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ADVANCED COURSE ON ETHICS IN ONCOLOGY

June 25-28, 2000
Bled, Slovenia

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ADVANCED COURSE ON
ETHICS IN ONCOLOGY

PROGRAM AND COURSE MATERIAL

Editors: M. Zwitter and P. Ećimović

Chairmen of the Course:
M. Zwitter (SI)
C. G. Vella (IT)

June 25-28, 2000
Bled, Slovenia

Local Organising Committee

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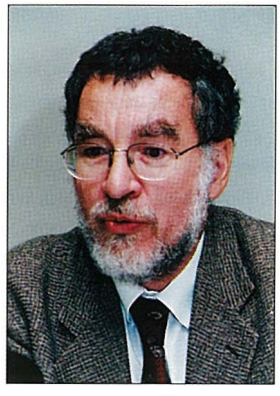
This course has been organised as a joint venture of European School of Oncology, Milano, Italy and Institute of Oncology, Ljubljana, Slovenia

Under The High Patronage of Mrs. Štefka Kučan

Introduction and welcome

It is easier to adapt to technical innovations than to sociological and cultural changes of the modern world. It is often easier to perform a complex medical procedure than to bring a decision about what should, or should not be done.
We share a special privilege to chair the first course of the European Scool of Oncology devoted to ethical issues in oncology. We wish you a pleasant, vivid and memorable time.



Matjaž Zwitter

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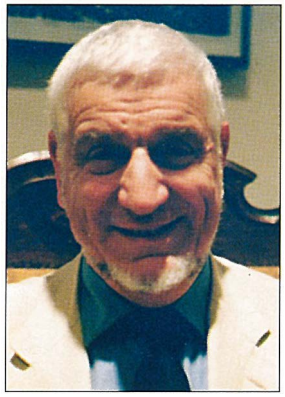

Prof. Raanan Gillon, MD is a philosopher and general medical practitioner. He works part time as Professor of medical ethics at Imperial College School of Medicine and part time as Senior National Health Service Partner in a London general medical practice. He is also the editor of the Journal of Medical Ethics, which is one of the most frequently cited medical ethics/bioethics/healthcare ethics journal in the world. He has written extensively on medical ethics, including Philosophical Medical Ethics (Wiley 1985 and ten subsequent re-prints) and is senior editor of and contributor to a massive prizewinning 100-author textbook, Principles of Healthcare Ethics (Wiley 1994, reprinted 1996). In 1999, along with Alastair Campbell, he was awarded the Hastings Center Henry Knowles Beecher award "for contributions to ethics and the life sciences" and was the first non-American to achieve this award.

Prof. Raanan Gillon, MD, general practitioner and philosopher, Imperial College, London University; editor, Journal of Medical Ethics

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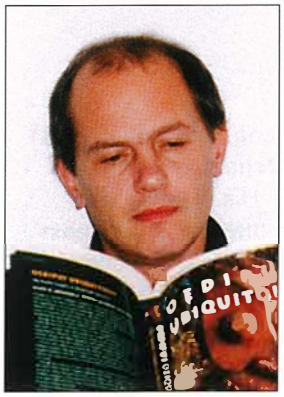

Prof. Borut Telban, PhD studied pharmacy at the University of Ljubljana, Slovenia. After graduation, he carried out 38 months of anthropological research in Papua New Guinea, which lead in 1994 to PhD in anthropology at Research School of Pacific and Asian Studies, Australian National University in Canberra, Australia. From 1995-96 he was Leach/RAI Fellow at the University of Manchester and in 1997, he was a Visiting Fellowat the Anthropology Department of Australian National University. He wrote many publications and books on anthropology, among them "The Role of Medical Ethnobotany and Ethnomedicine: A New Guinea Example". He is currently working as a Research Fellow at the Scientific Research Centre of the Slovene Academy of Sciences and Arts.

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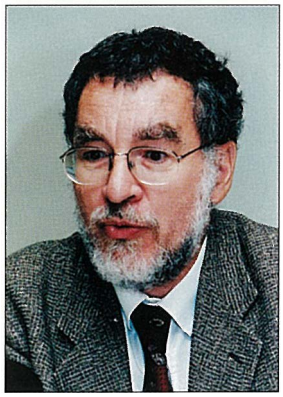

Prof. Matjaž Zwitter, MD, PhD is Head of the Department of Radiation Oncology at the Institute of Oncology in Ljubljana, Slovenia, and Associate Professor for Radiotherapy and Oncology at the University of Ljubljana Medical School. He is a graduate of the Ljubljana University where he also completed his training in radiotherapy and oncology. After fellowships in London and Stanford, he returned to his home University and conducted a number of clinical trials in the fields of malignant lymphomas, pediatric oncology, brain tumors, and lung cancer. In 1997, Drs. Antonella Surbone and Matjaz Zwitter co-edited a book entitled Communication with the cancer patient: information and truth which was published in the Annals of the New York Acadademy of Sciences. His current research interests include ethical issues in oncology, treatment for lung cancer, and biology of Hodgkin's disease.

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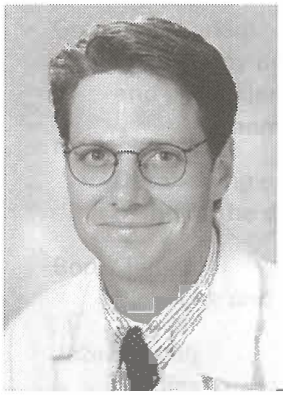

Prof. Gregory Luke Larkin, MD, MSPH, FACEP is the Director of Research for the Department of Emergency Medicine at the Mercy Hospital, Mercy Providence Hospital, and Emergency Medicine Association of Pittsburgh, USA, and Clinical Ethics Consultant, Eastern Mercy Health System. An Associate Professor of Emergency Medicine at the University of Pittsburgh School of Medicine, he also works as a physician at the Emergency Department of the Mercy Hospital. He has served as Chair of the American College of Emergency Physicians (ACEP) Committee on Ethics, and as Chair of the Society for Academic Emergency Medicine (SAEM) Code of Ethics Subcommittee. He is author of many publications on ethical issues, including "A Code of Ethics for Emergency Physicians" and "Virtue in Emergency Medicine".

Gregory L. Larkin, MD, Mercy Hospital and University of Pittsburgh Medical School, Pittsburgh

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CONTRIBUTIONS, ABSTRACTS AND READING MATERIAL

Medical ethics: four principles plus attention to scope

Raanan Gillon

The "four principles plus scope" approach provides a simple, accessible, and culturally neutral approach to thinking about ethical issues in health care. The approach, developed in the United States, is based on four common, basic prima facie moral commitments—respect for autonomy, beneficence, non-maleficence, and justice—plus concern for their scope of application. It offers a common, basic moral analytical framework and a common, basic moral language. Although they do not provide ordered rules, these principles can help doctors and other health care workers to make decisions when reflecting on moral issues that arise at work.

Nine years ago the *BMJ* allowed me to introduce to its readers[1] an approach to medical ethics developed by the Americans Beauchamp and Childress,[2] which is based on four prima facie moral principles and attention to these principles' scope of application. Since then I have often been asked for a summary of this approach by doctors and other health care workers who find it helpful for organising their thoughts about medical ethics. This paper, based on the preface of a large multiauthor textbook on medical ethics,[3] offers a brief account of this "four principles plus scope" approach.

The four principles plus scope approach claims that whatever our personal philosophy, politics, religion, moral theory, or life stance, we will find no difficulty in committing ourselves to four prima facie moral principles plus a reflective concern about their scope of application. Moreover, these four principles, plus attention to their scope of application, encompass most of the moral issues that arise in health care.

The four prima facie principles are respect for autonomy, beneficence, non-maleficence, and justice. "Prima facie," a term introduced by the English philosopher W D Ross, means that the principle is binding unless it conflicts with another moral principle —if it does we have to choose between them. The four principles approach does not provide a method for choosing, which is a source of dissatisfaction to people who suppose that ethics merely comprises a set of ordered rules and that once the relevant information is fed into an algorithm or computer out will pop the answer. What the principles plus scope approach can provide, however, is a common set of moral commitments, a common moral language, and a common set of moral issues. We should consider these in each case before coming to our own answer using our preferred moral theory or other approach to choose between these principles when they conflict.

Respect for autonomy

Autonomy—literally, self rule, but probably better described as deliberated self rule—is a special attribute

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BMJ 1994;309:184-8

of all moral agents. If we have autonomy we can make our own decisions on the basis of deliberation; sometimes we can intend to do things as a result of those decisions; and sometimes we can do those things to implement the decisions (what I previously described as autonomy of thought, of will or intention, and of action). Respect for autonomy is the moral obligation to respect the autonomy of others in so far as such respect is compatible with equal respect for the autonomy of all potentially affected. Respect for autonomy is also sometimes described, in Kantian terms, as treating others as ends in themselves and never merely as means—one of Kant's formulations of his "categorical imperative."

In health care respecting people's autonomy has many prima facie implications. It requires us to consult people and obtain their agreement before we do things to them—hence the obligation to obtain informed consent from patients before we do things to try to help them. Medical confidentiality is another implication of respecting people's autonomy. We do not have any general obligation to keep other people's secrets, but health care workers explicitly or implicitly promise their patients and clients that they will keep confidential the information confided to them. Keeping promises is a way of respecting people's autonomy; an aspect of running our own life depends on being able to rely on the promises made to us by others. Without such promises of confidentiality patients are also far less likely to divulge the often highly private and sensitive information that is needed for their optimal care; thus maintaining confidentiality not only respects patients' autonomy but also increases the likelihood of our being able to help them.

Respect for autonomy also requires us not to deceive each other (except in circumstances in which deceit is agreed to be permissible, such as when playing poker) as the absence of deceit is part of the implicit agreement among moral agents when they communicate with each other. They organise their lives on the assumption that people will not deceive them; their autonomy is infringed if they are deceived. Respect for patients' autonomy prima facie requires us, therefore, not to deceive patients, for example, about their diagnosed illness unless they clearly wish to be deceived. Respect for autonomy even requires us to be on time for appointments as an agreed appointment is a kind of mutual promise and if we do not keep an appointment we break the promise.

To exercise respect for autonomy health care workers must be able to communicate well with their patients and clients. Good communication requires, most importantly, listening (and not just with the ears) as well as telling (and not just with the lips or a wordprocessor) and is usually necessary for giving patients adequate information about any proposed intervention and for finding out whether patients want that intervention. Good communication is also usually necessary for finding out when patients do not want a lot of information; some patients do not want to be told about a bad prognosis or to participate in deciding which of several treatments to have, preferring to leave this decision to their doctors. Respecting such attitudes shows just as much respect for a patient's autonomy as does giving patients information that they do want. In my experience, however, most patients want more not less information and want to participate in deciding their medical care.

