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EDITORIAL

Next Edition of the ISPOR Code of Ethics: Is It Setting Us up for the Era of Digitized Health Care?

In this Issue of *Value in Health*, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Code of Ethics Task Force has published the next edition of the *ISPOR Code of Ethics* [1], updating the previous version from 2008 [2]. This completes an elaborate process of consultation and deliberation, which started in September 2015 [3].

Most of the 2008 statements have been maintained, at times with some rewording. New topics, such as on data protection and privacy, safety reporting and risk/benefit, incentives to research participants, registration of studies, research based on secondary data, data access, members acting on advisory boards or as Key Opinion Leaders, and patient engagement, have been added. These additions are in keeping with the stated objectives of the Task Force [3] to address gaps in the 2008 *Code*.

Compared with the previous *Code*, the number of chapters has increased, as has the number of statements: from 30 statements in five chapters in 2008 to now 72 statements in nine chapters. "Publication and Dissemination" was retained as a chapter; the chapter on research conduct (previously "Design and Research Practices") was renamed as "Research Design Considerations," and the previous chapters "Sponsorship" and "Relationships with Others" have been merged into one. The previous chapter "Role of ISPOR" has been moved to the Introduction. New chapters that have been added are "Ethical Principles," "Scope," "Data Considerations," "Patient Centricity and Patient Engagement," and, "Conclusion and Limitations."

Given previous criticism on the geographical representation and expertise of the Task Force [4], it is noteworthy that the Task Force members came from academic institutions as well as commercial entities located in Asia, Europe, and North America, including members with a background in ethics [3]. Two rounds of peer-review, via invitations to all ISPOR members, preceded this publication.

The Task Force report, including its appendices, provides detail and context for the statements by explaining why certain behavior is expected. However, arguably, this is mostly presented in an abbreviated form. Increasing the number of statements from 30 to 72 also led to some redundancy and overlap between statements. For example, staying truthful and transparent to what has been done in the research and to who has funded and conducted it, is currently the subject of at least six different statements. It may be debatable what the appropriate length of a code should be, but as more topics will likely need to be added in the future, great care had to be taken in maintaining a succinct code—not always easy in a multiauthor endeavor.

As health care and research continue to move into an electronic environment, the debate on informed consent has recently garnered renewed interest. Although research participants' informed consent is central to the Declaration of Helsinki [5], questions have emerged over the last years as to whether this requirement should be "streamlined" or waived in certain situations. For example, Faden et al. [6] discussed this in the context of learning health care systems and comparative effectiveness trials. They provide prerequisites as well as reasons and justifications for informed consent not being required in some situations. However, this position created considerable commentary [7], with diverse opinions being documented. This highlights the challenges of deriving norms that may not be as universally agreed upon as one might think, and illustrates the need of adapting previous norms to changing health care environments. Matters of informed consent, which were absent in the 2008 *Code*, are addressed in the revised *Code* in several statements.

Data sharing is another example of how the changing environment is impacting expected behaviors. Heated debate has been created by editors of major medical journals on data sharing requirements alongside publications of clinical trials, at the end of which, agreement was reached to have a statement accompany the manuscript submission regarding *if and when* data will be made available [8]. This outcome is less than what was initially intended, but editors remain optimistic, stating, "We envision a global research community in which sharing deidentified data becomes the norm." Looking into the respective statement in the *ISPOR Code of Ethics*, one could question whether the demand on ISPOR members is too high or too low and whether the society is divided on this, as the stated norm is: "Researchers should offer the right to access the anonymized, *group-level data* [italic font added by author] used in their research" [1]. In other words, did ISPOR have enough discourse to decide what the expected behavior on data sharing should be—deidentified subject-level data to all, deidentified subject-level data to peer-reviewers (upon their request or always), group-level data, or no requirement of sharing at all?

Now, let's come back to the question at hand: Is the *Code* setting us up for the era of digitized health care? It is a good start, as previous gaps that relate to the availability and analysis of "big data," such as data protection and privacy, safe storage, and data linking, have been closed [1]. However, digital transformation moves at a pace that makes it unlikely to fit the review and revision cycles of a Task Force. ISPOR may, therefore, consider the creation of a standing Ethics Committee, an idea already

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proposed in the editorial accompanying a previous edition of the *Code* [9]. Following the model of the *British Medical Journal*'s Ethic Committee, the scope of such a committee could include, among others, advising the ISPOR on emerging moral questions with potential applicability to the Society's members as well as ensuring that ethics topics are appropriately covered in the Society's activities [10].

An emerging question is, for example, about the ethics of using artificial intelligence (AI) in health care, including for resource allocation—a topic of high relevance to the ISPOR, given its mission statement: "To promote health economics and outcomes research excellence to improve decision making for health globally" [11]. The questions could be: What makes AI derived algorithms just? How can we ensure that we "do no harm" and provide benefit? What type and how complete would data input need to be to create the learning environment and to derive the algorithms? Other questions that arise relate to how ethical consideration can be fed into the AI system? Surprisingly, so far, autonomous driving seems to have received more attention on such topics compared with medical applications [12], potentially because the consequences are more visible and readily understood.

In summary, the Task Force should be complimented for revising the *ISPOR Code of Ethics*, expanding it to include the aspects missing in the previous *Code* and incorporating suggestions received from Society members. The publication of this edition will, however, merely signal the starting point for many more questions that need to be asked in the context of rapidly evolving digitized care and everything that comes with it. This will require much debate and input from Society members. Given that the Declaration of Helsinki has been revised nine times since its first publication in 1964 [5], we should expect no less in the coming decades. The channel or platform for future revisions is secondary so long as the discourse is lively and encouraged.

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