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Towards hospital standardization in Europe

CHARLES SHAW[1], CHARLES BRUNEAU[2], BASIA KUTRYBA[3], GUIDO DE JONGH[4] AND ROSA SUNOL[5,6]

[1]European Society for Quality in Healthcare, Limerick, Ireland, [2]Haut Autorité de Santé, Paris, France, [3]National Centre for Quality Assessment, Krakow, Poland, [4]Programme Manager Innovation and Business Development, Comité Européen de Normalisation, Brussels, Belgium, [5]Avedis Donabedian Institute, Autonomous University of Barcelona, Barcelona, Spain, and [6]CIBER Epidemiología y Salud Pública (CIBERESP), Barcelona, Spain

Address reprint requests to: Charles Shaw, 1 St Nicholas Cottages, Arundel, Houghton BN18 9LW, MI, USA. Tel: +44 1798 831884; E-mail: cdshaw@btinternet.com

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Abstract

Quality problem. There is no simple tool to assess compliance with common national and European directives, guidance and professional advice on the management of healthcare institutions. Despite evidence of unacceptable variations in the protection of patient and staff safety little attention has been given to harmonizing the way services are organized and managed.

Initial assessment. Existing systems which define organizational standards, or assess compliance with them, are not in a position to extend this activity into or across national borders in Europe. Certification, accreditation and licensing programmes are too variable to provide a common basis for consistent assessment. Consensual standards would inevitably be minimal if they were to achieve acceptance by all or a majority of member state governments; they would not be standards for excellence or help the majority of organizations to improve performance.

Proposed solution. This paper proposes the development of a framework and measurement tool, initially for hospitals, which could be used for self-assessment or peer review to demonstrate compliance with European legislation, guidance and public expectations without infringing national responsibilities. A common code of management practice could be developed through a process similar to that adopted for clinical practice guidelines by the European commission-funded project on appraisal of guidelines research and evaluation.

Conclusions. In practice, the legal relationships between member states and intergovernmental organizations inhibit the harmonization of management practice across-borders. Faster progress to higher levels of performance would be achieved by voluntary, non-regulatory cooperation of enthusiasts to define, measure and improve the quality of healthcare in European hospitals.

Keywords: Quality improvement, External quality assessment, Standards, Health policy, Hospital care, Europe

Quality problem or issue

There are many potential sources, but there is no European guide to the management of quality and safety in hospitals. There is no simple tool for managers to assess institutional compliance with common national and European directives, guidance and professional advice on organizational culture and behaviour. Without these there is little opportunity for hospitals to identify and share best organizational practice, to support the mobility of patients, staff and services across-borders, or to address issues that are specific to cross-border patients.

Initial assessment

Background

Within the European Union, concerted efforts have been made towards harmonizing standards for medical equipment, professional training and clinical practice, and approval mechanisms for the marketing of pharmaceuticals. But little attention has been given to the way services are organized and managed, or to the internal systems used by providers to improve quality and safety.

Successive analyses [1] and research projects [2–4] have identified opportunities for more consistency between member states. Most recently, 'Methods for assessing response to quality improvement strategies' (MARQuIS) [5] has verified by on-site assessment that hospitals studied in six countries do not consistently apply some basic safeguards concerning patient identification, infection control, medications and environmental safety. Efforts towards sharing best practice include the European network for health technology assessment (EUNEHTA) and the European Network on Patient Safety (EUNetPaS) project which aims to collate and share, among member states, advice on patient safety.

This paper examines potential interests and approaches to consistent assessment of hospitals which could promote

compliance with basic common principles and the safety of staff and patients. It describes the scope and limitations of existing standards for the organization of health care, and of the capacity of existing external assessment organizations to disseminate standards in Europe. It proposes the development of a framework and measurement tool which could be used for self-assessment, peer review—or by external assessment agencies—to demonstrate compliance with European legislation, guidance and public expectations.

Government and governance in Europe

The three regional intergovernmental bodies—Council of Europe, World Health Organization and the European Commission—have different definitions of 'Europe'. A national government holds prime responsibility for stewardship and public protection, including quality and safety in provider institutions, but in many states, health care is the statutory responsibility of provincial or regional government.

European commission. The promotion of free movement of trade, services and skills, public protection and health service research require harmonization between member states. Directives, guidance and research-based recommendations are issued but service delivery is the responsibility of national governments; the EC has limited legal competence and currently there are few mechanisms to track the implementation of recommendations or their impact on individual hospitals.

