findings public, but ISO and accreditors issue certificates for public display and publish occasional lists of recognized organizations. However, it is argued that accreditation programmes run by governments generate documents which are by definition in the public domain, and that the extension of legal requirements for freedom of information will require the same of independent assessors also.

Visitors, surveyors, assessors, auditors

Competence and credibility are essential attributes of individuals, and each team needs a balance of clinical and managerial expertise as well as a sound understanding of the standards and assessment process. Selection, training, assessment (and de-selection) of auditors are clearly defined under ISO, but are also systematic under EFQM and accreditation programmes (which invariably train their own surveyors). Some *visitatie* programmes rely on career experience rather than training.

Validation, quality procedures

Validity of standards and reliability of assessment are crucial to consistency of reports within programmes (e.g. between identical hospitals, or between visits to the same hospital). Unless these variations are reduced through collaboration and convergence, rather than competition between the models and their individual programmes, there is little prospect of reciprocal recognition between them either at national or at European levels.

Within-programme consistency has been approached through a variety of mechanisms, including: internal audit procedures, performance targets, assessment protocols (e.g. ISO 10011: guidelines for auditing quality systems), surveyor training and evaluation, consumer feedback and independent panels.

Within-model consistency demands effective monitoring at national and European levels. EFQM and European Accreditation, a regional collaboration of national organizations that recognizes agencies competent to issue certification under ISO, aim to provide this but there is no comparable organization for *visitatie* or accreditation programmes. For accreditation, this issue has been approached at an international level by ISQua in initiating the ALPHA programme to define standards for the operation of accreditation programmes and to offer independent assessment against them.

Between-model consistency will require assessment of the same scope of activities, with the same methods and the same purpose. Even in the long term, this may be neither achievable nor desirable but in the short term, convergence between models would reduce fragmentation and increase the potential for external improvement systems in health care.

Reconciliation and convergence

Policy

The four models have begun to converge. So far this convergence has been spontaneous and opportunistic, rather than planned collaboratively. Given that the models were originally designed for different purposes, complete harmony may be neither feasible nor useful. But clearer demarcation of scope and contribution of each model could increase efficiency and reduce duplication in the external quality

improvement market. This would require a range of compromises in response to the findings of this project. These include:

- priorities: putting improvement of health care ahead of model-loyalty and commercial competition;
- explicit values: recognizing the differing agendas of stakeholders and being clear how they are addressed by the programme;
- continuous improvement: aiming for sustained achievement and dynamic development [e.g. plan-do-check-act (PDCA) model] ahead of static compliance testing; while recognizing the need for assessment to be independent of external help in preparation, the overwhelming majority of ExPeRT project participants agreed on the benefits (in terms of efficiency and effectiveness) of combining these two functions within one external agency;
- conceptual framework: adoption of the revised EFQM model as an explicit, tested and consistent framework to describe the scope and relative weighting of assessment domains;
- customer response: adapting models to the specific needs of health care delivery, and defining standards in appropriate language without the need for third party interpretation;
- transparency: providing users and public with accurate descriptions of the validity of standards, the reliability of assessment and what assurances are implied by awards or certificates;
- legislation: avoiding prescriptive selection of any model without the capacity and will to converge standards and procedures towards European harmony.

Converging organization

- National co-ordination: identifying mechanisms to promote consistency within and between models; in The Netherlands a council for harmonization of external quality review in health care has been set up to recognize and integrate the four models with national policy and legislation; in the UK a voluntary forum aims to promote convergence of over 30 accreditation and *visitatie* programmes.
- European communication: establishing a European forum for *visitatie* and accreditation able to communicate with EFQM, European Accreditation and the European Organization for Quality; the formation of the European Societies for Quality in Health Care could provide that vehicle.
- International liaison: national and European collaboration with international initiatives towards robust methodology, and convergence on ISQua's ALPHA standards [14].

Converging methods

- Language: adoption of common definitions between models, especially reconciliation with ISO terminology.
- Standards: adoption of international conventions (e.g. agenda for leadership and principles in health care accreditation ALPHA standards) consistent with principles of ISO and EFQM; testing new programmes (e.g. JCI accreditation) against these principles.
- 'Cross-walking': mapping existing standards to international conventions in order to define gaps, overlaps and conflicts; identifying equivalent standards and criteria between models to enable comparison and conversion through relational databases.
- Assessment: adoption of ALPHA standards for programme operation, particularly internal mechanisms to minimize observer variation and promote reliability and consistency.
- Quantification: making explicit the measurement and weightings of compliance with standards as a basis for the evaluation of reports, and for tracking progress of health care providers over time and in relation to similar organizations.
- Clinical performance: incorporating tests to demonstrate measurement and improvement against evidence-based clinical standards; defining and embedding standardized indicators of clinical process and outcome.
- Assessment skills: adopting a common core curriculum of knowledge, attitudes and skills required of assessors; developing reciprocal training programmes.

