

Franz Kainberger
Heinrich Czembirek
Franz Frühwald
Peter Pokieser
Herwig Imhof

Guidelines and algorithms: strategies for standardization of referral criteria in diagnostic radiology

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F. Kainberger (✉) · P. Pokieser · H. Imhof
Department of Diagnostic Radiology,
University of Vienna,
Allgemeines Krankenhaus,
Währinger Gürtel 18–20,
1090 Vienna, Austria
E-mail: franz.kainberger@billrothhaus.at
Phone: +43-1-404005803
Fax: +43-1-404003777

H. Czembirek
Zentralröntgeninstitut, Lainz Hospital,
Wolkersbergenstrasse 1, 1130 Vienna,
Austria

F. Frühwald
Frühwald-Institute of Diagnostic Imaging,
Kremsgasse 16A, 3100 St. Pölten, Austria

Abstract Guidelines can be regarded as special forms of algorithms and have been shown to be useful tools for supporting medical decision making. With the Council Directive 97/43/Euratom recommendations concerning referral criteria for medical exposure have to be implemented into national law of all EU member states. The time- and cost-consuming efforts of developing, implementing, and updating such guidelines are balanced by the acceptance in clinical practice and eventual better health outcomes. Clearly defined objectives with special attention drawn on national and regional differences among potential users, support from organisations with expertise in evidence-based medicine, separated development of the evidence com-

ponent and the recommendations component, and large-scale strategies for distribution and implementation are necessary. Editors as well as users of guidelines for referral criteria have to be aware which expectations can be met and which cannot be fulfilled with this instrument; thus, dealing with guidelines requires a new form of “diagnostic reasoning” based on medical ethics.

Keywords Diagnostic imaging · Evidence-based medicine · Radiology · Practice guidelines · Decision support techniques

Introduction

Referral of patients to a diagnostic procedure is determined mainly by empirical and intuitive reasons [1, 2, 3]. Generally, it has been estimated that only 10–20% of medical decisions have been rigorously evidence based, although more recent studies have shown a higher proportion of patient management based on strong evidence of research [4]. According to Dehn et al., approximately 40% of referrals to imaging investigations in the U.S. were classified as inappropriate or at least not contributing to establishing a diagnosis [5]. The insufficient knowledge of clinicians and the abuse of self-referral were identified as main sources of this fact.

The implementation of standardized referral criteria in diagnostic radiology has been driven mainly by two independent developments in North America and in Europe. In the U.S., the aim was to contain rising health care costs, fueled by increased demand for care, more expensive technologies and an ageing population [6, 7]. In Europe, the Council Directive 97/43/Euratom (Medical Exposure Directive, MED; internet address: http://europa.eu.int/eur-lex/en/lif/dat/1997/en_397L0043.html) was released to avoid unnecessary radiation exposure [8].

In the MED, a new concept of radiation protection with a shift from protective measures to a more complex system of prevention has been designed [9]. It reflects a paradigm shift in the whole field of safety technologies from a problem-solving to a goal-directed access. A

Table 1 Guidelines for referrals to imaging procedures published by radiological societies of EU member states. Selection based upon weblinks listed in www.eur.org

Country	Society	Weblink of guideline
Austria	Österreichische Röntgengesellschaft (ÖRG), Verband für Medizinischen Strahlenschutz in Österreich (VMSÖ), Bundesfachgruppe Radiologie der Österreichischen Ärztekammer (BURAD)	www.oerg.at/quali.htm
Denmark	Dansk Radiologisk Selskab	http://www.dr.dk/guidelines/rtg/procedure.htm
France	College des Enseignants de Radiologie de France (CERF): L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)	http://www.med.univ-rennes1.fr/cerf/guide.html
Germany	Deutsche Röntgengesellschaft (DRG), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF)	http://www.drg.de/
Great Britain	Royal College of Radiologists (RCR)	http://www.rcr.ac.uk/
Spain	Sociedad Espanola de Radiología Médica (SERAM)	http://www.seram.es/

crucial part is the request for standardized indications to imaging procedures that is expressed in Article 6(2) of the MED: “Member States shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure.” [8]. With the list of guidelines issued by the Royal College of Radiologists an important example was set in accomplishing this task [10]. Various other guidelines have been published in European and North American countries (Table 1) [11, 12, 13, 14, 15].