Beneficence and non-maleficence

Whenever we try to help others we inevitably risk harming them; health care workers, who are committed to helping others, must therefore consider the principles of beneficence and non-maleficence together and aim at producing net benefit over harm. None the less, we must keep the two principles separate for those circumstances in which we have or recognise no obligation of beneficence to others (as we still have an obligation not to harm them). Thus the traditional Hippocratic moral obligation of medicine is to provide net medical benefit to patients with minimal harm—that is, beneficence with non-maleficence. To achieve these moral objectives health care workers are committed to a wide range of prima facie obligations.

We need to ensure that we can provide the benefits we profess (thus "professional") to be able to provide. Hence we need rigorous and effective education and training both before and during our professional lives. We also need to make sure that we are offering each patient net benefit. Interestingly, to do this we must respect the patient's autonomy for what constitutes benefit for one patient may be harm for another. For example, a mastectomy may constitute a prospective net benefit for one woman with breast cancer, while for another the destruction of an aspect of her feminine identity may be so harmful that it cannot be outweighed even by the prospect of an extended life expectancy.

The obligation to provide net benefit to patients also requires us to be clear about risk and probability when we make our assessments of harm and benefit. Clearly, a low probability of great harm such as death or severe disability is of less moral importance in the context of non-maleficence than is a high probability of such harm, and a high probability of great benefit such as cure of a life threatening disease is of more moral importance in the context of beneficence than is a low probability of such benefit. We therefore need empirical information about the probabilities of the various harms and benefits that may result from proposed health care interventions. This information has to come from effective medical research, which is also therefore a prima facie moral obligation. The obligation to produce net benefit, however, also requires us to define whose benefit and whose harms are likely to result from a proposed intervention. This problem of moral scope is particularly important in medical research and population medicine.

One moral concept that in recent years has become popular in health care is that of empowerment—that is, doing things to help patients and clients to be more in control of their health and health care. Sometimes empowerment is even proposed as a new moral obligation. On reflection I think that empowerment is, however, essentially an action that combines the two moral obligations of beneficence and respect for autonomy to help patients in ways that not only respect but also enhance their autonomy.

Justice

The fourth prima facie moral principle is justice. Justice is often regarded as being synonymous with fairness and can be summarised as the moral obligation to act on the basis of fair adjudication between competing claims. In health care ethics I have found it useful to subdivide obligations of justice into three categories: fair distribution of scarce resources (distributive justice), respect for people's rights (rights based justice) and respect for morally acceptable laws (legal justice).

Equality is at the heart of justice, but, as Aristotle argued so long ago, justice is more than mere equality—people can be treated unjustly even if they are treated equally.[15] He argued that it was important to treat equals equally (what health economists are increasingly calling horizontal equity) and to treat unequals unequally in proportion to the morally relevant inequalities (vertical equity). People have argued ever since about the morally relevant criteria for

regarding and treating people as equals and those for regarding and treating them as unequals. The debate flourishes in moral, religious, philosophical, and political contexts, and we are no closer to agreement than we were in Aristotle's time.

Pending such agreement health care workers need to tread warily as we have no special justification for imposing our own personal or professional views about justice on others. We certainly need to recognise and acknowledge the competing moral concerns. For example, in the context of the allocation of resources conflicts exist between several common moral concerns: to provide sufficient health care to meet the needs of all who need it; when this is impossible, to distribute health care resources in proportion to the extent of people's needs for health care; to allow health care workers to give priority to the needs of "their" patients; to provide equal access to health care; to allow people as much choice as possible in selecting their health care; to maximise the benefit produced by the available resources; to respect the autonomy of the people who provide those resources and thus to limit the cost to taxpayers and subscribers to health insurance schemes. All these criteria for justly allocating health care resources can be morally justified but not all can be fully met simultaneously.

Similar moral conflicts arise in the context of rights based justice and legal justice.

PERSONAL DECISION MAKING

The best moral strategy for justice that I have found for myself as a health care worker is first to distinguish whether it is I or an organisation, profession, or society itself that has to make a decision. For example, "how should I respond to a particular patient who wants an abortion?" is distinct from, "what is this hospital's organisational view on abortion?" and "what is the medical profession's collective view on abortion?" and "what is society's view as expressed in law and practice?"

Firstly, for decisions that I must take myself I must try to exclude decisions that have no moral basis or justification. Neither pursuit of my own self interest —for example, accepting bribes from patients, hospitals, or drug manufacturers—nor action that discriminates against patients on the basis of personal preference or prejudice can provide a just or morally acceptable basis for allocating scarce health care resources or for any other category of justice. Moreover, it is not my role as a doctor to punish patients; withholding antibiotics from smokers who do not give up smoking or refusing to refer heavy drinkers with liver damage induced by alcohol for specialist assessment on the grounds that they are at fault is not a just or morally acceptable basis for rationing my medical resources.

Secondly, I should not waste the resources at my disposal; so if a cheaper drug is likely to produce as much benefit as a more expensive one I should prescribe the cheaper one. Cost and its team mate opportunity cost are moral issues and central to distributive justice. If I believe, however, that an expensive drug is clearly and significantly better for my patient than a cheaper alternative and I am allowed to prescribe it then I believe that I should do so. Thus, like many British general practitioners, I try oxytetracycline first when treating acne, but if it does not work well I prescribe the more expensive minocycline; for depression I usually start with tricyclic antidepressants, but if they do not work well or the side effects are unacceptable I prescribe the new and expensive 5-hydroxytryptamine uptake inhibitors.

Thirdly, I should respect patients' rights. For example, my disapproval of a patient's lifestyle would not be a morally acceptable justification for refusing to provide a certificate of sickness if he or she cannot work because of sickness. I have no special privilege as a health care worker, however, to create societal rights for my patients. For example, while I might think that all my unemployed patients should receive sickness benefit, in Britain they have a right to receive it only if they cannot work because of sickness; I have a right, therefore, to provide a certificate of sickness only if this is the case.

Fourthly, I ought to obey morally acceptable laws. Thus, even though I may disapprove of breaking a patient's confidence, if he or she has one of several infectious diseases I am legally obliged to notify the relevant authorities. If I believe that the law is morally unjustified I am morally entitled to break the law; but this gives me no legal entitlement to break the law, and I should be prepared to face the legal consequences of disobeying it. I should also decide exactly what I mean by a morally unjustified law. I suggest, though here do not argue, that it is the processes through which laws are enacted that confer moral legitimacy not the content of the laws. Thus if a law is enacted through a democratic political system—and hence one that fundamentally respects autonomy—which represents conflicting views within its population and makes laws on the basis of certain common moral values that reflect the four principles then that law is morally acceptable, and prima facie we are morally required to obey it.

ORGANISATIONAL, PROFESSIONAL, AND SOCIETAL DECISIONS

My role in taking decisions about justice that are organisational, professional, or societal should only be as a member of the relevant organisation, profession, or society. It is therefore morally consistent to pursue at different levels objectives that are mutually inconsistent. The medical directorate at the hospital where I work may have decided to prohibit the prescription of a particularly expensive drug. As a member of that directorate I may have argued in favour of prescribing the drug in special cases, but my arguments were rejected. It is morally proper for me as a clinician to accept the directorate's decision and act accordingly even when faced with an exceptional case in which I believe the expensive drug would be preferable. It is also morally legitimate for me to point to such cases ("shroud waving") in my political role as a member of a democratic society, arguing, for example, for more resources for health care than, say, for defence.

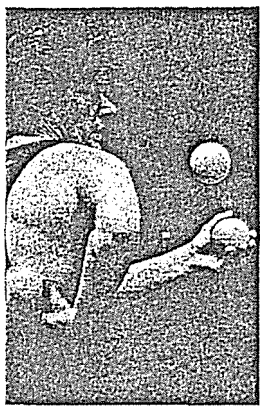
As members of society we are still feeling our way even at the level of defining what the competing moral concerns of justice are. We must be particularly wary of apparently simple solutions to what have been perceived as highly complex problems for at least 2500 years. For example, populist solutions in distributive justice such as have occurred in Oregon in the United States[6] and technical and simplistic economic solutions such as the system of costed quality adjusted life years (QALYs)[7] are tempting in their definitiveness and simplicity; they fail, however, to give value to the wide range of other potentially relevant moral concerns. Until there is far greater social agreement and understanding of these exceedingly complex issues I believe it is morally safer to seek gradual improvement in our current methods of trying to reconcile the competing moral concerns—to seek ways of "muddling through elegantly" as Hunter advocates[8]—than to be seduced by systems that seek to convert these essentially moral choices into apparently scientific, numerical methods and formulas.

As Calabresi and Bobbitt suggested in the 1970s, rationing scarce resources that prolong life and enhance health often entails tragic choices—choices between

people and between values. Societies seek strategies to minimise the destructive effect of such choices, including tendencies to change their strategies over time.[9] Calabresi suggests that we are like a juggler trying to keep too many balls in the air; like the juggler we must do our best to improve our juggling skills to keep more balls in the air for more of the time and to avoid letting any ball stay on the ground for too long. We must accept, however, that in the context of competing and mutually incompatible claims there will always be some balls on the ground. Moreover, we should not be surprised that there will always be some people dissatisfied after justice has been done because by definition not everyone's claims can be met.

Scope

We may agree about our substantive moral commitments and our prima facie moral obligations of respect for autonomy, beneficence, non-maleficence, and justice, yet we may still disagree about their scope of application—that is, we may disagree radically about to what or to whom we owe these moral obligations. Interesting and important theoretical issues surround the scope of each of the four principles. We clearly do not owe a duty of beneficence to everyone and everything; so whom or what do we have a moral duty to help and how much should we help them? While we clearly have a prima facie obligation to avoid harming everyone, who and what count as everyone? Similarly, even if we agree that the scope of the principle of respect for autonomy is universal, encompassing all autonomous agents, who or what counts as an autonomous agent?



PETITPREX FEATURES

Pursuit of justice—keeping all the balls in the air

Who or what falls within the scope of our obligation to distribute scarce resources fairly according to the principle of justice? Is it everyone in the world? Future people? Just people in our own countries? And who or what has rights? Do plants have rights? Does the environment have rights? Does a work of art have rights? Do animals have rights and if so, which animals? Conversely, against whom may holders of rights claim the correlative moral obligation? Similar questions concern the scope of legal justice.

SCOPE FOR HEALTH CARE WORKERS

Fortunately for health care workers some of these issues of scope have been clarified for them by their special relationship with their patients or clients. In particular, the controversial issue of who falls within the scope of beneficence is answered unambiguously for at least one category of people: all health care workers have a moral obligation to help their patients and clients. Patients or clients fall within the scope of the health care workers' duty of beneficence. This fact is established by the personal and professional commitments of the health care professionals and their organisations—they all profess a commitment to help their patients and clients, and to do so with minimal harm. This commitment is underwritten by the societies in which they practise, both informally and through legal rules and regulations that define the health care professionals' duties of care.

Two issues of scope are of particular practical importance for health care workers. The first is the question of who falls within the scope of the prima facie principle of respect for autonomy. The second is the question of what is the scope of the widely acknowledged "right to life"; who and what has a right to life?

