Standardisation - a doctor‘s point of view

Dr. med. Günther Jonitz

Conference on Standardisation and Health
12. October 2017, Brussels

Dr. med. Günther Jonitz, President of the Berlin Chamber of Physicians, member of the board of the German Medical Association


[Quelle: Tate Images]

„All doctors have a romantic notion of what it means to be a doctor. Many British doctors, for instance, remember Sir Luke Filde‘s famous picture of a doctor treating a sick child.
The room is dark; the pale child sick unto death; and the bearded, besuited doctor worried.
The focus is on the intense relationship between the doctor and the child.

Nobody else but the child‘s parents are there;

certainly no economists.“ ***…and no standardisation experts.“***

Dr. med. Günther Jonitz, President of the Berlin Chamber of Physicians, member of the board of the German Medical Association

[BMJ 1998;316 (30 May) Editor‘s choice]

Medicine is about patients

-

not consumers!

Very private concerns

Suffering

Call for help

Life-and-death-questions

Existential fears

Medical action is based on…

Patient-doctor relationship

- **Medical professional ethics, skills, knowledge and attitude**
- **Patients self-determination**
- **Therapeutic freedom**

High-quality medical care

✓**Evidence based medicine**

✓**Clinical practice guidelines**

„Knowledge is the enemy of the disease“

„In the 19th century ‚clean water‘ was the most important ressource for health.

In the 21st century it is ‚clean knowledge‘.“

Sir John Muir Gray

former „Chief Knowledge Officer“ of the NHS

www.bettervaluehealthcare.net

Evidence based medicine…

- **Best external evidence**
- **Individual clinical expertise**
- **Patients' preferences**

"Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied."

David L. Sackett

AIM

Standardisation is

- for **markets/ economic benefits**

- **Guidelines** are

  for **quality and safety in healthcare/ individual patients**

METHODS

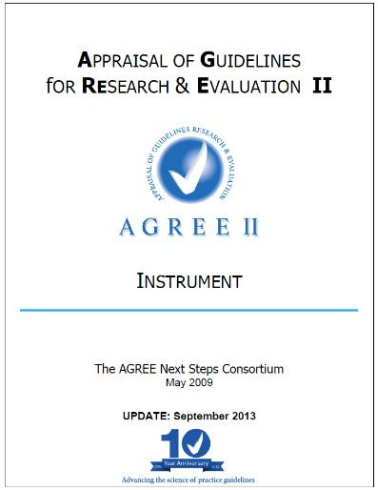
Standardisation

- „GOBSATT“, interested parties, interests

GOBSATT = good old boys sitting around the table“, eminence-based i. e. sub-standard

Guidelines

- Defined methodology
- systematic and science-based approach
- critical appraisal
- clinical recommendation that has been differently verified and therefore weighted.



Systematic Approach!

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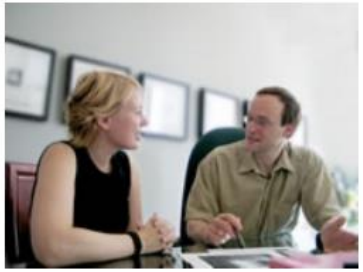
Practice Guidelines

What are practice guidelines?



Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (1).

In addition, practice guidelines can play an important role in health policy formation (2,3) and have evolved to cover topics across the health care continuum (e.g. health promotion, screening, diagnosis).

Practice guidelines are evidence-based if they undertake a review of the literature and link their concluding recommendations to the evidentiary base identified through the literature search.

Authors of practice guidelines are usually experts in the content topic area and in research methodology. Authors provide interpretation of the evidence and include their expertise to formulate the recommendations.

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Appraise practice guidelines with the My AGREE PLUS online appraisal platform.