Converging resources

- Access to information: making programme standards, processes, costs, results and bibliography freely available (such as on the Internet), and linking sites with other programme providers to enable comparison.

Converging evaluation and quality

- Programme performance: identifying, monitoring and improving against internal indicators of corporate achievement.
- Independent verification: external assessment of accreditation and *visitatie* programmes under the ALPHA programme; mapping EN 45010 (general requirements for the assessment and accreditation of certification/accreditation bodies) to ALPHA standards for programme operations in order to seek reciprocal recognition.
- Research: seeking opportunities to demonstrate associations between compliance with external assessment standards and benefits to patient care; to quantify the comparative results (for patients, staff and society) of the four models; to identify the evidence base for organizational standards.

Trends and prospects

Despite the assurances of the Maastricht and Amsterdam Treaties that the rules of subsidiarity will preserve the delivery of health care as a responsibility of each state, numerous factors point to a future climate in which health care standards and their assessment processes will converge across the EU. These influences may be summarized as follows.

Legal influences

- European health ministers agreed to collaborate in the development of quality systems, and acknowledged that there is no legal demand to do so [15].
- The interpretation of competence in public health is steadily extending (e.g. pharmaceuticals, blood products, exchange of information on health care delivery).
- Non-health legislation is increasingly binding health systems together (e.g. training, workforce mobility, freedom of information, freedom of trade, portability of health benefits and insurance coverage).

Cultural influences

There are common and growing pressures from a range of stakeholders for accountability, transparency and equity of access to health care.

Professional influences

- In defence of their challenged autonomy, clinical professions are seeking increasingly formal and robust mechanisms for professional development and public reassurance (e.g. the Royal Colleges in the UK see effective speciality peer review as a collegiate contribution to 'clinical governance').
- The harmonization of speciality clinical training implies harmonization of working practices and environment.
- The international nature of evidence-based medicine and convergence of clinical practice also implies increasing consistency of care pathways and service provision in primary, secondary and tertiary care (e.g. ANAES operates the French national accreditation programme in parallel with the national development of practice guidelines, and has the capacity to enforce organizational compliance with such clinical standards).
- Increasing emphasis on objective measures of personal and organizational results promotes the use of comparative data and clinical benchmarking.
- The achievement of public health targets (e.g. Health for All 2000) depends substantially on the delivery of individual patient care and on the exchange of data (e.g. through the European Public Health Network).

Commercial influences

- Health insurers are increasingly anxious to contain costs by avoiding inappropriate and ineffectual treatments, and by making explicit agreements with clinicians on standards of clinical care and services (e.g. the joint accreditation initiative in Germany between doctors, hospital managers and insurers).
- Insurers are also keen to reduce over-provision of facilities by identifying preferred providers selected on the results of standards-based assessments (e.g. British United Provident Association 'BUPA' insurance in the UK).
- Hospitals which can demonstrate effective risk management (such as through an external quality programme) may be rewarded with lower premiums for liability insurance.
- Increasing mobility of patients and staff, portability of health benefits and growth of multi-national health care providers increase cross-border competition and demand marketing of independent approval.

Conclusions

The ExPeRT project has identified four principal models, and national variants, of external quality improvement in health care. It has analysed the apparent strengths and weaknesses in terms of validity and reliability and identified many features that would ideally be incorporated into a convergent model for Europe.

As a descriptive study, it has not demonstrated the relative effectiveness or efficiency of the models (nor has it found any evidence in published literature). If it is the privilege of research to propose more research, this project would recommend controlled trials of the operation and impact of these programmes in order to define their active ingredients.

Whether the overall conclusions and recommendations of the project will constructively affect the development of health care quality in Europe or elsewhere will depend on the willingness and ability of many individuals and organizations to adapt standards and methods, and to plan for a common future.

A common model for health care quality need not await legal endorsement by national or European parliaments; the world's oldest and most successful programmes developed in countries smaller than Europe, and they were independent of the state and provincial authorities that had statutory responsibility for managing health care services.

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