Obviously the scope of the principle of respect for autonomy must include autonomous agents—we cannot respect the autonomy of a boot or anything else that is not autonomous. But who or what counts as an autonomous agent? When we disagree about whether or not to respect the decision of a girl of 14 to take the oral contraceptive pill we are in effect disagreeing about the scope of application of the principle respect for autonomy.

Similar questions about the scope of respect for autonomy arise in other paediatric contexts, in the care of severely mentally ill or mentally impaired people, and in the care of elderly people who are severely mentally impaired. Some patients clearly do not fall within the scope of respect for autonomy; newborn babies, for example, are not autonomous agents as autonomy requires the capacity to deliberate. But 7 year olds usually can deliberate to a degree. How much capacity for logical thought and deliberation and what other attributes are required for somebody to be an adequately autonomous agent? Possible other, necessary attributes include an adequately extensive and accurate knowledge base, including that born experience and of accurte perception, on which to deliberate; an ability to conceive of and reflect on ourselves over time, both past and future; an ability to reason hypothetically—"what if" reasoning; an ability to defer gratification for ourselves as an aspect of self rule; and sufficient will power for self rule.

However these philosophical questions are answered, health care workers increasingly acknowledge that the autonomy of even young children and severely mentally impaired people should prima facie be respected unless there are good moral reasons not to do so. Moreover, those reasons will depend highly on the context; a young child or a severely mentally impaired person may not be autonomous enough to have his or her decision to reject an operation respected but be autonomous enough to decide what food to eat or clothes to wear. When patients who are not adequately autonomous for all their decisions to be respected make decisions that seem to be against their interests then important issues arise about who should be regarded as appropriate to make decisions on their behalf and about the criteria that they should use to do so.

The second important issue of scope for health care workers concerns the "right to life." Who or what has this right to life? To answer the question we have to determine what is meant by the right to life. Specifically, is it simply the right not to be unjustly killed or does it also include a right to be kept alive? The scope of the first right will clearly be greater than the scope of the latter: we have prima facie moral obligations not to kill all people but we have obligations to keep alive only some people. Even with the first definition of the right to life (a right not to be unjustly killed) a question of scope arises; although all people clearly fall within its scope, do (non-human) animals? And what do we mean by people? In response to this last question much debate, often extremely acrimonious, occurs in health care ethics over the right to life of human embryos, fetuses, newborn babies, and patients who are permanently unconscious or even brain dead.

It is salutary to reflect that these contentious issues are not about the content of our moral obligations but about to whom and what we owe them—that is, they are questions about the scope of our agreed moral obligations. Our answers are reasoned and carefully argued but deeply conflicting, either religiously or philosophically. Such disagreement about scope does not justify accusing those who disagree with us of bad faith or incompatible moral standards; in principle it is open to resolution within our shared moral commitment.

Conclusion

The four principles plus scope approach is clearly not without its critics. And the approach does not

purport to offer a method of dealing with conflicts between the principles. But I have not found anyone who seriously argues that he or she cannot accept any of these prima facie principles or found plausible examples of concerns about health care ethics that require additional moral principles.

The four principles plus scope approach enables health care workers from totally disparate moral cultures to share a fairly basic, common moral commitment, common moral language, and common analytical framework for reflecting on problems in health care ethics. Such an approach, which is neutral between competing religious, political, cultural, and philosophical theories, can be shared by everyone regardless of their background. It is surely too important a moral prize to be rejected carelessly or ignorantly; for the sake of mere opposition; or for the fun of being a philosophical "Socratic gadfly."

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BEDSIDE ETHICS AND HUMANISATION OF CARING

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1. INTRODUCTION

There is today a very striking gap between theory and practice in the debate on ethical issues. There is often the feeling that academic debates do not consider bedside ethics, which need to be person centered.

Often answers are given based on "licit" and "non licit". Academic or economic arguments alone do not suffice, we need above all a philosophy of care and a person centered ethics. Health care economists often do not have such a basis.

2. THE SITUATION OF HEALTH CARE

Health care differs in many countries, even within Europe itself. Today the emphasis is often on "managed health care". Globalisation of business has even invaded health care systems.

Arnold Relman, former editor of the New England Journal of Medicine, deplores the intrusion of methods and jargon into medicine, at the cost of pushing aside ethical values. Health care - he affirms - is a service to the human person in which words like "profit" and "marketing" should be heard very little if at all.

I think the challenge is how to be able to twin through justice management with humanisation, in a perspective of ethical values.

3. HEALTH: A PRIMARY VALUE

Health is the most important value in human life. Every choice made should safeguard the value of the human person. There should be greatest respect to the ethics of responsibility, subsidiarity and solidarity.

This calls for the principles of justice and equity, which are central in any health policy, which concerns choices, accessibility, costs and benefits, priorities and profit.

I would like to comment on the ethical term of justice. Justice in various contexts, as in the Bible or in non-religious context as in Aristotle, is used almost interchangeably with the word "rights". Rights as conceived in the U.N. "Declaration of Human Rights", in the "European Social Charter" and in "The Rights of the Patients".

In the light of these documents the term "justice" is seen within the ethical values of: equality, freedom, responsibility and efficiency.

Within the concept of Bedside Ethics the basic concept emerges from these values. This implies that fundamental to the health care system is solidarity, which means we have to build a caring society and not just a welfare society (T.Beauchamp - J.F.Childress 'Principles of Biomedical Ethics').

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4. PERSONALISTIC ETHICS

On all these values we build our approach to "Bedside Ethics", where the patient is a partner (E.Pellegrino) and a brother. These values are applied to the doctor-patient relationship in a personalistic approach. This type of ethics can be applied by all, whether they are believers or not, for there is a general orientation by philosophers and ethicists of various creeds.

Ethics should not be just the concern of university teachers or of Ethics Committees. It is the way of being, relating and professional know how of all those in health care (doctors, nurses, administrators, cares, etc.).

Today in many hospitals there is the Ethical Consultant, who is a specialist in bioethics and operates as a clinic consultant in the wards of the hospital. Often this person works with the Ethics Committee, the doctors, the chaplains and nurses.

The Ethical Consultant does not have to be a doctor, though he works daily with various departments in the hospital (emergency, medicine, surgery, gynaecology, intensive care, etc.). He is often asked for an ethical consultation from the doctors and at places he also make "the rounds" with the doctors.

The Ethical Consultant should not be confused with the social worker or the psychologist.

5. HUMANISATION

The concept of humanisation is founded on the human and spiritual values of man. For Christians man is "the image of God" and "the glory of God", who is "above all other creatures" (Salm 8,9).

The Hunker Krehl affirmed that "a doctor is not an academic, he is not an artist, neither is he a technician". He is exclusively a doctor. His skill has many things in common with all three, but essentially he is above all three, because the motive of his action are men as much as man" (Un'Ala per Guarire - Don Luigi M.Verzé).

Humanisation is not an added comfort in the hospital, but it means receiving, accepting, caring and healing man with a deep sense of humanity. The dignity and rights of man are first and foremost. What makes a hospital of excellence is not the structures or the technologies, but the humanity of the men and women who work day in and out therein.

Doctors and nurses are all called to be experts of great human sensitivity, in a relation of giving with generosity and authenticity.

At "San Raffaele" we believe that: (i) the hospital is first and foremost for those who work therein, otherwise they cannot create a human climate for the patients; (ii) all are called to give their very best to the patients and (iii) each doctor is invited to consider his profession as "medicina-sacerdozio" (medicine-priesthood).

As a framework for humanisation the Lombardy Region (Regione Lombardia) has established the Project "Umanizzazione del Servizio Sanitario Regionale" (Humanisation of the Regional Health Service) to promote the humanisation hospitals.

In conclusion, here are some practical strategy and methodology to render the hospital more human in its caring and healing:

1. Construction of a Humanisation Working Group (or Committee) to plan and work out a programme for hospitals carers and patients.
2. The welcoming of patients on admittance in the hospital (welcome by head nurse, distribution of "Carta dei Servizi", information, etc.).
3. Humanisation of the Emergency Division (with a special section for children: toys, TV, etc.).
4. The guarantee of the "privacy" and confidentiality of the patients.
5. Open spaces for the patients and their families.
6. Religious and social assistance of the patients and their families.
7. Psychological support and counselling services.
8. Service of voluntary group, well motivated and prepared.

The integration of values in a process of humanisation can improve the quality of health-care.

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UNDERSTANDING CULTURAL DIVERSITY: THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS AND THE PRINCIPLE OF AUTONOMY

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I. INTRODUCTION

General presentation of the Universal Declaration on the Human Genome and Human Rights, adopted unanimously and by acclamation by the General Conference of UNESCO on 11 November 1997 and endorsed by the General Assembly of the United Nations on 9 December 1998.

II. Universal DECLARATION on the Human GENOME and HUMAN Rights

Preambular paragraphs and articles relevant to the principle of autonomy, in particular, about informed consent and about the information of a patient (article 5), as well as about confidentiality of genetic data from third parties (article 7).

III. The principle of Autonomy and imparting information

Some of the issues will be outlined in the context of: genetic screening and testing; genetic counselling; genetic finger-printing; population genetics; and, experimentation on human subjects.

IV. Conclusion

Importance of national legislation and international co-operation.

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Learning from the World

The Editors' Perspective

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UNIVERSAL VALUES, PLURALISM, AND CULTURAL DIVERSITY

One of the most important lessons that we learned from the work of the colleagues from all over the world who have contributed to this book is that Western cultural hegemony is indeed a myth—a myth we should deny and oppose and for which we should substitute a universal cultural sensitivity. As was recently said, "ethical norms and human rights are universal not because they are recognized by certain countries or cultures, but because the human dignity in which they are grounded is universal." And "genuine respect for human dignity requires deeper understanding of the patient's values, culture, family and community."[1]

The implications are twofold: that differences exist, and that there is something universal about human dignity and therefore an ethical duty to respect it.

The first of these is what we could also refer to as pluralism. Pluralism is a de facto reality of our multiethnic societies, but also—most importantly—it is an essential principle of democracy. Pluralism does not have to lead to the intrinsic pessimism of cultural relativism, by which the ethical debate is paralyzed.[2] On the contrary, pluralism enriches ethics by fostering historical concreteness and by adding the dimension of the nonrepeatibility of values,[3] which always express themselves within a precise contextual dimension. The common ethical principles that stem from the equal right of every human being to life and dignity[4] and that have led to the Universal Declaration of Human Rights[5] are real and cross-cultural in their essence. However, the modality in which they are expressed is influenced by cultural and historical differences—i.e., by their context.

The medical act is no exception, as it always takes place in a contextual dimension. Both physician and patient are bound in a network of beliefs, customs, experiences, prejudices, rules, responsibilities; and both have limited choices. This is why, for example, formalistic informed con-

sent requirements can be possible and beneficial in certain contexts (see the prevailing Western attitude), but not in others. The different emphasis that different cultures place on autonomy versus community as basic ethical principles shapes the medical act as well as any other interaction among members of a society.