There is existing EU legislation in areas such as pharmacovigilance, medical device safety, and on the safety and quality of blood and blood products, human tissues and cells. Apart from the EU Health Strategy 2008–13 [6], recommendations on patient safety [7] and the draft directive on the application of patients' rights in cross-border healthcare [8], current specific priorities of the EC also include proposals on health workforce food safety, safe services, occupational safety and patient safety, including healthcare associated infections.

The original draft of the cross-border directive included an Article 5 which would have required member states to define and monitor compliance with standards for quality and safety for healthcare provided on their territory; these standards would have been required to be consistent with 'international medical science and generally recognized good medical practices'. Article 5 was progressively diluted by the European parliament and then by member states, effectively removing the requirement for published national standards.

Comité Européen de Normalization. The European Committee for Standardization is the legally competent body of the European Union and European Free Trade Area (EFTA) Member States to elaborate and publish European standards. These standards aim to harmonize the European market by transposition into national standards. In many cases, these European standards are established on request of the economic operators (bottom-up approach). Alternatively, the EC can mandate Comité Européen de Normalization to elaborate standards to harmonize the European market (top-down approach). Mandated European standards, referenced in the Official Journal of the European Union, support European Union legislation.

In the healthcare field, European standards are established for medical devices. Healthcare service providers also use European standards, such as the EN ISO 9000 management standards to certify their organization. Some healthcare professions are now defining in European standards the professional requirements for service to patients.

World Health Organization. The European Regional Office (EURO) sponsored many workshops and publications during the 1980s to stimulate the quality movement in Europe, including the meeting in Udine in 1985 which led to the foundation of the International Society for Quality Assurance (then ISQA, now ISQua).

Recommendations to member states on quality in healthcare were embedded in policy targets [9] and in European and global initiatives of World Health Organization (WHO), such as for health promoting hospitals 1991 [10], baby-friendly hospitals 1991 [11], the Performance Assessment Tool for Quality Improvement in Hospitals [12] and patient safety 2004 [13], rely largely on voluntary uptake by peer group networks and individual hospitals.

The Council of Europe. Like WHO, the Council adopted recommendations to member states on management of patient safety and prevention of adverse events in health care (2006) [14].

Standards-based assessment systems in Europe

The EC-funded research project on external peer review techniques (ExPeRT) identified ISO certification and organizational accreditation as the most prevalent standards-based assessment systems for healthcare in Europe [15]. The study did not include statutory licensing and inspection, or the accreditation of training institutions.

ISO certification. The ISO 9000 series of standards focused originally on quality management systems for manufacturing industry, but are now applied to assess quality systems in specific aspects of health services, and in whole hospitals and clinics. Hospitals (or, more commonly, parts of them) are assessed by independent auditors who are themselves regulated by a national 'accreditation' agency. Certification is widely available from independent certificated auditors and is recognized in many other service and manufacturing industries, and across national borders.

Healthcare accreditation. In the past 10 years, several studies have explored the potential of healthcare accreditation to reduce variations in the quality and safety in hospitals in Europe [16–18] and internationally [19–21].

The majority of EU countries have national programmes with varying degrees of stakeholder governance, of compulsion and of national uptake. Sub-national programmes, such as in Spain and Italy, are mostly run by regional government (Table 1). Some 60 hospitals in Europe have been accredited by Joint Commission International (JCI) using published international standards [22]. JCI Europe is part of a worldwide programme; it is not specific to the EU.

Table 1 Examples of national programmes for healthcare standards

Country	Agency	Website
Czech Republic	Spojená akreditační komise	www.sakcr.cz
Denmark	Danish Healthcare Quality Programme	www.ikas.dk
Finland	Social and Health Quality Service	www.qualitor.fi
France	Haut Autorité de Santé	www.has-sante.fr
Germany	Transparenz und Qualität im Gesundheitswesen	www.ktq.de/
Hungary	Institute for Healthcare Quality Improvement	www.emki.hu
Ireland	Health Information and Quality Authority	www.hiqa.ie
Lithuania	Accreditation programme for health care institutions	www.vaspvt.gov.lt
Netherlands	Nederlands Instituut voor Accreditatie van Ziekenhuizen	www.niaz.nl/
Poland	Centrum Monitorowania Jakości	www.cmj.pl/
Switzerland	SanaCERT Suisse	www.sanacert.ch
UK	CHKS Healthcare Accreditation & Quality Unit	www.chks.co.uk

There is currently little consistency and no reciprocity between these accreditation programmes but a 2007 survey for the Belgian health ministry [18] found that 11 of the 17 programmes in Europe are already committed to harmonize by meeting the principles and standards which have been defined by the International Society for Quality in Healthcare (ISQua) for standards development and for standards-based assessment [23, 24]. Several accreditation programmes—such as JCI, France, Ireland, Denmark, the Netherlands and some programmes in the UK—have already been thus independently assessed and accredited.