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http://www.agreetrust.org/practice-guidelines/

CONFLICTS OF INTEREST

Standardisation

- Interested parties, lobby groups, profiteers

Guidelines

- **Scientific Experts** declaring any potential conflict of interest, including patient organisations

AVAILABILITY

Standardisation

- You have to pay

- **Guidelines**
- **For free**

EU Characteristics of Standardisation

L 316/12 EN Official Journal of the European Union 14.11.2012

REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 October 2012

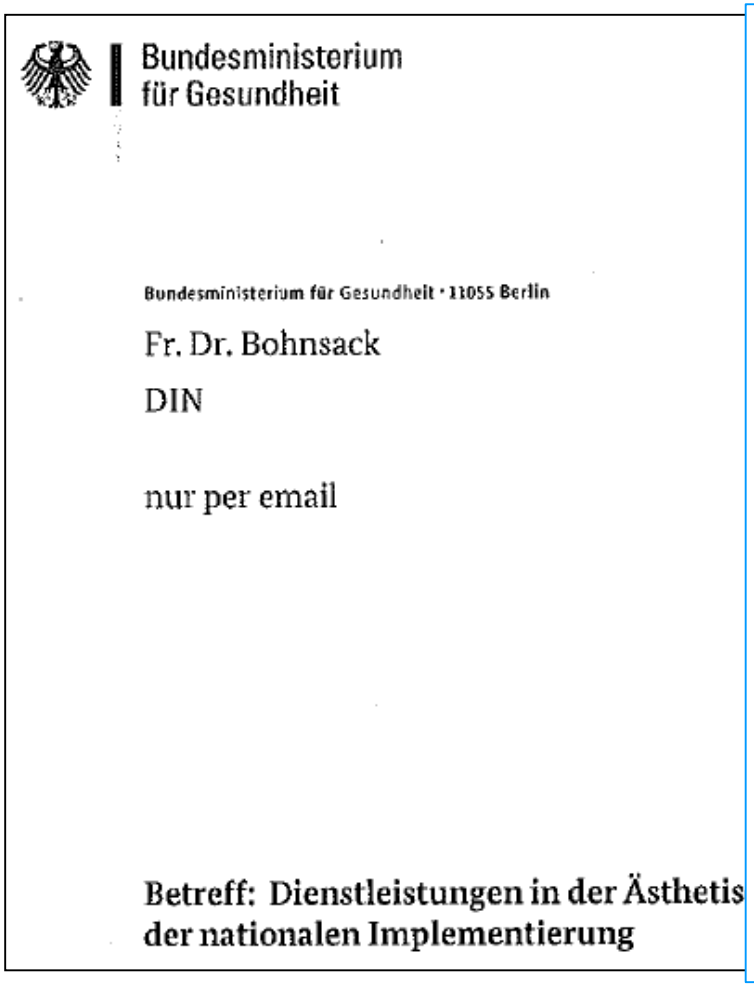
on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

„….is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency ('the founding principles').“

GJ: **Real Life of Standardisation?**

- **CEN WGs are not *transparent***
- **Open only for payers: *„openness???“***
- ***„Consensus“* by randomly assembled groups, definitely no *independence from special interests* and no signs of added value for patients = *efficiency!?*** *(see ‘the founding principles’).*
- **CEN ignoring sustained opposition: EU Council,** *CPME, UEMS, Governments of Germany, Spain, Poland, ESIP, HOPE, CED, ETUC, EPSU, AEMH, CEOM, EANA, EJD, EMSA, EFMS, UEMO…*

Letter concerning EN 16372



Bundesministerium für Gesundheit

Bundesministerium für Gesundheit · 11055 Berlin

Fr. Dr. Bohnsack

DIN

nur per email

Betreff: Dienstleistungen in der Ästhetis der nationalen Implementierung

Norm an den entsprechenden Stellen folgende Bundes- und Ländergesetze keine Beachtung:

- Bundesdatenschutzgesetz
- Telekommunikationsgesetz
- Telemediengesetz
- Signaturgesetz sowie die Verordnung zur elektronischen Signatur
- Archivgesetz
- Gesetz über die Ausführung des Gesetzes zu Art. 10 Grundgesetz (NRW)
- Datenschutzgesetze / Gesundheitsdatenschutzgesetze der Länder
- Gesetze der Länder über den öffentlichen Gesundheitsdienst
- Gesetz über Hilfen und Schutzmaßnahmen bei psychischen Erkrankungen
- § 630f BGB
- § 203 Strafgesetzbuch
- § 3 Berufsordnung Heilberufs- und Kammergesetze der Länder sowie Berufsordnungen der Ärztekammern (insbesondere die § 3 der Musterberufsordnung für Arztinnen und Ärzte entsprechenden Vorschriften)
- Krankenhausgesetz
- Medizinproduktegesetz
- Medizinprodukte-Betreiber-Verordnung
- Medizinprodukte-Sicherheitsplan-Verordnung
- Qualitätssicherung in der medizinischen Versorgung
- Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriums-medizinischer Untersuchungen – Rili-BÄK
- Empfehlungen der BÄK zur ärztlichen Schweigepflicht, Datenschutz und Datenverarbeitung in der Arztpraxis

Collision with pre-existing regulations!!

Market

- Standards

– Exchange and comparison of products and procedures

– Economy/Profit

Healthcare

- Clinical guidelines

- High quality care of individual patients

- Ethics/ Value

Irregular proceedings within the CEN Healthcare Services Focus Group (HSFG)

The meeting minutes have in the past often misrepresented the discussions and omitted important arguments that were presented, often with the incorrect justification "out of scope".

[Source: Extract from the Joint Letter by the Healthcare Stakeholder Group on the CEN Healthcare Services Focus Group (HSFG), September 2017]

Existing standards of CEN

- DIN EN 16372, Aesthetic surgery services
- DIN EN 16844, Aesthetic medicine – Non surgical medical procedures
- DIN EN 16872, Services of Medical Doctors with additional qualification in Homeopathy
- DIN EN 16686, Osteopathic healthcare provision
- DIN EN 16244, Healthcare provision by chiropractors

Driven by specific lobby groups
Fields without scientific basis

EU-PSQCWG 2/2014

In the discussion after the presentations the following points were raised:

- It is not clear whether the CEN standards are voluntary or mandatory. CEN explained that once a CEN standard is agreed, conflicting standards adopted by national standardisation bodies have to be withdrawn, but the use of the CEN standards is voluntary.

- The added value of CEN standards was questioned by several Group
CEN standards are perceived as developed by non-specialists and
account the scientific basis; they are not sufficiently cons evant
stakeholders at their development: they enter into e, where
traditionally standards (i.e. clinical guidelines) have by clinicians
themselves. CEN explained that the existing st to healthcare have
been requested by health professionals of alties themselves or by
patient groups, and emphasized that th ed by a consensus of experts
in a specific field, in a transparen cess. The purpose of the standard
was to regulate the service p the clinical procedures.

- Experience of so owed that ISO standards are accepted in
healthcare in r cts but not in services.

- Regar nity study there were strong views from some members of
th ist it. However, it was also noted that the study could help
th clear line between areas that could be covered by CEN standards and
hat should not be. Replying to the questions from the Group, the EC
explained that the study would not be launched before the adoption of the second

4

„What is the added value of your standards?“

Yes, standards are helpful !

…according to products and processes, e.g. quality management etc…

Need: **A standard for standardisation**! (GJ)

- ✓ ***Which problem is to be solved?***
- ✓ ***Relevance of the problem?***
- ✓ ***Scale of the problem?***
- ✓ ***Who is concerned?***
- ✓ ***How is the target group identified and involved?***
- ✓ ***Conflicts of interests!!!***
- ✓ ***(Scientific) basis of solution?***
- ✓ ***Basis and methods of development, pilot test?***
- ✓ ***Assessment - added value for patients***
- ✓ ***Evaluation!?***
- ✓ ***Expiry date!?***
- ✓ ***Total costs*** *(development, operating business and consequences)?*
- ✓ ***Adaptability to different health care systems?***

BUNDESÄRZTEKAMMER

Bekanntmachungen

On the recommendation of the Scientific Advisory Board, the Executive Board of the German Medical Association adopted at its meeting on 25 September 2015:

Statement on the

"Standardisation proposals regarding healthcare services from the physicians point of view"

Foreword

Standards regulate the safety of medical devices and technical operations for diagnostic and therapeutic procedures. But standardisation efforts have now also set their sights on services in the healthcare sector. Healthcare services must, however, categorically be regarded as complex interventions. Accordingly, quality assurance of medical activities rests both internationally and nationally upon the state-of-the-art in medical science and technology and thus on the principle of evidence-based medicine and guidelines. The primary intentions behind this are to protect patients, provide assurance for the physicians treating them and to ensure high-quality healthcare, bearing in mind the individual physician-patient relationship and the therapeutic discretion of the physician.