However, the issue goes beyond cultural differences, and facing some more fundamental questions will help us move from the descriptive level to the ethical. When speaking of truth-telling, we imply that we know the meaning of truth. Do we? Do we know what truth is as persons? Do we know it as doctors? It seems that the answer is no, we do not know what truth is. What we can know, though, is how we perceive truth. If we perceive truth as the mere opposite or absence of falsehood, we imply that truth is a fixed object that merely awaits description and/or verbalization.[2] In medicine, this leads to seeing information as a procedure, rather than a process. The justification for this is that there exists an objective static medical truth, and that truth equals information; hence, information suffices. But this is not the case, for truth is a relational state and develops over time and space through interactions that modify and shape truth itself. Accurate, comprehensible, continuous information remains an essential element of truth, but truth goes well beyond information alone to reach the level of communication.

This is no easy task, and it will be increasingly difficult in the face of modern medicine with its high technology, superspecialization, and economic pressure. But it is indeed now that we need to restore a human face to medicine, and one way of doing so is by practicing cultural sensitivity[6,7] and intense, systematic imaginative empathy.[8] All the contributions to this book seem to be in favor of this approach: they are not only honest reports of various ways of facing the issue of truth-telling, but they are also an incredible source of practical and theoretical suggestions for each one of us to practice imaginative empathy.

Imaginative empathy is difficult, as it requires a reappraisal of the physician's role that we will achieve only through major changes in the educational system. The education and training of doctors must aim at developing not only the scientific curriculum but also the moral character of each physician. Sooner or later we will all be patients, and we will hope to meet a doctor to trust for his or her moral character no less than for his or her expertise, because it is only on the basis of both that healing is possible.

Communication requires honesty, humility, and the complete abandonment of the doctor's more or less explicit desire for power. Imposed formalistic information,for instance, can be a means of increasing the doctor's power, rather than of giving freedom to patients. Giving such information can, as much as witholding the truth, be a way of delegating the entire burden of decisions to the patient, thus avoiding professional responsibilities.[9] Excessive medicalization of life and death, in which

technology, hospitals, and health-care teams leave no place for the patient's personal system of support—family, friends, values, religious beliefs and practices—is another sign of the abuse of the doctor's power; it is dangerous, ineffective, and ethically unjustifiable. Last but not least, there are things in life that cannot—and should not—be communicated. Forcing the barriers of the incommunicable is an intrusion into the patient's privacy and intimacy—another abuse of the doctor's power.

The patient-doctor relationship is asymmetrical. For the patient disease is a personal—most often devastating—event in his or her life, with a past, a present, and a future, however short it might be. The doctor, on the other hand, must focus on the objective dimension of the disease. The patient's and the doctor's narratives are different. The patient is inevitably in a more vulnerable position. The ethics of the patient-doctor relationship must take into account this asymmetry. All the contributions to this volume show us that we must *care*. We cannot stop at the view of the autonomous moral agent, whose moral responsibility exhausts itself in relationships among peers. We need to add the dimension of trust and of respect of the patient's vulnerability: the doctor as a moral agent is called to acknowledge the asymmetry of the relationship with the patient and should consider sensitivity, including cultural sensitivity, as a fundamental ethical requirement.

CULTURAL DIVERSITY AND THE CHANGING WORLD.

When the relationship between communication in medicine and cultural diversity is analyzed, three conclusions emerge. First, cultural diversity is a reality that cannot be ignored. Second, in a rapidly changing world patients and physicians are among those who will most clearly experience the tension between the old and the new. Last but not least, justice in the availability of proper medical care is of great importance when sincere communication between patient and doctor is sought, particularly for underprivileged patients throughout the world.

Modern medicine is certainly not a folklore festival, and nice words about the rich diversity of cultures may sound idealistic when the primary objective of a physician is effective treatment for cancer. However, one of the important messages of contributors to this volume from all parts of the world is that the rich diversity of cultures is a reality. No matter how unusual some of the beliefs, rituals, and sociological patterns may be to an outsider, the physician cannot ignore the patient's cultural background and his or her support network. Human understanding of disease and death is an important part of all cultures and religions. It is closely linked to how we define the position of an individual in a society. The seeds of this understanding have been sown early in childhood, and

their roots are far-reaching. Beliefs about causes and classification of diseases, assumptions about the links between the body and external and internal spiritual forces, the existence and life of the soul before birth and after physical death of the body—these are eternal questions whose answers greatly influence the ways in which patients cope with disease and suffering. The consumer-oriented approach of favoring treatment over prevention, excessive emphasis on the effectiveness of modern treatments for cancer, and the lack of efforts to integrate the acceptance of our own mortality and the demands of our life seem to be typical products of the Western world and of this century. Most modern Western cultures appear to exorcise suffering and dying and limit exposure to these events. Thus the norm becomes health and happiness, while sickness is seen as a deviation to be avoided at all cost. In more traditional cultures, on the contrary, disease, suffering, and death are not taboo, not even for children; on the contrary, they are occasions and most powerful tools for instilling and inspiring religious, spiritual, and philosophical beliefs.

In our multicultural, multiethnic societies the outer appearance and behavior of an individual human being may change with the adoption of another cultural pattern. In critical situations, however, it is the roots, not branches or leaves, that determine our responses: when facing serious disease or death we often return to the cultural values and practices to which we were first exposed in childhood. Moreover, there is an active effort to preserve cultural identity, which is not only understandable but very appropriate: in the new world of continuous stress and of global marketing (including political marketing), old cultural traditions find a new and most important role in relieving tensions, preserving local identity, and preventing the dissolution of human diversity into a pool of six billion competing individuals.

The world is changing, however; and compared to changes in the past, those of today are rapid and global. People in remote villages feel the waves of modern life with new technologies and emphasis on everyone's individual capabilities, rights, and responsibilities. The tension between the old and the new is felt worldwide, very likely to an equal extent in developing and in economically well-developed countries. We have said that patients and physicians will clearly feel tensions between the old and the new—the patients, since their health and life are at stake; and physicians, since they have to strive to achieve an often impossible balance between responsibility towards the patient, which includes establishing a sincere relationship, and the expectations of the patient's support network. Often relatives or other figures in the patient's life attempt to dominate the situation in an effort to protect the ill person from too painful a truth. In such a situation, the patient may silently sink into a passive role—and offer a nice example to those physicians who still believe that most patients do not wish to be properly informed about their disease. The physician's task is also to reveal the true, often hidden expectations,

questions, fears, and misconceptions of the patient, while respecting his or her cultural and family backgrounds. This may involve lengthy, sometimes hostile argument with those who feel that they are in charge of the patient. Often the physician tries not to cross the line beyond which the family would reject him as healer, or beyond which the effort to introduce more sincerity into the interhuman relations would actually lead to their total obstruction. The goal is to break down, not to build, barriers.

JUSTICE

Justice in the availability of proper medical care, we have said, is the third aspect that illustrates the influence of a particular culture upon the process of communication with the cancer patient. There is no doubt that for many patients the possibility of a cure lies in the hands of those who decide on the allocation of resources for medical care and cancer treatment. Many of our colleagues, especially those from the developing countries, mention the critical shortage of appropriate medical institutions, equipment, drugs, and manpower. To what extent are patients informed about this? It seems that quite often physicians are reluctant to suggest a transfer of a patient to another institution, for instance, very likely at substantial financial and emotional cost, without a guarantee for a cure. Although this might be seen as a paternalistic position, it is often the most honest solution. The major impact of economic considerations on the quality of health care for patients in different socioeconomic groups and in different societies is an ethical quandary, and it also affects the issue of communication.

Specific problems of communication with women in the developing countries and with the underprivileged in some of the most developed countries, such as the United States—two groups particularly suffering from lack of proper medical care—have rarely been mentioned even in this volume written by very open, sincere, honest physicians. Discrimination against women is not only linked to certain traditions, religions, or cultures, but also extends to the so-called democratic societies. Behind almost ideal constitutional rights we still find men in dominating positions, and this is reflected in differences of access to health care and research.

The existence of grossly underprivileged populations in some affluent countries seems to be an unavoidable consequence of the Western emphasis over the last two centuries on personal achievement and success. Yet, even for a large part of the North American and European populations, reliance on complete autonomy and individual self-determination may be more illusion than reality: the underprivileged and those who are simply unlucky (perhaps because of the unexpected occurrence of a serious disease) would probably be happy to subscribe to a system of greater inter-

dependence and solidarity. For the majority of the world population, emphasis on absolute autonomy is neither a goal nor a dream.

What are the specific aspects of communication with the cancer patient if this patient is, for instance, a single mother of two preschool children in Russia, or a man in the United States whose potentially life-saving treatment will not be covered by insurance? Clearly, many pressing questions remain unanswered.

We hope that this book will open an intense, productive discussion on all aspects of truth-telling, from its philosophical and anthropological foundations to its social and political implications.

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Information, Truth, and Communication

For an Interpretation of Truth-telling Practices throughout the World

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On se fait un idole de la verité elle meme: car la verité, hors de la charité, n'est pas Dieu; elle est son image, et un idole qu'il ne faut point aimer ni adorer.
—PASCAL

Pascal's words ("We make an idol of truth in itself. But truth, outside of love, is not God: it's simply His image, an idol that we should neither love nor adore") still represent one of the most powerful warnings against the idolatry of truth—an idolatry that is perpetuated by our limited reflection upon the many epistemic and ethical implications of truth.

Truth and epistemology: What is truth? Is truth a simple matter of coherence account? Is truth a matter of adherence? If so, to what? Does a single truth exist? If more than one truth exists, will the many truths one day reconcile in a single one? Does truth exist outside of relationships (the "love" of Pascal), outside of a connectional dimension?

Truth and subjectivity: Does truth exist outside of contexts? Are facts sufficient to determine truth?

Truth and medicine: Is the objective component of medical truth sufficient to speak of truth? Should medicine not combine cognitive and affective information to reach the truth? Is truth a unilateral concept or is it a concept shared between patient, doctor, and society? Finally, are patient and doctor simply engaged in discovering a truth that is already there, or are they creating a truth? If the latter, is it an historical or a narrative truth?

Truth and ethics: Can there be a technology of ethics? Are truth and truth-telling objects of ethical inquiry?

ETHICS IN MEDICINE

For the ancient Greeks, the sphere of ethics was not distinguished from that of esthetics; according to Aristotle courage is beautiful.[1] Exactly what, then, does ethics mean?

The word *ethics* has two different roots: $\varepsilon\theta o\sigma$ and $\eta\theta o\sigma$. The word $\varepsilon\theta o\sigma$ means habit, custom. There is a dimension of ethics that has been called reactive,[2] aimed at preserving the identity of mankind. In this respect, ethics relies on a system of rules of behavior, hence on habits reflecting ethical virtues. The word $\eta\theta o\sigma$, on the other hand, means home or usual place. Ethics, then, is the home of human beings, and it implies an active, continuous effort at understanding how mankind remains in this home.[3]

Ethics in medicine can be defined as the dimension in which both patient and doctor find themselves at home—a home in which they remain by acting according to ethical virtues.