New forms of validation of medical procedures have been implemented with evidence-based medicine (EBM) being the one of highest importance [16, 17]. As an example, for referrals of lumbar spine radiographs the high value of guidelines could be shown [18]. All of these developments have led to a steadily increasing number of guidelines issued by many health care institutions and with some of their contents contradicting each other [19, 20, 21]. Critics have faulted this trend for paying not enough attention to clinical experience and reasoning [22]. Profound concerns have been expressed about limitations in “freedom of choice” of medical decisions [23]. Cabana et al. catalogued 1500 guidelines and practice recommendations from which the majority was accepted only by a small number of physicians [24]. Similarly, for radiological guidelines a low acceptance rate has been reported by Tigges et al. [25].

The controversies among different opinions and between theory and practice indicate that a new form of diagnostic reasoning may be necessary to cope with the requirements of modern medicine [9, 26]. The aim of this review is to describe principles of implementing guidelines and algorithms basing on own experiences.

What is a guideline, what an algorithm?

Guidelines are, because of their feasibility in clinical practice, the most commonly used instruments to support a medical decision. As defined by the Institute of Medicine, clinical guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” [27]. Guidelines can be regarded as simple forms of algorithms.

Algorithms, or decision trees, are systematic processes consisting of an ordered sequence of steps with each of them depending on the outcome of the previous one [28, 29]. Originally used in mathematics and informatics (and named after the Arabian mathematician M. al-Khwarizmi) this term has been applied in clinical medicine for structured protocols of medical decisions [30, 31]. Besides the advantage of precisely formulated iterative thought processes there is an inherent reduction of patient care into a sequence of binary (yes/no) decisions [20]. In Germany, such algorithms have been developed for several subspecialties of diagnostic imaging (Internet address: www.drg.de) [14].

Other options for improving the quality of medical decisions are practice recommendations, consensus reports, or techniques of quality control programs. Generally they are, in contrast to guidelines and algorithms, less advanced in their development and applications.

Objectives

Guidelines, algorithms, practice recommendations, etc., are instruments for a structured approach to establish a

Table 2 Quality criteria of guidelines and checklist of items (modified for radiological purposes after [17, 29])

Item	Details
Development	Editors: representative experts from three fields: statistics; clinical speciality; clinical practice Objectives: relevance, definition of targeted groups of persons' consensus Structure: evidence-based and instructional component, comparability to be reviewed Content: systematic methodology in development; validity, reliability and reproducibility of evidence; flexibility (covering of controversial points and exceptions to the rules); practicability (clearness, user-friendliness); analysis of cost-effectiveness
Distribution and implementation	Educational activities
Review, updating	Definition of date and modality of reviewing success in clinical practice and update of content

medical decision. The term indication refers to a purpose-oriented medical decision which results in a treatment or a diagnostic test [28, 32]. Justification "shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause." (MED, Article 3) [8]. More rigorous proof for the process of indication has been attempted including cost-benefit analyses by Tversky et al. [36] and computer-assisted diagnosis [2, 33, 34, 35].

However, rational arguments should support, but not totally replace, any individual medical decision. The unique character of an individual patient's disease does not always follow strict guidelines. According to Gierer all formal thinking includes intuitive assumptions [37]. An important argument supporting the intuitive and the empiric component of clinical reasoning are relevant true-positive findings in radiological examinations.

A rational indication should provide a maximum current medical knowledge for a specific clinical situation. Medical knowledge, therefore, should be structured in a new symptom-based or problem-oriented manner through systematically catalogued guidelines. Development, implementation, and audit of the instruments of justification should follow the rules of EBM and comply with certain quality criteria (Table 2). The EBM is defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients [17].

Radiation protection, in this context, should be defined as a complex system of managing the process of diagnostics rather than a simple set of rules to improve X-ray procedures. With a systematically driven justification of radiological investigations a further significant reduction of radiation exposure may be expected. Other aspects of an evidence-based indication for imaging procedures with causal pathways to health outcomes are: consistency of care and cost-effectiveness; transfer

of medical information; and stimulation of research activities.

Consistency of care and cost-effectiveness

Variations in service delivery exist among providers, hospitals and geographical regions [38]. Guidelines and algorithms may be regarded as tools for making care more consistent and efficient. On the other hand, regional inconsistencies in clinical practice may be due to different epidemiological expressions of specific disease entities. The influence of local circumstances is even more important with respect to different traditions and to differences in health care systems. Such circumstances can only be addressed by a guideline if it is delivered on a national, regional, or local level. An example may be the indication for mammography in asymptomatic individuals between 40 and 50 years: in the U.K., such referral is regarded as not indicated [10]; in Austria, the same is recommended at 2-year intervals [11]. Another example concerns dysplasia of the infant hip: in the British guidelines this topic is not mentioned, whereas it is listed in the Austrian guidelines perhaps because this disease is more common in certain Alpine regions.