Strengths and weaknesses of existing standards systems and accreditation programmes

Access to service. Hospitals in some EU member states, such as Austria, Belgium, Greece, Hungary, Slovenia and Sweden, have no access to a national programme of hospital accreditation. Some hospitals in Belgium (Flanders) and Austria are accredited by programmes in The Netherlands (NIAZ) or Germany (KTQ), respectively.

Compatibility and consistency. The ISO 9001 and 9004 standards are consistent across Europe, but their interpretation varies when applied to hospitals by different auditors; recent interpretation documents aim to meet more specifically the needs of healthcare providers and to reduce this variation [25, 26].

The term 'accreditation' was originally applied in healthcare to the recognition of teaching (trainers, trainees or training environments). Later, following the hospital standardization programme of the American College of Surgeons, it was attached more generally to provider organizations (mostly hospitals) and, most recently (by ISO and the European Union) to recognition of competent assessors (auditors, testing laboratories etc.). In the vocabulary of ISO, hospital accreditation would be called certification; variation in terminology itself causes confusion.

Healthcare accreditation standards within Europe are generally similar in content and aim for active improvement, but there is wide variation in emphasis, assessment criteria, internal quality control and the use of statistical measures. Issues specific to cross-border patients are not systematically included in national standards programmes.

Regulatory standards tend to focus on resource inputs and minimal standards for safety. Requirements for licensing of healthcare organizations and for re-inspection vary within and between countries. Coordination of standards and assessments between local, regional and national authorities is limited.

The impact of external standards-based assessment models varies according to their purpose, standards, procedures and incentives. The MARQuIS study [27] showed that, for individual hospitals, higher levels of patient safety were associated with accreditation than with ISO certification but both systems were significantly better than none [28]. Mandatory accreditation programmes have a higher impact on the health system if only by involving a greater proportion of hospitals [16] (Fig. 1).

Coverage. Few voluntary accreditation programmes in Europe have grown as steadily as the predecessors in USA, Canada and Australia on which they were modelled; rapid uptake and extensive coverage there is strongly associated with direct or indirect financial advantage from being accredited. The result is that, even where accreditation programmes are available in Europe, they often do not provide a comprehensive view of hospitals in either the public or private sector. The statutory position of the Haute Autorité de Santé in France has generated rapid uptake and now has the widest national coverage in Europe (the Danish programme has yet to be fully implemented).

Availability of assessment results to the public. Whereas public agencies are generous with information (mostly via Internet) about standards, assessment procedures and the status of individual hospitals, proprietary programmes restrict such information in order to protect their own intellectual property and the confidentiality of their clients. Information on which hospitals hold which ISO certification of which department is not easily accessible.

