

Guidelines and evidence based medicine. The importance of stakeholder involvement

Francesco Massoni ¹, Pasquale Ricci ¹, Serafino Ricci ¹

¹ *Department of Anatomical Sciences, histological, legal medicine and locomotor apparatus - University "Sapienza" of Rome*

Abstract

With the depenalization of professional conduct of the physician in case of adherence to the guidelines proposed by L. 189/2012 the discussion on the quality of the available guidelines in the literature has led the authors to a review with particular regard to stakeholder involvement in the elaboration process. Evident critical points arise in the accessible studies that have used as an assessment tool a scientifically validated questionnaire (Appraisal of Guidelines for Research and Evaluation – AGREE). As a result the solution of the legislature, although useful to contain the phenomenon of defensive medicine, may be useless and ineffective in criminal cases where fundamental and absolute rights, as the right to life and health of patients, are involved.

Keywords

Guidelines, Stakeholders; Professional responsibility

Corresponding author

Prof. Serafino Ricci
Viale Regina Elena, 336
00161 Roma
Email: serafino.ricci@uniroma1.it

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Introduction

After the L. 189/2012 in Italy the debate on the topic of professional responsibility has increased and the attention of health policy has once again raised the issue of the definition of serious fault.

In order to put a stop to the phenomenon of defensive medicine and considerable increases in health care spending, the legislature depenalized the offense in the case of adherence to guidelines, without any reference to the quality of the recommendations proposed as *best scientific evidence*.

In particular, the stakeholder involvement is one of the most important aspects in the process of formulation of recommendations that could go also to influence their operational applicability.

And, therefore, serious doubts may arise in the evaluation of professional conduct also in case of adherence.

The authors propose a review of the literature on previous experience of assessing the quality of guidelines through the use of a standardized and validated scientifically tool.

Material and method

The used instrument in the selected articles is Appraisal of Guidelines for Research and Evaluation (AGREE), in both versions I and II, developed by the AGREE Next Steps Consortium and available on www.agreetrust.org.

This instrument consists of 23 items grouped into six areas: objectives and scope, stakeholder involvement, methodological rigor, clarity, applicability and editorial independence.

The items related to the domain “stakeholder involvement” are shown in Table I with clear removal of a single question in the new version of the AGREE II.

Each item is rated on a seven-point Likert scale from “strongly disagree” to “strongly agree” (1-7 respectively) [1].

The study predicts that the guidelines on a specific subject are submitted to the evaluation of more experts chosen on the basis of the interests in the management of type of pathology and patient. For each of the six dimensions of the instrument a score is calculated by adding together all the scores of each

evaluator for the items that compose the area.

The obtained score is standardized as a percentage of the maximum possible score for that area applying the following form:

$$\text{Score Domain} = \frac{\text{OS} - \text{MinPS}}{\text{MaxPS} - \text{MinPS}} \cdot 100$$

OS = Obtained Score;

MinPS = Minimum Possible score;

MaxPS = Maximum Possible score

In research of articles on Medline were used title’s keywords “guidelines” and “AGREE”. Forty-three results have been obtained, but removing the studies that did not provide for the use of the AGREE instrument or comments / letters to the editor or those that lacked one of the parameters considered (or just average, or median, or just only range) or was not possible to derive it, there are only eleven.

AGREE	4	The guideline development group includes individuals from all the relevant professional groups
	5	The patients’ views and preferences have been sought
	6	The target users of the guideline are clearly defined
	7	The guideline has been piloted among end users
AGREE II	4	The guideline development group includes individuals from all relevant professional groups
	5	The views and preferences of the target population (patients, public, etc.) have been sought
	6	The target users of the guideline are clearly defined

Table I. Items of area “stakeholder involvement” in AGREE and in AGREE II

Results

The articles selected are shown in Table II.

In the study of Lytras et al. [2] six expert evaluators examined seven guidelines on occupational asthma choices on the Medline database: two guidelines remained much below the 50%, EAACI [3] 39% and EAACI PEF [4] 36%.

In the systematic review [5] of published guidelines on the treatment of acne vulgaris from July 2002 to July 2012 in English, French, German and Spanish, three expert evaluators have worked on six selected articles and in this case 3/6 have reported values <50%: Strauss et al. [6] (27,7%), AFSSAPS [7] (31,4%) and Orozco et al. [8] (14,8%).

Sabharwal et al. [9] have studied the quality of cardiac clinical practice guidelines published in seven cardiac cardiovascular journals between January 2001 and May 2011 (one hundred and one!), and, examined by two researchers, the minimum value achieved 39.9%.

In the analysis of thirteen guidelines in English on genetic syndromes that confer susceptibility to breast cancer [10], selected until October 2010 and reviewed by three reviewers, 6/13 <50% with the recommendations of the University of Michigan even 8.3% [11].

