Can health care standards be standardised?

Dr Charles Shaw
Comparable assessment of health services requires comparable statements of requirements.

These may be expressed as:

- Standards (agreed levels of service)
- Guidelines (recommendations to guide decisions) or
- Directives (with which health services must comply)
Practical applications of standards

• Identifying “good” institutions eg referral networks, cross-border care
• Identifying “good” clinical services eg for breast cancer
• Promote quality and safety eg minimum safety standards
• Workforce: skills, training, mobility
• Applied health service research eg MARQuIS, Handover, DUQuE, EUNetPaS
• External assessment: regulation, ISO certification, HC accreditation
• Healthcare financing: universal health coverage
Standards development approaches

• Clinical practice
  – Biomedical research
  – HAS, NICE, SIGN, AHRQ, AGREE principles

• Institutional systems
  – health service research
  – Empirical learning eg patient safety, peer review

• Regulated (ISO) model
  – Consensus

• Legal
  – Institutional regulation, licensing
  – Professional regulation, licensing
Developing European standards, CEN

De Jongh G. A short insight in European Standardisation. Brussels, 2008-02-05
# CEN Technical Committees on healthcare

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<th>Committee</th>
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Integrating key definitions and steps

• Definitions
  – Language, taxonomy
  – Scope, quality dimensions and purpose
  – Stakeholders

• Evidence
  – Research, systematic review, referencing

• Drafting, consultation
• Piloting and field-testing
• Evaluation, feedback, revision
• Publication and public access
• Review and revision
Challenges and opportunities

Some challenges
– Conflicting terminology between approaches
– Limited research on impact of approaches on Q&S
– EC extending ISO accreditation to health services?
– AGREE principles not consistently applied in ISO or regulatory systems

• Some opportunities
– CEN seeking a strategy for healthcare standards
– JRC hosting
  • Putting Science into Standards, October 2015
  • EC initiative in breast cancer quality assurance and accreditation
– Clinical service accreditation in UK
  • Collaboration of BSI, professional bodies and regulator in England
  • UK extension needs support of government departments, and Europe
For consideration of Expert Group PSQ

- Clarify with DG SANTE current plans for extending directive 765/2008 (accreditation of goods and products) to health services
- Facilitate development of CEN strategy for application of standards to health care
- Develop knowledge base
  - Promote long-term on-line access to products and deliverables of EC health service research on quality and safety (MARQuIS, Handover, DUQuE, EUNetPAS etc)
  - Signpost access to relevant guidance eg WHO, Council of Europe
- Support UK proposal to develop a national “standard for healthcare standards” compatible with evidence-based medicine, regulatory requirements and ISO systems
EC/EU references

• Directive 2005/36/EC on the recognition of professional qualifications
• Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare
• Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products
• EC A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020 COM(2011) 311. Brussels 2011
• Call for tender Chafea/2014/Health/05 concerning the development of a manual and toolbox for the assessment of European Reference Networks
Publication references

• Towards hospital standardization in Europe International Journal for Quality in Health Care 2010; 22: 244-9

• Accreditation and ISO certification: Do they explain differences in quality management in European hospitals? International Journal for Quality in Health Care 2010

• The effect of certification and accreditation on quality management in 4 clinical services in 73 European hospitals. International Journal for Quality in Health Care 2014; 26 S1: 100-6

• How can healthcare standards be standardised. BMJ Qual Saf bmjqs-2015-003955 Published Online First: 30 June 2015