TRUTH AND MEDICAL ETHICS

Truth is not merely the opposite of falsehood; rather, it is a relational state, which evolves through interactions in time. Truth can suddenly reveal itself when least expected. Truth can develop slowly, and we may be asked to wait patiently for it. Truth is a matter of now as well as of tomorrow. Can we affirm truth with certainty? Even if we think we recognize it for ourselves, can we impose it on others? Truth should above all be respected.

In the patient-doctor relationship, we need to respect the truth by the act of truth-telling, in which telling does not strictly mean using words, nor does it indicate which words; and in which truth does not equal information, but goes far beyond it.

In its action/activity implications, in its epistemological and its narrative component, truth-telling seems to be the real object of medical ethics and of our daily work as physicians.

Truth-telling is, however, only a component of a larger project, that of making truth. Truth is no longer a matter of idolatry: it is a matter of discovering as well as creating and recreating, in medicine as well as outside of medicine, in disease as well as outside of disease.

INFORMATION AND TRUTH

Clearly, information is only one component of truth. Information reflecting mere objective scientific truth does not take into account that the latter is a chimera. No knowledge is ever abstract from the context in which it was produced: knowledge is always situated knowledge, and this includes scientific knowledge. Medical truth is never value free, nor does the patient-doctor relationship ever take place in a value-neutral context.

In medicine, there is an objective dimension of truth, which can be

expressed through information. The nature and likely course of disease itself, the treatment options, the possible side effects, the likely prognosis are all objective elements of medical truth. However, there are two more dimensions of truth in medicine, and they are equally important: the subjective—i.e., the patient's perception of the disease—and the contextual, which varies according to the historical, cultural, and religious backgrounds of the patient and the doctor. These three dimensions can be expressed only in the process of communication.

COMMUNICATION

Information becomes truth only in the context of communication. But what is communication? The origin of the word, from the Latin *communis*, implies sharing something in common. Hence, communication can be defined as the process by which meanings are exchanged between individuals through a common system of symbols, such as language, gestures, and signs. In the patient-doctor relationship, communication is the timely and appropriate answer to the problem of truth.

Communication is a bidirectional process. It implies information, but it goes beyond information. It is not only verbal, but also consists of a universal language of signs, gestures, objects. It develops over time. It takes into account all the variables that, by their interaction, can modify the truth in the patient-doctor relationship: the patient, the health-care team, the family, society in its entirety, the disease and its course, the medications. Communication is creative and never results from imposition. Communication respects and expresses the truth.

OBSTACLES TO COMMUNICATION

That communication is not an easy task we know from our personal lives, long before we enter our profession. In the patient-doctor relationship, many are the obstacles to communication. As in the rest of life, we face problems of language, reality and its limits, expectations and finally the presence of the incommunicable.

Language is about words, about meanings, and about imagination. Language is the major obstacle to communication, insofar as it refers not only to the linguistic property of a certain group of people, but also to the meaning that different persons attribute to the same words. "But is language the only language?" asked Ludwig Wittgenstein in his *Notebook*.[4] Later on, he wrote: "Since language stands in internal relation to the world, it and these relations determine the logical possibility of facts." Language is not merely a convention; on the contrary, it stands in a close, internal, logical relationship to the world. Language and facts are thus

connected in a new dimension.

When thinking of language in the patient-doctor relationship, we might wish to think of the role of narrative in medicine. Medicine is based upon narratives—the patient's but also the doctor's. Illness narrative is a mainstay of medical practice: the stories that patients tell us are the first moment of the relationship and, indeed, shape it. Do patients' narratives depict objective experience only? Do they follow cultural models (templates, plots, literary roles)? And finally, to what extent do patients and doctors share the narrative? Because doctors have their narratives too, they work in a cultural context, they belong to multiple contexts (the general culture and also the medical culture). Doctors speak about medical knowledge as absolute, natural, universal; but is not medical knowledge also a narrative?

Reality has limitations that communication does not overcome. On the contrary, the limitations of reality can become obstacles to communication. Let us think of the following: we are not immortal, economic pressure is increasing, distributive justice needs to be considered, major therapeutic advances are not common, available therapies have severe side effects, more is not always better. Finally the medicalization of life and its quality is ineffective and dangerous. Communication about these issues is difficult, as it engages us in facing those limitations of reality against which we struggle and fight. We do not like these limitations of reality, and we tend not to talk about them. Actually, we participate in creating different expectations for us and our patients.

That expectations are often unrealistic is a fact. But who creates expectations? Society and culture first, the patient and his or her microenvironment, doctors, and medicine itself. Our goal should be to establish realistic expectations without subtracting hope. It is often an impossible task, as it involves some aspects of our lives, some webs of our thoughts that are incommunicable.

There is a threshold in the patient-doctor relationship, as in every relationship of life, that we cannot overstep. We need communication, but we also need privacy and respect. The "ponderable imponderables" (in Simone Weil's powerful expression) exist; the "ultimate concerns" of Paul Tillich cannot be communicated. There is a time when the incommunicable takes precedence.

TRUTH IN MEDICINE THROUGHOUT THE WORLD

The medical act involves a moral agent as well as values and goals. The agent, who is both the patient and the doctor, has character and virtues, responsibility and rights, a certain degree of free will and control. The agent also has memory, imagination, creativity.

The values involved in the patient-doctor relationship are attributed to

the act by the agents. The values are attributed to an act before, during, and after the act takes place. The a priori attribution of values is contextual, insofar as it is learned and shared among persons in a particular context.

The *telos* of the medical act is healing. However, the goals of the medical act (and its consequences, too) might not necessarily be the same for the patient and the doctor, as they are strongly influenced by the asymmetry of the patient-doctor relationship. Think of the different meanings that a partial remission has for the patient and for the doctor where cancer is concerned, or consider the debate on quality of life and how to measure it.

Indeed, active work of communication is needed for the patient and the doctor to establish and reach a common purpose of the medical act. Unlike relationships among peers, the patient-doctor relationship cannot be described simply as a contract. There is a state of slavery induced by disease that renders the patient vulnerable; also, it makes the purpose of the medical act that of setting the patient free from the slavery of disease. We all are so familiar with our medical terminology that we probably no longer pay attention to its meaning: "disease-free," "freedom from relapse," "freedom from symptoms" are recurrent idioms in the medical, and especially the oncological, literature. Spiritual freedom, achieved by sharing the path to make truth, is also a goal of medicine.

In this book we read about the complexity of the issue of communication with a patient affected by a serious, often lethal, disease. We shall learn about different contexts, about different ways and—honestly—quite different degrees of informing patients, about different efforts to make a truth between the doctor and the patient. Also, we shall learn about different ethical frameworks and justifications of different practices of information—or noninformation—throughout the world.

FOR A POSSIBLE ETHICAL INTERPRETATION OF DIFFERENT PRACTICES THROUGHOUT THE WORLD

In reading the different chapters of this book, I first felt a strong positive feeling of breathing honesty—in itself a moral value. Then, I was fascinated by everything I learned, by the many facts and values that I had been ignoring. Finally, I tried to understand what the common ethical background behind such a tremendous variety of practices could be.

It is certainly not my intention to analyze or systematize the work of others. On the contrary, I am simply offering a review of what appear to me as the two dominant leitmotifs with respect to the ethics behind those practices: an interpretation resting on the interplay of the principles of respect for autonomy and of beneficence towards the patient on the one hand; an interpretation stemming from *phronesis*, or practical wisdom, on

the other—the former emphasizing the act, the latter the agent. As a matter of fact, after reading all the chapters, the two appear to be closely intertwined.

While "what is truth" is a metaethical question, ethics is faced with the issue of truth-telling—as previously alluded to, an action-oriented problem. And we might remind ourselves of the Kantian definition of ethics as a practical philosophy.[5,6]

Quite often, the issue of truth-telling is approached from the point of view of principles of medical ethics—namely, respect for autonomy and beneficence. Many contributors have employed this terminology, or implied it in their discussion. The word "autonomy" refers to the patients' rights to be respected in their life and dignity, as well as their right to self-determination with regard to their health. The word "beneficence," on the other hand, refers to a duty of the physician—that of doing the patient's good. Implicit in the latter is the assumption that the medical knowledge of the doctor translates into a certain responsibility to determine what is best for the patient; this need not necessarily be a form of paternalism, as most of the contributors show in their chapters. There are other principles of medical ethics, such as nonmaleficence and justice, although these are not directly involved in articulating the discussion about truth-telling. Most ethical theories see truth-telling as a specification of the principle of autonomy.[7]

Kant, in his *Foundations of the Metaphysics of Morals*,[5] defined truth-telling as essential in order to respect the autonomy of each individual—the only way to treat a person as an end and never as a means. For Kant, indeed, the "sublimity" of a person comes from being morally autonomous. Kant spoke of the "autonomy of the will," which he contrasted with "heteronomy"—the former referring to acting according to the categorical imperative, the latter to acting according to motivations other than universal moral principles. Never does autonomy in Kant assume any libertarian connotation, as it does in present Western cultures and bioethics. Mill, on the contrary, regarded autonomy as necessary for each person to shape her life—a process he preferred to call "individuality."[8]

The use of principles in bioethics is derived primarily from the work of W. D. Ross,[9] to whom we owe the definition of "prima facie" duties or principles. There are many different moral obligations that present themselves in any given situation, and at times they conflict. These different moral obligations are basic, valid moral principles, but because they can conflict, it may be impossible to honor them all at the same time. In this sense, they are not absolute, and they can be "rendered wrong": moral principles for Ross are thus conditional, prima facie. In Ross's work there is no hierarchy of principles, although he tends to assume that nonmaleficence takes priority over beneficence.

The lack of a hierarchical order leads, in my opinion, to an important

consequence—that any choice, even the right one, will always leave out something that we know to be of moral value, and that does not cease to be such. Hence moral life can be difficult, if not tragic: moral dilemmas exist; they are the rule rather than the exception. We do not live in Kant's world of noumenal moral duties, where "obligationes non colliduntur"; and when dilemmas arise, they do not destroy obligations as such. Moral dilemmas are a fact of life, a "misfortune of moral life."[10] They are not simply the result of imperfect understanding of the duties of the case; and Kantian theory ignores "regrets and related considerations" by eliminating "the ought that is not acted upon."[11]

There have been many lines of criticism of the use of prima facie duties, and excellent reviews of these issues have recently appeared in the literature.[12] I shall briefly summarize these criticisms for the reader who is not necessarily familiar with the subject. First, one could deny the existence of conflicts of duties when seeing conflicting duties as conditional. Second, acceptance of prima facie duties could devastate common sense morality, by hiding actual duties. The provisional character of prima facie duties with their qualifications has also been severely attacked as lacking a theory of reference and thus being inadequate in accounting for the complexity of moral life: autonomy per se, for instance, does not mean anything if we do not specify (somehow a priori with reference to a systematic moral theory) its subject and its content. Also, the use of prima facie duties has been criticized as being procedurally emphatic. Finally, it has been seen as abstracted from the real world of morality and from the sociocultural context. The latter indeed appears to be a valid criticism to me, while the previous seem to ignore the instrumental value of prima facie duties. If we consider them as being at an intermediate level between a systematic moral theory and the pluralism of different narratives, they provide us with an effective tool for a preliminary reading of the moral experience. They enable us to define the duties at stake in a particular moral experience and/or moral dilemma. They also enable us to recognize the elements necessary to formulate a moral judgment in a concrete situation.[13] Thus prima facie duties may help in the "delimitation of a range of acceptable actions"—which seems to be the purpose of an ethical code.

