Standards of Care: Good or Evil?

The legal necessity to compensate individuals for care received that caused injury due to negligence gave rise to the concept of standard of care. In the health professions, this has proved to be of some benefit when protecting patients, especially in the area of research and where it may contradict or not reflect prevailing services. However, a standard of care may also imply or even impose a treatment regimen that, when not followed, would be considered negligent. This invited commentary for the IJP explores briefly the history of the development of this concept and proposes a contrarian view, using by way of example the McGill consensus statement on the standard of care for the treatment of the edentulous mandible.

When I put the phrase "standard of care" into the Google search engine I received 22,100,000 possible hits. In PubMed, I received 37,842 items. Putting "criteria AND standard of care" into PubMed gave me 9,296 items. When I limited the search to only dental journals, there were 948 items for "standard of care" and 236 for "criteria AND standard of care."

If you were to look at some of these papers you would be confused; and indeed, many of them start with the phrase (or something similar to): "This is a confusing area and is changing all the time." So in order to try to unravel this confusion, this commentary will look at the concept of standard of care from three different aspects (legal, research, and practice), and contrast it with what in my opinion is a more useful concept—that of a Minimum Acceptable Protocol (or set of principles), a MAP for different treatment modalities.

This entire debate began as a legal necessity to prove negligence. An 1856 United Kingdom court case found that in order to not breach a duty of care, the defendant must have generally met the standards of a "reasonable man."[1] In 1873, another court case in the United States described the actions of a "reasonable man of ordinary prudence."[2] In 1933 in the United Kingdom, a "reasonable person" was defined as "the man on the Clapham omnibus" and in 1999, Lord Steyn described the term as "commuters on the London underground."[1]

Of course, the commuter on the underground may possess a variety of skills (and in many cases may be considered unreasonable and imprudent), and may even be a dentist. When it comes to the professions, a higher standard is automatically required, especially for those professions regulated by their own bodies as well as independent councils (which in itself gives the courts some concern since they generally only accept professional opinion if it is deemed logical).

The definition of standard of care from a legal point of view has therefore emerged from claims of malpractice, and is to be found in the elements that define negligence[2,3]:

- A duty of care was owed to the patient
- The applicable standard of care was violated
- A compensatable injury was in fact suffered
- Injury was caused by substandard conduct

All of these elements must be proven to claim negligence and win the case of malpractice. From a dentist's (or any other health professional's) point of view, it could therefore be argued that the concept of a standard of care was an evil born of a legal necessity to protect the patient.

However, there is an area where it could be said that a standard of care is a good born of humanitarian necessity and is also to protect the patient. That area is in research involving human subjects. This has given rise to some lively debates in the bioethics literature,[4–11] especially when dealing with the human immunodeficiency virus and AIDS. In dentistry, dental researchers must also answer to local ethics committees and much of the dental research that has been carried out in the past would most certainly not be allowed today. For example, in 1949 liquefied phenol was placed onto exposed pulps of human teeth prior to capping in order to follow, by histology, the healing pattern and any new dentin formation. This can only be done by extracting the experimental teeth after various time periods, which is precisely what was done whether the procedure had failed or succeeded![12]

In modern times we are required to practice evidence-based levels of care, but in a clinical discipline such as dentistry, this causes problems when it comes to treatment options. A randomized and blind offering of treatment to some patients is sometimes refused on the grounds that the patients wanted only one type of treatment in the first place, and not that which was offered.[13] It is precisely the dilemma over choice of treatment that affects researchers searching for evidence-based comparisons and creates another and more pressing problem with the concept of standard of care: It is increasingly being used to assume a standard of *treatment* without taking into account resources available to provide that treatment. This has problems on two fronts, both in the research and practice contexts.

In the research context, there has been an interesting debate concerning the definitions of standard of care in a developing country. The US National Bioethics Advisory Commission's report on clinical trials in developing countries[6] noted that a standard of care could describe types or levels of treatment in a clinical setting, but may not serve as a justification for what should be provided in a research trial, and especially in a situation where there may be no care currently being experienced at all.[10] To this end, it has been argued that there may be a distinction between *de facto* standards set by the medical practices

for a community, and *de jure* standards of what interventions have proven to be more effective for that community.[5] It has been argued further that the standard of care in research should go beyond specific treatments to include political, economic, and social conditions.[4] There would therefore seem to be a compelling argument in research design for including the exigencies of the health care system within which such research is taking place, since that system is most likely to be responding to local conditions and resources.[10]

What then of the practice context—are there parallels here? To return for a moment to the legal issues founded on malpractice suits, it is accepted that, provided the treatment remains within the standard of care, proof of negligence is not dependent on an unfavorable outcome. The doctrine of "error of judgment" holds that the health professional has the "right to choose amongst reasonably acceptable therapeutic approaches" even if the choice turns out to be less than beneficial.[2] This then raises the issue of the use of the term "standard of care" in relation to the choice of treatment, which would from a legal point of view seem to be subsumed within that standard. This has the potential to create many dilemmas in terms of the manner in which any particular standard of care is determined. A recent infamous example will illustrate this.

