

EDITORIAL

On transparency in health care guidelines

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The US Institute of Medicine (IOM) defines clinical practice guidelines as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” [1]. Health care guidelines and their appropriate implementation are of interest to health care providers, national health organizations, professional societies, policy-makers, patients and the public.

The need for quality standards in the development of health care guidelines is universally recognized and several tools are available to achieve them [2] as well as to evaluate their quality and credibility [3].

AGREE II [4], an update of the Appraisal of Guidelines for Research & Evaluation instrument [5], is widely accepted as the international gold standard for the appraisal of guidelines. The instrument is composed of 23 items within 6 quality domains: 1) scope and purpose, 2) stakeholder involvement, 3) rigor of development, 4) clarity of presentation, 5) applicability, and 6) editorial independence.

The possibility for the general public to access guidelines is a fundamental requisite. In Italy, for example, the National Guidelines System (*Sistema Nazionale Linee Guida*) [6], which prepares recommendations for clinical behavior based on the most recent and updated scientific data, also elaborates versions for the public. The duty of guideline developers to make them available and easily accessible is absolute, especially when the issues addressed are of social and ethical importance. A classic example of this is the issue of “assisted suicide” in countries in which some form of euthanasia is allowed. One would expect total transparency in this, of all subjects, so that it is surprising to discover that it is not always present.

It is as well to begin with a few preliminary considerations:

- decisions regarding persons who are close to dying are of fundamental importance in bioethics. They directly involve the patients, their families, and health-care workers. The ethical and regulatory framework surrounding this topic has received considerable attention from legal, medical, and bioethical experts, as well as from those in numerous other fields. It is an issue to

which no-one can remain indifferent, whatever their health status;

- the debate raging in various national parliaments foments a constant confrontation between the supporters and opponents of so-called “assisted suicide”, and there is an ample body of literature on the subject;

- the authors are convinced that assisted suicide is incompatible with medical ethics: the practice of medicine is by its very nature aimed at the prevention, diagnosis, cure and treatment of disease: assisted suicide has no place in these aims. However, this is not the subject of the present article.

On 5th June 2014 the Assemblée Nationale du Québec adopted the “Loi concernant les soins de fin de vie” (Law concerning end-of-life care), which was passed on 10th June 2014 [7].

On 10th September 2015 the Collège des Médecins du Québec (Quebec College of Physicians), the Ordre des Pharmaciens du Québec (Quebec Order of Pharmacists), and the Ordre des Infirmières et Infirmiers du Québec (Quebec Order of Nurses) published the “Practice Guideline for medical aid in dying” (“Guide d’exercice sur l’aide médicale à mourir”) [8]. The guide “proposes regulations for the best possible medical aid in dying (MAD)” and has been applicable since December 2015, together with the law of 5th June 2014.

As noted above, it is not our intention here to add to the already ample literature on the subject of euthanasia. We would like instead to draw attention to a lack of transparency in the document published by the Collège des Médecins du Québec that has already been pointed out by the Physicians’ Alliance Against Euthanasia, according to which in Article 7.2 of the Guide: “the College orders doctors to falsify the real cause of death on the death certificate that is required by the Public Health Act, for patients who die by ‘medical aid in dying’ (MAD). This article clearly states that ‘the physician must write as an immediate cause of death the disease or morbid condition which justified the MAD. (...) The term ‘medical aid in dying’ should not be included in this report. Indeed, such information, if revealed to uninformed relatives, could firstly go against the will of a patient wishing to keep this information confidential and, secondly, cause them harm. This instruction by the

College is contrary to Article 19 of the Public Health Act Regulation which stipulates that 'the cause of death must be indicated in the most accurate manner possible'. It goes without saying that such a practice constitutes a severe breach of ethics, and it will inevitably lead to serious abuse, in addition to distorting the official statistics on the real causes of death in Quebec" [9].

This accusation of violation of medical ethics led us to check the original document, which, since it addresses a crucial issue for patients, physicians and physician-patient relations, one would expect to be readily available to everyone. Instead, an internet search for the document entitled "Guide d'Exercice sur l'Aide Médicale à Mourir" on the website of the Collège des Médecins du Québec surprisingly leads to a notice advising visitors to the site that the document can be found on the College's secure site, while "toutes les autres personnes qui souhaitent obtenir ce document doivent en faire la demande selon la procédure d'accès à l'information" (all other persons wishing to obtain the document should apply in accordance with 'Access to Information' procedures), for which an email address is supplied. We applied as instructed and with laudable promptness received, after only a few hours, the pdf version of the document and a courteous accompanying letter from the College secretariat. The letter contained this cautionary note: "Considérant que ce guide contient des informations cliniques sensibles, nous vous invitons à

faire preuve de prudence dans la diffusion de ces informations et à diriger les gens qui souhaitent avoir un exemplaire du document vers le Collège des Médecins du Québec" (As this guide contains sensitive clinical data, we would invite you to use prudence in circulating this information and to direct anyone wishing to obtain a copy of the document to the Collège des Médecins du Québec). In every nation the term "clinically sensitive data" is used to describe an individual's physical or mental health condition. In a non-clinical setting, "sensitive data" are those relating to racial or ethnic origin, political opinions, religious or other similar beliefs, membership of a trade union, sexual preferences, criminal convictions or proceedings [10]. The College Guideline, however, contains no "sensitive data", only generic procedures. It is therefore difficult to understand why such a document which, because of the importance of its subject matter should be available to everybody and freely debated, is instead kept under wrappers.

The Supreme Court's ruling has been attacked as placing people "at risk with no procedural safeguards, no ongoing monitoring and unclear policies around access" [11]. This unclear policy around access seems a lack of transparency and an infringement of the Canadian "Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise" [12], which devote a whole step (n. 16) to "Dissemination and implementation" of guidelines.

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