The use of principles in bioethics has been extremely valuable in providing instruments by which to frame moral dilemmas in medicine.[7] Truth-telling, for instance, can easily be framed in terms of autonomy and beneficence, although often our final ethical choice finds its justification outside the framework of principles alone.

This is first because autonomy and beneficence cannot be abstracted from the contextual dimension. As seen repeatedly in the discussion about truth-telling in medicine, contextual aspects can never be eliminated, as moral life does not happen in the world of ideas; it happens in a here and now, in a given society, with its cultural background, its eco-

nomic and political circumstances. And the patient-doctor relationship is no exception: it is, indeed, always part of a broader patient-doctor-society relationship. Contextualism does not necessarily mean relativism, but it brings to the surface the reality of pluralism in our world: different interpretations and different expressions of moral principles in different cultures coexist with the same universal right to dignity of every human being and with the same universal duty to respect this dignity.[14,15]

It is, indeed, the aim of this book project to show in how many different ways truth-telling can occur and under which circumstances truth-telling might not occur, at least not in the Western understanding of the word. An initial explanation for these cultural differences, as we have just seen, is that the two principles of autonomy and beneficence cannot be abstracted from the contextual dimension, and, on the contrary, depend on the shared meaning of each in any given culture.[16] A second explanation is that autonomy and beneficence are interrelated principles, never existing without each other; truth-telling, then, stems from a balance between the two. That this is not a "semantic somersault"[17] is proved by the extensive literature on the subject, and certainly by the many contributions to this book.

Also, as previously alluded to, important justifications for the different ways of approaching truth-telling in the patient-doctor relationship lie outside the strict world of principles. Virtues, responsibility, and trust play equally essential roles, by emphasizing the moral agent and her character and role in solving ethical dilemmas.

Thus truth-telling becomes a matter of phronesis, of practical wisdom—which is itself a leitmotif of our book and its narratives. Phronesis —in Aristotelian terms[1]—refers to the "prudent weighing of the alternatives in situations of uncertainty and stress."[18] Its roots resting upon the integrity of the physician, upon his or her moral character, phronesis leads to the timely and appropriate way of responding to each individual patient's needs, including that of being told the truth that he or she wishes to hear.

Thus truth-telling becomes a matter of responsibility, both the doctor's and the patient's. The professional responsibility is the doctor's, whose situation in the patient-doctor relationship is that of the more knowledgeable, hence more powerful, figure. The doctor has responsibility as a healer; and we all know to what extent cultural and personal sensitivity can increase the therapeutic efficacy of the medical act. The patient's responsibility lies in his or her narrative, as well as in being honest in the relationship with the doctor. Finally, there is their mutual responsibility in sharing the process of making truth, in coauthoring a truth for the present and the future.

Thus truth-telling becomes a matter of trust.[19] The patient-doctor relationship is an asymmetry, and as such it escapes the realm of contractual relationships among peers. Kantian autonomy, based on reciprocal

promises and on a moral accountability limited to autonomous equal relationships, does not cover all aspects of the patient-doctor relationship. The patient and the doctor are, indeed, equal human beings, with equal moral and social status and deserving equal respect. The patient-doctor relationship is also a form of covenant, and as such it calls for special attention to the expectations and promises of both partners. But the patient-doctor relationship is in essence a fiduciary act, based on mutual trust. Unlike most other contracts, it involves a very delicate aspect of our being human: the dependence that we all have on our body and its functioning—the basis of human life. When we put our health and life in someone else's hands, we need to trust in more than the doctor's honoring his or her part of the contract. We need to trust in the doctor's caring for us. After all, do we not all speak of medical *care*?

CONCLUSIONS

Truth-telling is only one step in the patient-doctor relationship and in the process of communication. Many other variables contribute to the cocreation by the patient and the doctor of an evolving truth: the role of society both as macro- and microenvironment, the evolution of the disease, the pharmacological component, the "unexpected" in life.

Truth-telling is an essential step, though, to care; and we should never feel relieved of our responsibility to be truthful to our patients, according to our cultures and to sensitivity to individual circumstances.

Truth-telling, finally, is not only toward our patients, but also among our professional colleagues: the honesty of each of the contributions to this volume is proof of this dimension of truth-telling. Honesty is at the core of this project, its main value. We will learn from others' experiences about different ways of making truth within the context of a highly valued patient-doctor relationship.

Can it be that one of the determining aspects of the healing process is, indeed, how much the patient and the doctor value their particular relationship? It does appear to be so, from my personal experience and, if I have correctly interpreted the contributions to this volume, from the experience of many others throughout the world.

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Sounding Board

Unlimited Human Autonomy — A Cultural Bias?

AUTONOMY has become a dominant bioethical value in the Western world. It is the basis of many ethical decisions, and considerations of autonomy influence legislators, judges, and the public alike. The predominance of autonomy has been described by one of its critics as verging on the "tyrannous."[1]

In this essay I describe three recent events in Israel that run counter to this trend. They include court decisions and the enactment of laws that clearly place Israel in a unique, and perhaps lonely, position in the Western world. The most recent event was a decision[2] by a district judge who ordered the force-feeding of a group of political prisoners engaged in a hunger strike. They had reached a stage of the strike that, in the opinion of physicians in the prison service, was endangering their lives. The judge stated clearly that when there is a conflict between life and dignity, the preservation of life takes precedence.

By coincidence, one of the prisoners was hospitalized in the department of internal medicine that I head. Since this was a most unusual and delicate situation for the entire staff, I decided that rather than have the house officer proceed immediately to the admission history taking and physical examination, I would first meet with the prisoner to discuss the issues. He was a pleasant, articulate young man in his 20s who had the usual appearance of an ultra-orthodox Jew, with a beard, side locks, and a large skullcap. He was engaged in reading a religious tract.

After a few pleasantries, I explained that he had been sent to the hospital to be fed, even against his will. I pointed out that I was under two sets of orders, one from the legally constituted Israeli court and the other, since I am an orthodox Jew, from a divine edict that commands me not to let a fellow human die if such an event can be prevented. He responded quite calmly that he rejected the authority of the court, since he regarded it as part of the corrupt system against which his protest was directed. With respect to the divine edict, he pointed out that there are situations in which one is commanded by this same divine authority to sacrifice one's life for a greater cause. He indicated that he would not be dissuaded from this firmly held position.

I indicated that we had the will and the ability to feed him even against his will and that it would be much more pleasant for all concerned if he did not resist being fed through a nasogastric tube. He asked for time to think it over and shortly thereafter stated his position. He requested assurance that the tube feeding meet his particularly high standards for kosher food and that he be permitted to deposit a letter, with copies sent to a list of government authorities, indicating that he was being fed against his express wishes and that I would bear the legal and criminal consequences. When this was accomplished, he offered no resistance and accepted tube feeding "under protest."

The decision by this Israeli court stands in striking contrast to a recent situation in Turkey in which at least 12 hunger strikers died; to previous political hunger strikes in Ireland and South Africa; and to the generally accepted position of Western bioethicists, as reflected in the Tokyo Declaration.[3] I am convinced that my particular hunger striker was ultimately pleased with the turn of events. He received the necessary attention, yet he was prevented from dying by a superior power. In essence, he was able to have his cake and eat it too.

The second event, which took place a month earlier, was the enactment of a patients' rights bill[4] by the Knesset, Israel's national legislature. Much of the law was relatively noncontroversial, but one clause in the original bill created considerable debate. It required that informed consent be obtained before treatment, as in most Western countries, and it spelled out in some detail the information to be provided to the patient. The legislators were faced with a major dilemma, however: what to do when a patient refuses a treatment that is clearly lifesaving. The government's chief legal counsel convened a meeting of about 30 physicians, philosophers, lawyers, and clergy to discuss this issue. The civil libertarians in the group, of course, took the standard Western position — namely, that under no circumstances could therapy be rendered against the will of a competent patient, unless the patient's illness threatened the welfare of others, as in the case of certain communicable diseases.

But others in the group would not accept this position. As one of Israel's leading philosopher-ethicists stated dramatically: "I simply am incapable of standing idly by and watching while someone lies on the railroad tracks waiting for an approaching train in order to commit suicide, without making an effort to prevent that person's death, even against the person's will." The final compromise, a bit unusual by any standard, permits a competent patient to be treated against his or her expressed will if the legally constituted hospital ethics committee is convinced that there is "reason to believe that after receiving the treatment the patient will give . . . retroactive consent."

This compromise might legitimately be seen as a bit of Talmudic legerdemain to justify physicians' paternalism and disregard of patients' wishes. But I

would contend that it allows a less simplistic approach to a patient's refusal of therapy than does the conventional Western view. Indeed, on occasion, patients who are fully competent in the legal sense refuse lifesaving therapy, but the reason for the refusal may well be an irrational fear, which is not always overcome even by repeated attempts at persuasion. One might perhaps see forcing people to undergo lifesaving therapy as an action that does respect their autonomy and for which they may ultimately be grateful; their judgment may be temporarily compromised by irrationality, although they remain within the bounds of legally defined competence. Such overriding of patients' expressed wishes should be rare, and indeed is so in Israel, but the Israeli system now provides an avenue of escape from rigid adherence to the constraints of laws based on autonomy, which may lead to needless deaths.

The two events I have described were preceded by a landmark decision in 1993 by the Israeli Supreme Court[5] that perhaps best articulates the Israeli position on autonomy. In the decision, which concerned the treatment of a child with Tay–Sachs disease, the vice-president of the Court described Israeli law and society as an amalgam of two values that may at times conflict. On the one hand are the values of Jewish tradition, which place great emphasis on the sanctity of human life. On the other hand are the values of Western democracy, which stress human autonomy. These two fundamental principles may conflict when questions about ending a patient's life at the patient's request are raised. The vice-president therefore enunciated a precedent-making position that, in accordance with the principle of the sanctity of human life, unequivocally ruled out any action that could be construed as active euthanasia or physician-assisted suicide, even when it was taken in response to a patient's express wishes. At the same time, the decision recognized, out of respect for human autonomy, the right of a terminally ill, suffering patient to reject intrusive and uncomfortable therapy that cannot cure the basic illness.