Cost-effectiveness may be improved by reducing unnecessary investigations. With this, either overuse or underuse of services should be avoided. Performing too many examinations leads to false-positive diagnoses (errors of commission). With further diagnostic measures, such errors may be discovered at even higher cost [2]. The underuse of diagnostic tests (errors of omission) may result in false-negative diagnoses. Stender pointed out that the risk of omitting an X-ray examination might be higher than the assumed stochastic risk of radiation exposure [39]. Officially approved recommendations may reduce both costs and unnecessary radiation exposure by strengthening the confidence of clinically acting physicians in their attempts to find the right decision.

The development as well as the implementation of guidelines is an expensive enterprise. For Germany, the cost of developing a single evidence-based practise-guideline for therapy was calculated to be approximately 200,000–250,000 Euro [40]. Costs of the Austrian project launched for the development of the first issue of referral guidelines in diagnostic radiology were 45,000 Euro, even with the involved experts working without salary. Such efforts of development of guidelines are only justified in case of disease entities with high clinical relevance.

Transfer of medical information

With respect to the continuous decrease of the half-life of medical knowledge and concomitant increase of its complexity, information has to be provided in a form that is directly applicable in clinical situations. With structured and practice-oriented comprehensive texts containing relevant information, such as guidelines or algorithms, the gap between what clinicians do and what scientific evidence supports may be reduced [41].

Medical teaching has a long tradition, with main steps made by Arabian and Jewish scholars in the Middle Ages to structure the content of scientific knowledge [42]. In the context of modern medicine, guidelines and algorithms may be regarded as important educational instruments that should be used to refine medical information [43]. Plans exist to integrate the catalogue of referral guidelines in the pre-graduate training of students at a medical school as suggested by Levin [22]; thus, they can be considered as part of a new form of knowledge management in medicine with a strong focus on problem-oriented learning.

Stimulation of research activities

Recognising the presence or absence of evidence can redirect the work of investigators and encourage funding organisations to support studies [44]. Specific questions to be answered may be detected by the evidence to justify conclusions of effectiveness. Gaps in the evidence, for which future research is needed, may be identified [45]. This includes the level of evidence of radiological research that has been shown to support less than 10% of standard imaging procedures with sufficient randomised controlled trials, meta-analyses or systematic reviews [10, 16]. Risk assessment studies and aspects of radiation protection are of specific interest in the field of diagnostic radiology and may be faced more clearly.

Indicators are needed to measure how good guidelines are practised. They have to refer to medical knowledge, to the practise and to the health outcome.

Ongoing research is performed to improve strategies for measuring the quality of guidelines [20, 45]. With respect to quality control and audit programs, guidelines and algorithms may be used as a basis for developing standards and can be used for comparing and improving different diagnostic strategies [18, 46].

Development and integration in clinical practice

Distinct rules for the development, implementation and evaluation of guidelines can be extracted from experiences and recommendations existing in the literature [26, 45, 47, 48, 49].

Development

The quality of guidelines strongly influences their acceptance by clinicians. Controversial, vague or non-specific guidelines have been reported to be a major source of rejection by general practitioners [49]. Besides keeping ongoing contact with institutions with experience in defining the evidence, the implementation of data-collecting systems and of computerized decision analysis, such as the decision-tree methodology, should be advanced [50, 51, 52]. A specific example in establishing a rational indication for an imaging procedure is the application of the Ottawa ankle rules [53]. Medical societies play a crucial role in the creation of guidelines that afterwards are approved by governmental bodies [46, 54]. The list of experts enrolled in the process of development should include statisticians and biometricians as well as carefully selected clinicians. Guidelines edited by governments or payers to maintain cost-effectiveness may be resented by clinicians and patients as an invasion of personal autonomy.

The development of guidelines should be performed in three steps: firstly, a planning phase with analysis of the background and the relevance. The second phase is to gain interdisciplinary consensus among all involved health care professionals (Table 3) [15]. In Great Britain, historically most guidelines have been derived from consensus conferences or expert opinion [20]. In Austria, the process of finding consensus among radiologists, non-radiological professionals, general practitioners, insurance companies and governmental bodies took approximately 6 months. Various conflicts of interest have to be expected mainly arising from economic backgrounds [29]. Such opinion-based consensus methods are of high importance to gain primary acceptance of the projects. They are, however, more vulnerable to bias and conflicts of interest than EBM that link recommendations directly to data [20]. The most commonly used strategies of gaining consensus are consensus conferences and Delphi reports [17]. In a modified