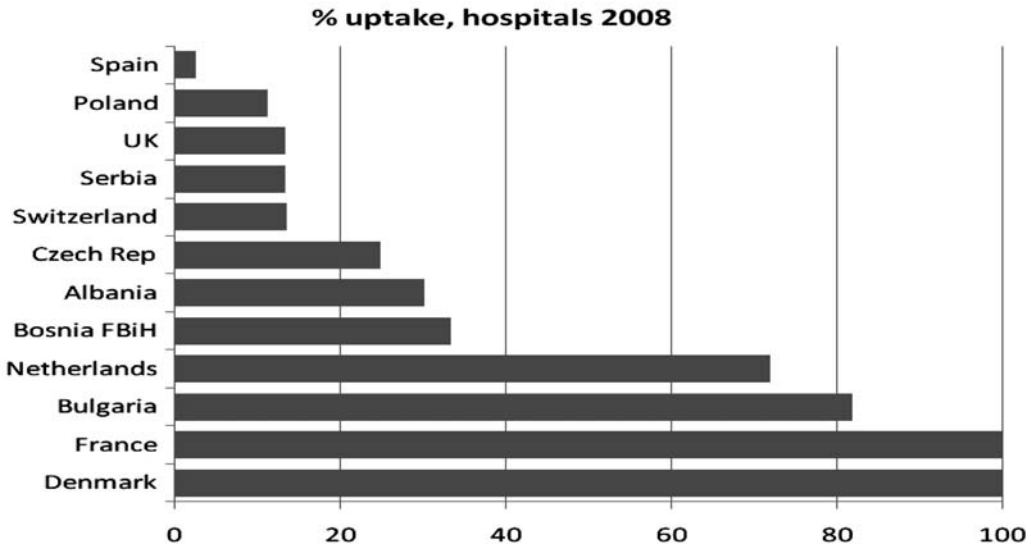

Figure 1 Percentage hospital coverage, national accreditation/certification 2008.

Proposed solution: towards common management practice

Existing programmes of standards-based assessment could provide greater value to European hospitals, consumers and other stakeholders by sharing information which is already available, and by making it more accessible to the public. Such sharing should also lead to greater consistency in assessment procedures within and between countries. Two specific approaches could contribute to this consistency.

Existing assessment programmes could be more actively harmonized by adopting common principles for standards and for assessment procedures, such as those of the International Accreditation Program of the International Society for Quality in Healthcare (ISQua). These principles could also apply to developing national programmes.

Current efforts to develop European standards for patient safety go some way to achieving more comparable assessments but quality of health care is more than this; safety is a large part of that agenda but it should not distract managers from concerns for patients' rights, efficiency, clinical effectiveness and other dimensions of performance. All of these need sustainable structures and internal systems designed for comprehensive, integrated management. Standards specific to patient safety would inevitably be minimal in order to achieve acceptance by all or a majority of member state governments; they would not be standards for excellence or for quality and safety improvement that would help the majority of organizations to strive to improve global performance. In the context of the EU, faster progress to optimal performance may well be best served by a voluntary process such as the one described below.

Proposed implementation

A common code of practice for hospital management could be developed through a process similar to that used for clinical practice guidelines by the Scottish Intercollegiate Guidelines Network (SIGN) [29] and the EC-funded project on appraisal of guidelines research and evaluation (AGREE) [30]. The process would need to be focused on organizational development systems already in place but should also take into account existing international measurement systems such as the WHO PATH [10] and OECD [31] indicator projects.

Following the methods offered by the AGREE principles, the development of an assessment tool for quality and safety in hospitals would involve a series of steps:

(i) Development group: define enthusiasts, participants and project leader among non-governmental European organizations. Involve healthcare insurers, interested external evaluation agencies, management and professional associations, and observers from the EC and other intergovernmental organizations.
(ii) Literature review: identify and collate existing advice and directives which could translate into explicit guidance for hospital management.
(iii) Drafting the document: design practical structure for departmental and functional management, import guidance and measurable criteria based on the above.
(iv) Consultation: refer draft to interested stakeholders for comment and revision.
(v) Field testing: training and self-assessment in pilot sites, revision of document and procedures; retraining and peer review among participating hospitals.
(vi) Evaluation: feedback from assessors and assessed hospitals on the guidelines, measurement processes, and the impact on hospitals Table 2.

The resulting toolkit and procedure manual should be freely available in electronic format for individual users in order to encourage voluntary uptake, networking and sharing of good practice.

Table 2 Guidance sources for review

Recommendations from biomedical and health service research
EC implementation guidelines and directives for healthcare management related to safety of staff, patients and public, including needs specific to cross-border care
Complementary standards and criteria from existing external assessment programmes, professional associations, governmental and intergovernmental agencies
Existing measurement systems for international comparisons
International guidance on standards-based assessment

Conclusions

In practice, the legal relationships between member states and intergovernmental organizations inhibit the harmonization of management practice across-borders. Consensus on healthcare standards among 28 EU governments would take years, unless reduced to a level far below the aspirations of most providers, purchasers and consumers. Even without political, legal and geographic constraints, consensus would be slow—if not impossible—to achieve among all stakeholders.

Thus, we conclude that faster progress to higher levels of all-round performance would be achieved by voluntary, non-regulatory cooperation of enthusiasts to define measure and improve the quality of healthcare in European hospitals. Common evidence-based guidance for healthcare management could offer a vehicle for sharing best practice and rolling across European borders.

The regulation of healthcare should not be confused with the pursuit of excellence.

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