These three examples provide a glimpse into how a society that by many standards is an integral part of the Western scientific and medical world deviates considerably from Western norms in certain fundamental respects. The reasons are multiple and complex. Clearly, however, Jewish faith and culture place enormous emphasis on the value of human life. This position has been expounded in terms of what I call the "mythology" of the infinite value of human life.[6]

The biblical admonition "Do not stand idly by your friend's blood"[7] creates an imperative for extensive involvement in the affairs of others, for their benefit — more so than is generally accepted in the West. In addition, the concept of mutual responsibility among Jews has been clearly articulated: "All Jews are responsible for each other's deeds."[8] Furthermore, the trauma of the Holocaust, whose survivors abound in Israel, is often remembered in terms of the failure of the nations of the world to take action to prevent the death and suffering of others. These are a few factors that, I believe, contribute to the Israeli ethos, which calls into question a policy of nonintervention when human life is at stake.

The conventional Western view says to competent people who wish to end their lives, "If that is your autonomous desire, we will not obstruct you in any way." Indeed, most Western countries have abolished the criminality of suicide. The traditional Jewish view says, "You are so valuable to us, beyond what you mean to yourself, that we simply cannot permit you to die. We care so much about you that we are willing even to violate your human rights in order to save your life." These two contrasting approaches represent, on the one hand, an individualistic view of society, and on the other hand, a perception of society more as a community, even a family. It is perhaps no coincidence that one of the chief proponents of the communitarian movement in the United States[9] is a former Israeli.

Classic Western bioethics and law do not accept unlimited human autonomy, either. They override individual autonomy when respecting it would endanger others, as when antituberculous therapy must be imposed, but they respect autonomy almost totally when others are not directly affected. The Israeli view described here may be seen as a rejection of the idea that a person's actions in ending his or her life affect only that person. Instead, it asserts that a person's death diminishes others as well and that therefore society is permitted to intervene.

The widely accepted Western approach by which a hunger striker's expressed desire to die is accepted at face value and by which society is absolved of any responsibility for preventing such a death seems somewhat simplistic, as is clear from the story of the hunger striker I have told here. A Western court would have had no difficulty deciding not to feed him, and indeed the issue would probably not have been brought to a court, but that might have been a tragic error.

Even the strongest advocates of autonomy would do well also to consider the possibility that some of the most articulate, seemingly determined hunger strikers may not be fully autonomous in their actions. Pressures from politically like-minded colleagues, the need to save face, and other factors may preclude a totally autonomous decision. An error by which dignity is denied in favor of life may be remediable, but one that denies lifesaving action is irreversible.

In describing the case of this hunger striker, I do not in any way mean to assert that people do not have the right to sacrifice their lives for a higher

cause. The world is a better place because of many such martyrs. Nor do I countenance the complicity of physicians with totalitarian regimes when they force-feed fasting protesters in a manifest attempt to break the resistance of legitimate protest movements. But I do think that the issue is much more complex than is suggested by the politically correct view that feeding hunger strikers by force is always unethical.

Israel is not alone in limiting autonomy in favor of preserving life. At a 1992 conference on the cross-cultural dimensions of medical ethics, a speaker described the prosecution and conviction in India of a physician who allowed a patient to die because he did not impose treatment against the patient's will.[10]

There is deep disagreement in the West about many bioethical issues, whether they are classic ones such as abortion and euthanasia, or issues related to advances in biology and medicine, such as genetic engineering and new techniques of reproduction. But there is a fairly strong consensus about the respect given to patients' autonomy in a wide range of ethical situations, and about the priority that autonomy should be accorded. The consensus may create the illusion that this Western approach is almost a canonical truth. It is important, however, to be aware of and sensitive to trends that run counter to prevalent Western axioms and dogma and that may contribute significantly to bioethical thinking.

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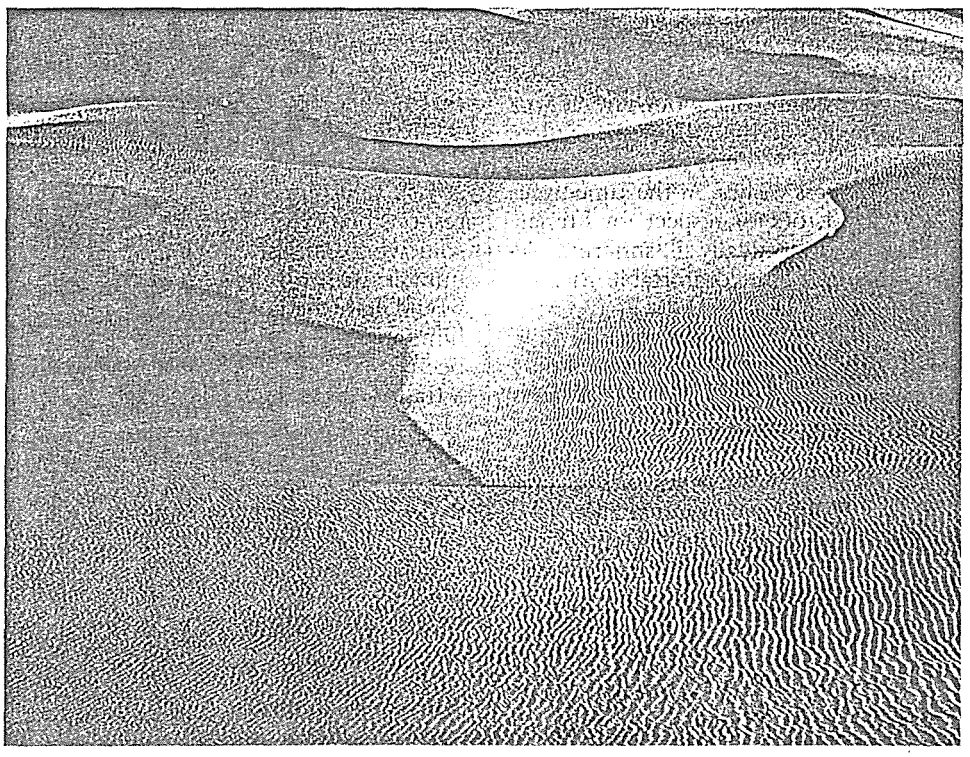

Sand Dunes ERIC BLAU, M.D.

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MEDICAL GRADUATES IN ONCOLOGY

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Oncology is emotionally as much as professionally a demanding medical field. Stigmatization of cancer by lay people and medical professionals alike, and frequent helplessness while encountering dying or palliative patients are the main emotional burdens and cause many young doctors to turn away from residency in any of the oncological specialties. Those of us who enter oncological residency are thrown in the realm of ethically difficult decisions combined with strong emotional reactions from patients, their relatives, and our own.

Lacking any formal training from the medical school, we mostly deal with all that by empirical on-the-job learning and random experience, sometimes just copying often-inadequate practices of our older colleagues. Some of us make it; others hide behind good technical skills and minimize communication with the patients, moving towards imminent burn-out syndrome.

It does not need to be like that. While being successful in dealing with ethical dilemmas may require certain character traits, it is also definitely something that can be learned. Many medical schools in Western Europe and the USA have recognized that and provide active courses in biomedical ethics (1,2). Learning at bedside and from clinical colleagues is also beneficial if it is done properly. The third very effective way of learning to deal with ethical dilemmas is by guided discussion about ethical problems. It also helps to lessen the emotional stress, thus preventing the development of the burn-out syndrome. It is also an efficient way of developing moral character, as was established by Kohlberg (3).

The skill a young oncologist needs to develop the most is communication. Learning about biomedical ethics and ethical dilemmas remains purely academical if we don't know how to communicate our decision to the patients and their relatives. Or better, to communicate a common decision with them. It is also the paramount skill for dealing with emotional reactions of all involved.

As a conclusion, I would like to appeal to senior colleagues and faculty members to encourage, promote and contribute to teaching of biomedical ethics and communication skills to medical students and residents. It is the next step from mastering their technical skills to making them better doctors.

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COMMITMENT OF A NURSE IN COMMUNICATION WITH CANCER PATIENTS

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Let us not pretend that Slovenia is a country where cancer patients are properly informed of their desease. A personal appreciation of cultural values and ethics norms of health workers has an arbitrary role in deciding what should be told to cancer patients as well as in presuming what the patients expect to be told. The commitment of a nurse to provide the patient with adequate information is extremely valuable. The recent training course on communication with the cancer patient, held this spring in Ljubljana and organized by the Section of Oncology Nurses of Slovenia, was the right opportunity to find out what is their viewpoint regarding the communication of the truth to cancer patients. Most of the participants to this course had, on average, 12 years of experience in nursing cancer patients in hospitals.

After the introductory part of the course in which the communication dilemmas were approached only theoretically, we continued the work in five focus groups. Open conversations of an hour and a half in the groups revealed what cancer, a severe, chronic disease, bringing along distress, pain, fear, uncertainty and death, means to any of the nurses involved in cancer patients care. The general opinion was that the patients are not sufficiently informed, irrespective of the questions which they do or do not ask. Many communication barriers may stand in the way to an open talk with the patient: lack of knowledge, lack of time, lack of experience, work overload, and, in addition to that, feeling the heavy burden of the disease to the patient, as well as fear and helplessness. During the course, the need for a training seminar that would teach the nurses how to master and improve the comminication with cancer patients, became apparent.

On the other hand, the most painful experience for a nurse is the patient who does not wish to learn and face the truth. Are there any limits in empathizing with the patient who should be ready to fight the diseases despite the threat of the death? Though the term commitment to inform properly is being frequently mentioned, it has not been materialized yet because, in practice, cancer is, as it has always been, a taboo. It does not concern us as long as it does not touch us.

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ETHICAL PROBLEMS IN COMMUNICATION WITH CANCER PATIENTS: RELATIONSHIP BETWEEN THEM AND SOCIETY

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Diagnosis of cancer is a shattering experience for patients and their relatives and the community. For them. it is often the beginning of a long trip into the world of torments and painful hesitations. Paradoxically, the advances in methods of cancer treatment are not changing the general position of society to consider cancer patients as persons of another class or even to exclude them from the community.

What are the reasons for this attitude? Why do the persons, who face malignancy, meet unfriendly and, sometimes, opposed attitude? It is a general knowledge that they are not contagious and cannot transmit the disease to others. Many oncologists can confirm that the word "cancer" is such a shock to patients that they cease to follow most of what the doctors has to say. Why is cancer so shocking a diagnosis, while the mortality of for example heart diseases is higher then in most malignancies?

These and other questions are not so ungrounded as it may seem at first sight. As soon as we, oncologists, are unable to prevent cancer in general, it is absolutely required to reduce its destructive psychological impact on society. Unfortunately, it is exactly professionals, who remain the most conservative in terms of skills to communicate both with patients and with people in general. Cancer patients are afraid of death as well as of the unpredictable reactions of their family and close neighborhood.