In recognition of these basic principles of medical practice, the Treaty on the Functioning of the European Union (TFEU) stipulates, with good reason, the protection of each Member State's responsibility for defining its own health policy and for the organisation and delivery of its health services and medical care. However, despite the fact that these responsibilities are explicitly acknowledged under European law, both individual representatives of so-called "interested parties" and the European Commission are increasing their efforts to regulate healthcare services by means of technical standardisation. The current negotiations regarding the proposed free trade agreement (TTIP) also raise fears that its purview could include and regulate healthcare services, thus subjecting them to standardisation.

Through numerous initiatives, the German Medical Association has already expressed that the standardisation of healthcare services at the national, European and international level should be firmly rejected. However, given that there had been no scientific study of this topic to date, the Executive Board of the German Medical Association commissioned its Scientific Advisory Board to examine the methodological foundations, as well as the implications of standardisation in the health sector from a scientific medical point of view. Based on the understanding that patients and the progression of their diseases are neither standardised nor capable of being standardised, it was especially important in this case to bring out the basic principles for individualised state-of-the-art medical care.

The statement at hand clearly illustrates the divergent objectives and conceptual differences between the drafting of guidelines, on the one hand, and standards on the other. At the same time, it becomes clear that standards are not an appropriate regulatory tool for the field of healthcare services and, in particular, for the work inherent to the practice of medicine, since, in this field, information or specifications must be interpreted and evaluated on an individual basis.

To do justice to this complex issue and take into account a variety of perspectives, the Working Group was staffed with an interdisciplinary team, in cooperation with the Association of the Scientific Medical Societies in Germany. In sometimes controversial, but always constructive discussions, members and guests of the Working Group carefully formulated the statement and recommended it to the Executive Board of the German Medical Association for a decision. For this we would like to take this opportunity to sincerely thank all parties involved.

The unabridged version of the statement presents a profound analysis of this subject matter. The abridged version offers a supplementary compact treatment of this argument. The hope is also to make the standardisation efforts of the European Commission widely known and, in particular, to alert policy makers at the national as well as the European level to questions and problems associated with the standardisation of healthcare services. With this in mind, the Executive Board of the German Medical Association reached a decision to translate the statement into English. The stated goal of these efforts is to ensure that standardisation is introduced in a way that is nuanced and appropriate going forward and thus bring to an end the inappropriate attempt to standardise healthcare services.

Prof. Dr. med.
Frank Ulrich Montgomery
Präsident der Bundesärztekammer
und des Deutschen Ärztetages

Prof. Dr. med. Dr. h. c. Peter C. Scriba
Vorsitzender des
Wissenschaftlichen Beirats
der Bundesärztekammer

Prof. Dr. phil. Robert Jüttte
Federführender des Arbeitskreises

Preamble

The primary objective of standardisation is the methodical, collaborative achievement of uniformity of tangible and intangible goods. The task of physicians is to preserve life, protect and restore health, alleviate suffering, support the dying and participate in the preservation of the natural foundations of life with regard for their importance for human health. By practicing medicine any exercise of the profession is understood by which medical knowledge can be used or used among other things. Practicing medicine thus requires the necessary professional qualifications and compliance with the accepted state of medical knowledge.

Against this background the present statement of the Scientific Advisory Board of the German Medical Association calls attention to the questions of what constitutes individualised state-of-the-art medical care, where might standardisation be reasonable from the point of view of physicians and patients (see chapter

Source: Deutsches Ärzteblatt | Ausgabendatum | DOI: 10.3238/arztebl.2015_SN_Baek_Normung01_engl01

http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/WB/Normung_Langfassung.pdf

Patient care does not need

mechanising and bureaucrazy

but

humanising and values.

So does Europe!

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