In 2002 a prosthodontic conference in Montréal concluded with the so-called McGill consensus statement on the standard of care for the treatment of the edentulous mandible, which was an overdenture retained by two implants.[14] This was described as the "first choice" standard of care, an astonishingly insensitive statement to those of us working in developing countries. All contributors were from highly industrialized countries and seemed to have forgotten that the majority of the world's population is poor, almost certainly contains the majority of the world's edentulous population, and lives on less than US$2 per day. As Fitzpatrick[15] has pointed out, does this mean that patients who have adapted and are satisfied with their mucosa-borne dentures (which just happens to be the majority of complete denture wearers) are wrong? That the provider of those dentures is providing less-than-adequate treatment? Or indeed, that a fixed implant-supported prosthesis is *over*treatment?

This resonates well with the bioethical concerns of research cited above, and one could conclude that in this sense the concept of standard of care may be an evil born of the complacency of professionals stuck in the comfort zones of their high socioeconomic lives and circumstances with apparently no sense of what is happening in the rest of the world. I would suggest that this blinkered approach to health care is in itself negligent. My hope is that with the new world economic order that has inevitably to emerge from the current disastrous global economic meltdown, people will not remain silent and will engage with the needs of the many and retract from the complacency of the few, and also start to listen to the patient and their own choice and opinion. As Dr Martin Luther King, Jr once said, "Our lives begin to end the day we become silent about things that matter." I therefore call upon the profession to denounce such statements as that from McGill and for those who were part of it to reflect on its consequences, and to have the moral, ethical, and professional courage to retract.

My indignation aside, is there an alternative to standard of care when it comes to choice of treatment? My thesis is simple: there is, and that is to develop a series of principles gathered together into a protocol for each treatment modality for which there is a need to determine a minimum standard (which is just about everything). I have referred to this as a Minimum Acceptable Protocol, or MAP,[16,17] where the "P" is also synonymous with Principles. These can be agreed upon by the profession or a specialist branch of the profession using the best agreed evidence available, even if the highest available is expert opinion or "eminence-based" (Osswald MA, unpublished data, 2007). Now this is similar, but not identical, to clinical practice guidelines, because as Preston has pointed out, these often have a narrow focus, can have time-dependent limitations, and also, like standards of care, fail to recognize different therapeutic solutions.[18] So the difference is this: the standard of care (meaning treatment) implies that anything else is inferior, whereas a MAP does not specify a standard from the point of view of care (meaning treatment), but allows for a *variety* of treatments provided the principles are complied with. A standard of care that specifies treatment assumes the availability of resources to comply with that treatment, whereas a MAP, although absolute, allows the resources to be adapted to circumstances whilst at all times complying with the principles. This is also in accordance with the suggestion that guidelines should be combined with economic analyses to maximize treatment outcomes while minimizing outlay of resources.[18]

This issue of what standard of care we mean has become a kind of Garden of Good and Evil, and I would conclude that a MAP is most definitely a good born of the needs of the many. For the many in this world are poor and have as much right to a high standard of treatment as those who are rich. That standard can be maintained within a set of agreed-upon principles and can be applied in a more cost-effective manner. For example, it is possible to construct a set of mucosa-borne complete dentures in a few visits using inexpensive materials and techniques,

while at the same time complying with the principles set out in the guidelines[17] of a MAP for complete dentures. I have referred to this concept or philosophy of providing cost-effective treatment without violating any principles as "appropriatech"—the use of appropriate technology cost-effectively—and I believe it is the means by which we can provide high standards of treatment for the many, not just for the few.

In summary, the concept of standard of care was born originally of the necessity of the legal court process to understand a commonly accepted level of care when having to deal with alleged negligence and malpractice. This concept in the health professions has proved to be of some benefit when protecting patients, especially in the area of research and in circumstances where care is lacking because of resource constraints. However, the phrase "standard of care" has come to be used all too frequently to imply a particular treatment regimen; furthermore, it *imposes* a treatment regimen and implies that anything less is inferior and therefore negligent. This view takes no account of the resource constraints that usually affect the majority of people in this world who may require such treatment, for the majority are poor. It also takes no account of the patient's own preferences, nor does it allow for the fact that treatment options change with time.[15,18] An alternative concept is proposed: that of a Minimum Acceptable Protocol, which describes a set of principles that allow resources and therefore treatment to be adapted to those principles. It would be the violation of those principles that would be negligent, not the manner of complying with them.

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