In 1993, a research group was established at the department of Medical Informatics, Epidemiology and Bio-statistics of the University of Nijmegen, for studies in the field of health care technology assessment. It was a joint initiative of the University Hospital St Radboud and the Medical Faculty of the University. From the outset, the originators have emphasized that this research group should pay specific attention to analysing ethical and social aspects of health care technologies. Professor Henk ten Have was one of the originators, and he is among the few who have published in this area (ten Have, 1995). Health care technology assessment is usually defined as analysis of the medical, economic, social, ethical and legal impact of health care technology (see for instance Banta and Luce, 1993). In practice, however, emphasis is usually on medical and economic aspects (cost-effectiveness analysis), while other issues are relatively neglected. The mission of the Nijmegen medical technology assessment group was, and is, to pay more attention to the ethical, social, and legal issues when analysing the value of health care technologies. In the following, I will briefly describe how we try to establish this objective. I will start by describing a specific case, the assessment of cochlear implants in young deaf children.

A cochlear implant is a device which can give totally deaf children a certain hearing sensation. It works by relaying electrical signals, generated
by sound, directly to the acoustic nerve. The technology has been developed some decades ago, and has been the object of several evaluation studies. These studies have focused on the safety and efficacy of the device. Children who had received an implant were tested for their ability to produce understandable oral speech and for their ability to understand spoken language. In addition, several cost analyses have been carried out. Without exception, these studies conclude that the cochlear implant is a safe, and cost-effective device. The social controversies surrounding cochlear implants in deaf children are usually mentioned in passing, if at all. These controversies resulted chiefly from the fact that deaf adults considered cochlear implants as a threat to deaf culture. They also viewed cochlear implants as yet another sign of the hearing community that it considers deaf culture and communication in sign language as inferior. They maintain that deaf children with a cochlear implant remain deaf children, and that the huge resources that are spent on cochlear implants should not be withdrawn from services for the deaf (special education, courses in sign language etc.). Parents of deaf children are concerned that implanted children may be neither deaf, nor hearing. Instead of having the best of two worlds, they may end up with nothing at all.

What we see here, is that the social issues were largely ignored in health care technology assessments. As such, there was a certain bias in these studies, favouring the technology. A group of stakeholders has not succeeded in getting access to the research agenda of health technology assessment. They have not been able in translating their concerns into research questions, addressed in the various studies. The result is that policy decisions on cochlear implants have to be based on a number of facts regarding safety and cost-effectiveness and on a number of 'other issues' that have not been examined with the same rigour. As such, these 'other issues' are unlikely to have a substantial impact on the decision making process, and uncertainties and concerns in this respect are likely to persist. Inadvertently, then, health care technology assessment may reinforce existing inequities in these decision making processes. 'Other issues' are likely to remain 'end of the day considerations'.
Generally speaking, by analyzing examples such as the one above, we try to argue that health care technology assessment is not a matter of collecting the facts about a technology, but a matter of collecting facts that are relevant, given a particular value framework. As we all know, these value frameworks need not be shared by all parties involved. In the practice of health care technology assessment, this is reflected in differences in problem definition, in identification of feasible and acceptable solutions, and in defining criteria for evaluation. Many health care technology assessments finally end up with a cost utility ratio of a health service. Only rarely, the utilitarian underpinnings of this are mentioned explicitly. The rich analyses on pros and cons of ethical utilitarian theory (e.g. the assumptions of commensurability and aggregation) rarely enter the field of health care technology assessment. Adopting a different conception of justice (e.g. the Rawlsian theory of justice as applied to health care by Norman Daniels) would require collection of qualitatively different data on the use of health care technology.

Fortunately, due to the influence of leading professionals in the field of health care technology assessment such as David Banta, the appreciation of the value of ethical analysis is gaining acceptance. Last year, during the annual meeting of the International Society of Technology Assessment in Health Care, we were given the opportunity to organize a workshop on ethical issues in technology assessment. Contributions of Andrew Edgar (Cardiff), Stuart Blume (Amsterdam), Medard Hilhorst (Rotterdam) and Heitman (Houston) met with considerable enthusiasm. Yet, much needs to be done, not in the least in the field of methodology. Also, and this is only understandable, clinicians are sometimes reluctant to cooperate when it comes to ethical issues. Frequently, 'ethical issues' are identified with 'negative, adverse effects'. Although this may be the case, this need not be so. I feel that here, the misconceived fact-value dichotomy takes its toll.
RESEARCH PROJECTS

A study of the definition of 'medical necessity'
This is the central theme of a EC-BIOMED project 'Limiting access to health care in various European countries'. It is also a central theme of a research grant which was recently submitted to the Dutch Organization of Scientific Research (NWO), together with Hilhorst (Erasmus University Rotterdam, and Grin, University of Amsterdam). We try to incorporate the findings of projects like these into the evaluation projects that are carried out in the University Hospital.

'Eurassess'. This is a research project, co-ordinated by prof. dr. David Banta from TNO Leiden, and funded by the European BIOMED programme. In the methods subgroup, chaired by prof.dr. Trevor Shelden from York, we have contributed by developing methods for assessing social and ethical aspects in health care technology assessment.

The other participants to this EC-project are:
Bengt Brorrson, Swedish Council for Health Care Technology Assessment, Stockholm, Sweden; Frederick Fleurette, ANDEM, Paris, France; Torben Jorgensen, Danish Hospital Institute, Denmark; Albert Jovell, Departamento de Sanitat I Seguretat Social, Barcelona, Spain; Jim Kahan, RAND/European-American Center for Policy Analysis, The Netherlands; Alessandro Liberati, Instituto Mario Negri, Italy; Trevor Sheldon, NHS Centre for Reviews and Dissemination, University of York, England; Harri Sintonen, Department of Health Policy and Management, University of Kuopio, Finland; Gabriel ten Velden, Health Council of the Netherlands, The Netherlands.

The social context of health care technology assessment.
In the context of this project, we analyzed the case of assessing cochlear implants in deaf children. We submitted a grant to the university of Nijmegen to continue this project.

26 European Philosophy of Medicine and Health Care 4:2, 1996
STAFF

The MTA group presently consists of seven researchers; two of them have had a training in philosophy and ethics (van der Wilt and Reuzel).

COOPERATION WITH OTHER RESEARCH GROUPS

We have been fortunate in getting a grant from the European Community (EC-BIOMED programme), which allows us to cooperate with the following people and organizations:

dr. O.F. Norheim, Institute of Medical Ethics, Oslo
prof. dr. E. van Leeuwen and drs. S. van de Vathorst, Vrije Universiteit, Amsterdam

dr. P. Rossel and dr. S. Holm, Institute of Theoretical Medicine, Copenhagen

dr. Andrew Edgar, Institute for Ethics, Cardiff
prof. dr. H.M. Sass, Bochum / Kennedy Institute of Ethics.

Prof. dr. Norman Daniels from Tufts University, Boston, US, has kindly accepted to act as a consultant to this project.

The Hastings Centre has been very hospitable, also to us; especially dr. Philip Boyle's research project on Technology assessment in hospitals is of great interest to us.

Finally, we cooperate with the MTA-unit of TNO, Leiden (prof. dr. H. David banta, dr. T. van Beekum, drs. W. Oortwijn), to further operationalize the concept of interactive technology assessment (as described for instance by Guba and Lincoln, in Fourth Generation Evaluation, Sage, 1989).

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