Scientific Guidelines and Their Implementation in Health Policy

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The comments of Kolominsky-Rabas and Caro [1] on the third edition of the Hanover Consensus provide an impression of the current nervousness and subtle positioning games of different stakeholders in Germany while discussing the use of economic evaluation techniques in medical care. As both authors present to the readers of their comment a strong belief that the Institute’s recently issued guidelines reflect the will of the sovereign and leave no room for discussion nor interpretation of their own methods, we intend to give a brief insight into some flaws of their own methods, as they are ignoring decades of health economic as well as economic research.

The Hanover Consensus in its tradition is a consensus of a large group of researchers and representatives from sickness funds, physicians’ associations as well as the industry. It does not duplicate textbook knowledge, nor does it interfere with the interest of the Institute for Quality and Efficiency in Health Care (IQWiG) in deriving disease-specific cost–benefit thresholds with methods, which will be unique worldwide, because they have never been used before in, or anywhere outside of, Germany. The Hanover Consensus is widely accepted in Germany; it became part of publication guidelines of scientific health economic journals and was referred to when the tool of cost–benefit analyses was implemented by the law. The various editions of the Hanover Consensus were even quoted in the current IQWiG methods paper itself.

As just mentioned, about 10 months after the new law became effective and the Hanover Consensus was released in Germany, the IQWiG has published a first draft of a shell of a methods paper, which is currently passionately debated in Germany.

One of the reasons why it is so hotly debated is because the technical annex that is supposed to contain all the important information, is only to be published after the end of the appeal period. In addition to breaking transparency rules, the recently published first draft of the IQWiG methods paper contains very little information on methodological issues, a point that the authors level at the Consensus. Furthermore, the IQWiG paper concentrates on trying to explain why a general threshold (e.g., “x” Euro per quality-adjusted life-year) would not be feasible in the context of the German health-care system. The alternative presented leads to a set of indication-specific thresholds, derived with the help of a vaguely founded efficiency frontier which lines up earlier available drugs merely on historical efficacy data. As a result of that failure to address economic theory, the concept has been rejected by a wide phalanx of health economists around the world—including members of the German Association of Health Economics. According to the German Social Law, the IQWiG is responsible for only the assessment, not for the appraisal. The latter is done by the Federal Joint Committee (G-BA) and the Federal Association of Sickness Funds, which is allowed to set maximum reimbursement prices for drugs.

Those institutions will have to make value judgments, regardless of the evaluation method used in the assessment, when they want to fulfil their legal responsibilities. With that in mind, it is common practice around the world that the perspective of analysis is chosen by the decision-making body and not by scientists issuing guidance on health economic methods. The economist is only the messenger within the boundaries of broadly socially accepted methods. This misunderstanding of the Consensus reflects a lack of experience the IQWiG has in conducting such studies, which we happily will discuss with them.

To be absolutely clear on one issue: we appreciate the fact that the IQWiG has come forward with a concept of its own to fuel discussion on this very crucial subject in implementing cost-effectiveness analyses, within the assessment of costs and benefits in Germany. This discussion has to be engaged in openly, as the results of this process have repercussions on the provision of health care to all of our citizens.

With that in mind, we strongly disagree with the authors’ statement that the Hanover Consensus is doomed from the start to end up “...as a search for the lowest common denominator.” We have to call to
mind that more than 70 researchers agreed to a scientific guideline aiming at setting areas where principles are unambiguous from experts to other experts in the field of health economics without repeating textbook knowledge which Kolominsky-Rabas and Caro ask us to quote.

The IQWiG positions itself in having legal autonomy in setting up methods and speaking for reimbursement decision-makers in Germany and therefore denying any relevance of other methodological approaches apart from their own. Decision-makers in that respect in Germany, from a legal standpoint, can be only sickness funds (and their legal bodies) and above all the G-BA, which is the self-governing body giving assignments to the IQWiG.

Among the members and therefore coauthors of the Hanover Consensus Group are several high-ranking current and also recent members of the G-BA as well as the Chief Executive Officers of all large sickness funds in Germany, representing almost 80% of those covered by the Statutory Health Insurance. Even one of the members of the International Advisory Board, which Caro is coordinating, is a member and therefore coauthor of the Hanover Consensus.

These people represent the legal entities to which the IQWiG has to present its methods, and they were sufficiently confident in the soundness of the consensus to endorse it, thereby fostering the application of methods relevant to them as decision-makers within the German health-care system.

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