Table 3 Formal steps of guideline development (modified after [45]) and details and amount of required time of the realisation of the Austrian referral guideline (www.oerg.at/quali.htm) [11]. Finalisation of the project is planned to be with support of supranational bodies

Task	Involved persons	Amount of time
Phase 1: Planning		
Preparation (data collection, testing, review of literature, funding)	Committee of proponents	7 months
Concept with identification and refinement of the subject area	Committee of proponents	2 months
Phase 2: Development and implementation of consensus guidelines		
Convening and running guideline development groups	Seven working groups (ca. 70 people)	4 months
Issuing a first release of a consensus guideline	Three editors	3 months
Educational program (seminars)	ca. 300	Ongoing
Phase 3: Development and implementation of evidence-based guidelines		
Assessment of evidence on the basis of systematic reviews		Planned
Translation of evidence into a guideline		Planned
External review of the guideline		Planned

Table 4 Specific items for establishing referral guidelines according to the MED (Article 3) [8]

1. Taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation
2. All new types of practices involving medical exposure shall be justified in advance before being generally adopted
3. Existing types of practices involving medical exposure may be reviewed whenever new, important evidence about their efficacy or consequences is acquired
4. Special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds

version of a Delphi report the appropriateness criteria issued by the American College of Radiologists were developed [13]. During the third phase explicit methods are installed to develop evidence-based guidelines to maintain quality and make them comparable to each other (Table 3). Such guidelines should contain information according to distinct rules of EBM and to issues of the MED [8, 10, 17].

Guidelines should be structured into two parts with the first comprising the best evidence and the second for implementation in clinical practice [17]. The first, the evidence component, is to describe the objectives and to summarize the recent evidence. A comprehensive review of the literature has to be carried out, preferably of that within the previous 12 months. Each recommendation should be validated by a specific citation with special attention drawn to a publication about the risk of radiation exposure (Table 4) [10]. Furthermore, it should be tagged by the level of evidence upon which it is based [17, 55]. The detailed instructional component is to refer to its applicability in clinical practice. This includes patients' expectations about the values and utilities compatible with the recommendations, the

amount of time and costs to develop a guideline with respect to the burden of disease as well as its prevalence and potential outcome, the potential sequels on a health care system (e.g. raising or lowering the number of investigations), and how to surmount potential barriers (such as fear of litigation, organisational barriers, inflexible medical traditions or authorities).

As the content of the evidence component is the result of an abstraction process and, in contrast, the instructional component will put the same content in concrete forms, these two components should be developed independently [17, 47]. For the users, the steps of development should be displayed in a methods section as clearly as possible.

Distribution, implementation and reviewing

Several authors have shown that a simple publication of guidelines in scientific journals or books on a national level will have at best a modest effect on providers [30, 41, 56]. To change practice behaviour effectively, active implementation strategies in the form of educational programs with feedback have to be implemented [30]. Access to the text of guidelines has to be as easy as possible, now preferably with support of the Internet. In Austria, an initiative has been started to educate actively all health professionals involved in the application of ionising radiation in medicine. It is integrated in the annual program for continuing education in radiation protection following regulations of Austrian laws.

Guidelines should receive external review to ensure their validity, clarity and applicability [45]. Reviewers should be familiar with the clinical content and should be experienced in systematic reviews or guideline development. The guideline can be updated as soon as each piece of relevant new evidence is published, but it is better to specify a date for updating the systematic

review that underpins the guideline. Structured quality control programs with audit cycles should be implemented.

Integration in a comprehensive concept of diagnostic imaging

The development of clinical practice guidelines has, similar to other decision-making procedures in health care, as much a political as a scientific component. Paradigm shifts in the fundamentals of diagnostic imaging are to be observed with a stronger consistency of care, information transfer with digital technologies, advanced cost-effectiveness calculations and new types of research projects. Moreover, all three partners in the triangular relationship "patient-referring physician-radiologist" are faced with modifications of their roles [57].

Especially the patients are changing from a state of being subjected to treatment to a partnership with more responsibility for own health and welfare [55]. Within this, guidelines as approved decision strategies are gaining increasing importance. Such fundamental changes in the roles and the behaviour of health professionals and patients seem only to be possible by integrating diagnostic radiology in the complex of medical ethics [9, 58, 59, 60, 61]. Issues of medical ethics, in a general sense, are regarded as necessary tools for performing good clinical practice and research to avoid fraud and harm to patients. Guidelines seem to be an effective instrument in overcoming problems resulting from applications of nonmedical values combined with intense pressures on health care provision.

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