In the study by Polus et al. [12] on the quality of four WHO guidelines on maternal and child health published between 2007 and 2011 can be appreciated a chronological evolution from 32% of the P-PPH (2007) [13] to 86% of PE/E (2011) [14].

In the work of Don-Wauchope et al. [15] the AGREE II was applied by two evaluators on eleven guidelines for laboratory medicine available until December 2011. Nearly half (5/11) less than 50%, with the lowest result 11% [16].

In the study by Van Den Berg et al. [17] on the methodological quality of twelve international clinical guidelines for the management of malnutrition in adult cancer patients and reviewed by three reviewers, 8/12 ≤ 50% with Bozzetti et al. [18] and Braga et al. [19] 17%.

Burda et al. [20] with five independent evaluators have reviewed eleven clinical practice guidelines on the frequency of screening mammography in asymptomatic women (40-49 years) and published from 2005 to 2010, and 9/11 <50% with Michigan Quality Improvement Consortium 0% [21] and Society of Breast Imaging 8% [22].

Study	Mean	Median	Range
Lytras, 2013 [2]	53,14	55	36-74
Sanclemente, 2013 [5]	46,23	43,45	14,8-81,4
Sabharwal, 2013 [9]	58,5	58,3	39,9-80,6
Simone, 2012 [10]	50,84	50	8,3-75
Polus, 2012 [12]	59,5	60	32-86
Don-Wauchope, 2012 [15]	50,18	50	11-100
van den Berg, 2012 [17]	42,83	36	17-83
Burda, 2011 [20]	26	22	0-70
Lo Vecchio, 2011 [23]	39,8	35	14-88,9
Manchikanti, 2008 [25]	6,25	6,25	6,25-6,25
Hulshof, 2007 [28]	67	65,6	58,3-81,3

Table II. Selected articles

In the study by Lo Vecchio et al. [23] on nine guidelines in English about the management of acute gastroenteritis in children examined from six auditors 7/9 <50%, with 14% of Sandhu et al. [24]. The evaluation of the chapters of ACOEM guidelines [25] on the management of low back pain [26] and chronic pain [27] score was not different from 6.25%. And finally, only in the study by Hulshof and Hoenen [28] on six guidelines of Netherlands Society of Occupational Medicine examined by twenty experts 6/6 > 50%.

Discussion

Stakeholders are all subjects who have an interest in the purpose / objective of the recommendations, such as health professionals, patients, public and private research funding, managers, entrepreneurs and producers.

The involvement of these subjects is justified by many reasons, in particular for transparency, but in some cases a stakeholder engagement inclusive, fair and appropriate can be difficult [29].

There have been experiences that have analyzed the stakeholder engagement only in the development and evaluation of the recommendations, neglecting the next and operational phase, that is sharing in the decision making process [30,31], maybe because they are not understood [32,33] or because the heterogeneity of “users” and their degree of involvement in decision making [34].

However it has been shown that the adoption of shared decision making and the involvement in the implementation process of the disclosure of scientific evidence [35] has had important and significant impact in efficiency [36], as was the case for infection control [37].

The involvement of a part / interest can lead, for example, to a simplification of complex innovations [32]. And also, like the involvement of the management can help to mobilize resources, so that patients, defined as “temporary members” of health care organizations, contributes to faster adoption of the recommendation [38,39].

Health policies, both U.S.A. than UK, explicitly promote stakeholder engagement considering a means to achieve the aim of reducing costs [40] and improving quality, increasing satisfaction [41]. These policies define user as a exacting subject and buyer of a service, with the responsibility to contribute to the common good through active participation [42].

The reasons for failure in stakeholder engagement, as can be appreciated in most of the articles examined in this paper must be sought in the scarce organization and competence, financial difficulties and time [43].

Resulting defective in this aspect, it is also conditioned the implementation of the recommendation and, therefore, also the subsequent use in the medico legal evaluation of professional responsibility where the respect for the prevalent right to the life or health of single patient is more important than health care cost containment.

Conclusion

The legislature, decriminalizing the professional conduct only on the basis of the adherence to guidelines, neglecting the consideration of the quality of the guidelines currently available in the literature, has strongly influenced the effectiveness of this instrument of health policy.

Question for further research

The development of an instrument that ensures the quality of guideline

The review in brief	
Clinical question	To assess the quality of guidelines through the use of a standardized and validated scientifically tool.
Type of review	Systematic
Search of the literature	Medline search for articles using the following keywords: guidelines and AGREE
Conclusions	The legislature, decriminalizing the professional conduct only on the basis of the adherence to guidelines has strongly influenced the effectiveness of this instrument of health policy.
Limitations	The AGREE doesn't evaluate the content of the guideline, but only the method

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