It is a pity that the information concerning cancer is not talked about openly in Russia as much as it should be in order to make it easier for people to cope with this disease realistically. The majority of information is more of fear and a miserable end rather than to educate them with the aim of to secure their cooperation in the battle against cancer.

The author is involved with breast cancer patients and analyses the problem of communication in this particular branch of oncology and suggests that there are four key elements to be considered. In Russia, there is no doubt that women with breast cancer are not sufficiently advised and educated in all aspects of the disease which would enable them to carry the responsibility for their own health. A survey of breast cancer patients showed that they are mostly influenced and educated about their disease by professionals, mass media, cancer patients' close relatives, and survivors of cancer, the latter contributing mostly psychosocial support. All of them should therefore function together in their separate manners, keeping in close contact with both healthy women and present patients to assist communication and understanding. The foundations of improved communication should be truth, training, patience, compassion, and respect. A correct communication must convince people that they can and have to be examined whenever they need to. It must help them understand what the words "malignancy and cancer" mean in terms of current research and has to help them accepting radical therapy confidently. The author is very proud that the Russian Reach to Recovery Organization HOPE and himself in his role of its president do all their best in promoting this process in our country.

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11

Paternalism and Health Behavior

Tore Nilstun

Smoking is a preventable health risk to smokers as well as to nonsmokers who are exposed to tobacco smoke (Eriksson, LaMaistre, & Newell, 1988; *Healthy People 2000*, 1991; Peto, 1994), and costs related to the use of tobacco are substantial (Hocking, Grain, & Gordon, 1994). It is therefore not surprising that far-reaching measures have been suggested to protect individuals against the dangers of smoking (Leppo & Verio, 1986; Roemer, 1993), frequently with strong opposition from the tobacco industry (Editorial, 1994; Stanton & Begay, 1994).

Attempts to modify smoking behavior raise the controversial issue of paternalism, and the purpose of this chapter is to discuss the ethics of paternalism in the context of health maintenance, health restoration, and health improvement. First, the concept of "paternalism" is defined; second, different types of paternalism are identified; third, the relevant value premises are formulated and applied in the analysis of paternalistic measures suggested to protect against the dangers of smoking.

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Handbook of Health Behavior Research IV: Relevance for Professionals and Issues for the Future, edited by David S. Gochman, Plenum Press, New York, 1997.

DEFINITIONS OF PATERNALISM

In the *Compact Edition of the Oxford English Dictionary* (1971), *paternalism* is defined as follows:

> *Definition 1*: the claim or attempt to supply the needs and to control the life of a nation, a community, a group or an individual in a way like that of a father towards his children.

There have been several attempts in the literature on medical ethics to make this definition more precise. Though the basic idea is usually preserved, the meaning is somewhat changed, as illustrated by the following examples:

> *Definition 2*: Paternalism, then, is the intentional overriding of one person's known preferences or actions by another, where the person who overrides justifies the action by the goal of benefiting or avoiding harm to the person whose will is overridden (Beauchamp & Childress, 1994, p. 274).
>
> *Definition 3*: Paternalism [is] the use of (varying degrees of) coercion to impose another's vision—where the other might be the state, private institutions, or individuals—on a single individual or class of individuals (Agich, 1993, p. 3).
>
> *Definition 4*: Paternalism refers to behaviour that attempts to interfere with the autonomy of an individual without his/her consent (explicit or presumed) for the express purpose of benefiting that individual (Veatch & Spicer, 1994).
>
> *Definition 5*: Briefly, paternalism is the belief that it

can be right to order the lives of others for their own good, irrespective of their own wishes or judgments (Harris, 1985, p. 194).

Definition 6: Paternalism is the protection of individuals from self-inflicted harm,... Decisions are taken, choices made and freedom inhibited, all for the good of the patient. There is no element of consent (Downie & Calman, 1994, p. 163).

Definition 7: Paternalism characteristically involves making people's decisions for them or keeping certain information from them on the grounds that it would be better for them not to know (Shinebourne & Bush, 1994).

Definition 8: Paternalistic actions [means that] A is acting towards B for the purpose of benefiting B but without B's informed consent (Nikku, 1994).

Definition 9: P acts paternalistically towards Q if and only if (a) P acts with the intent of averting some harm or promoting some good for Q, (b) P acts contrary to the current preferences, desires or dispositions of Q, (c) P's act is a limitation of Q's autonomy (Dworkin, 1992).

On the population level, however, there are several problems with these definitions. First, most of the definitions (2, 4, 6, 8, and 9; possibly also 5 and 7) require that the beneficiary be identical with the one whose autonomy is limited. But in health behavior modification, the would-be paternalist is usually an authority that acts toward the whole population or a group with the purpose of benefiting some unidentified persons (Nikku, 1994). When health behavior modification is the issue, acts with the motive of benefiting a group or class of individuals (and not a particular individual) would not be paternalistic by these definitions.

Second, according to some of the definitions (2, 3, and 9), an act is paternalistic only if the act, *as a matter of fact*, contradicts the current preferences, desires, or dispositions of the individual or the group. According to the other definitions (1, 4, 5, 6, 7, and 8), this condition is not necessary; they require only that the person who acts paternalistically not know what these preferences, desires, or dispositions are. The first condition (that the act should contradict such preferences ...) is, in the view of this chapter, too strong. But the second condition (that the paternalist not know what these preferences, desires, or dispositions are) is too weak. This chapter proposes a somewhat modified version of the second requirement in the last definition (9). The condition "P acts contrary to the current preferences, desires or dispositions of Q" should be replaced with a somewhat weaker requirement: "P has no reason to believe that the act agrees with the current preferences, desires, or dispositions of Q."

The following definition incorporating this substitute second condition and a slight rewording of the third is suggested:

P acts paternalistically toward an individual or a group Q if and only if

(1) P acts with the intent of averting some harm or promoting some good for Q;
(2) P has no reason to believe that the act agrees with the current preferences, desires, or dispositions of Q; and
(3) P's act is a limitation of Q's right to self-determination.

DIFFERENT TYPES OF PATERNALISM

On the basis of these three conditions, six different types of paternalism may be identified. The requirement that P act with the intent of averting some harm or promoting some good for Q suggests the first distinction. If the would-be paternalist's only motive is to benefit an individual Q (in one way or another) the act may be called *individual paternalism*. It is also called *medical paternalism* (Giesen, 1988). But if the motive is to protect a group or class of individuals from harm, the act may be called *social paternalism* (Kjellin & Nilstun, 1993). The expressions "pure paternalism" and "impure paternalism" are sometimes used to indicate this distinction (Beauchamp & Childress, 1994, p. 275).

In the clinical setting, individual paternalism is more common than social paternalism: The motive is primarily to benefit a particular patient. Antismoking policies (which are based on the idea that individuals are not to be relied on in assessing the health risks of tobacco use), how-

ever, aim at the prevention of harm to the general public, both smokers and nonsmokers. Most such attempts to modify health behavior therefore exemplify social paternalism.

The second requirement in the definition relates to the current preferences, desires, or dispositions of Q. Since Q may prefer in some situations that P act and in other situations that P abstain from acting, a distinction is sometimes made between *active paternalism* and *passive paternalism*. Passive paternalism obtains when P refuses to execute the positive preferences of Q. Debates about paternalism typically focus on active paternalism, i.e., situations in which P acts on the grounds that it is to Q's benefits even though Q prefers nonintervention (Beauchamp & Childress, 1994, p. 288).

Many smokers prefer nonintervention. Attempts to modify their smoking behavior would therefore, as a rule, exemplify active paternalism. Passive paternalism is probably more frequent in other areas, e.g., in sports medicine, when a physician refuses to provide an athlete with anabolic steroids.

The third requirement in the definition relates to the concept of autonomy. Depending on the degree to which Q is an autonomous person, *weak paternalism* can be distinguished from *strong paternalism* (Feinberg, 1971). In weak paternalism, the would-be paternalist intervenes to protect persons against their own nonautonomous actions; in strong paternalism, the purpose is to protect persons against their autonomous actions (Beauchamp & Childress, 1994, p. 277).

Unfortunately, there is no general agreement on where to draw the line between weak and strong paternalism. One attempt, which makes much sense, was made by Harris (1985, pp. 195–201). His point of departure was that perfect autonomy is, like any ideal, unattainable. The line should therefore be drawn where an individual is as autonomous as can reasonably be expected. This is the case when there are no apparent defects in the agent's control (such as mental illness or drug addiction), reasoning, or available information relevant to the decision at hand. Accordingly, most of the current attempts to modify health behavior related to smoking would be classified, if they were classified as paternalistic at all, as strong paternalism.

These six different types of paternalism are summarized in Table 1.

Other subclasses of paternalism have also been suggested. For instance, Häyry, Häyry, and Karjalainen (1989) distinguish three levels of paternalism: *paternalistic paternalism* (such as

Table 1. Six Different Types of Paternalistic Acts[a] by P toward Q, and Their Respective Frequency in Smoking Behavior Modification at the Population Level

Characteristics of the paternalistic act	Type of paternalism	Frequency in smoking behavior modification
P's intention is to:		
Benefit only an individual Q	Individual paternalism	Seldom
Benefit a group or class Q	Social paternalism	Often
Q prefers or desires:		
Interference	Passive paternalism	Seldom
Noninterference	Active paternalism	Often
Q is:		
Autonomous	Strong paternalism	Often
Nonautonomous	Weak paternalism	Seldom

[a]An act is paternalistic if and only if (1) P acts with the intent of averting some harm or promoting some good for Q; (2) P has no reason to believe that the act agrees with the current preferences, desires, or dispositions of Q; and (3) P's act is a limitation of Q's right to self-determination.

health education in schools, total ban on advertisements, and sale restrictions to minors), *weak paternalism* (such as health education in mass media, by health professionals, and by voluntary organizations), and *strong paternalism* (such as a ban on brands exceeding an upper limit of hazardous substances).

VALUE PREMISES

Justification of paternalism requires value premises. Such premises are often taken from or inspired by ethical theories. This chapter therefore provides a short summary of the three most discussed and applied theories in medical ethics: utilitarianism, libertarianism, and justice as fairness.

There are several forms of utilitarianism. According to *act utilitarianism*, an act is right if and only if it maximizes utility (Jeremy Bentham, 1789; John Stuart Mill, 1861)—or, in some versions, minimizes suffering (Popper, 1966). According to *rule utilitarianism*, an ethical rule is right if and only if general compliance with the rule maximizes utility, and a particular act is right if and only if it falls under such a rule. According to *classical utilitarianism*, the aim should be the maximization of aggregate utility, while *average utilitarianism* requires maximization of utility per capita. There is no general agreement on the definition of *utility*. Some define it as pleasure or happiness (and absence of pain or suffering); others, as satisfaction of preferences or needs.

The most influential modern exponent of the *libertarian* theory is Nozick (1974), but a similar theory was earlier formulated by John Locke (1690). The basic assumption of the theory is the liberty of all individuals to do what they please with themselves and their property, provided that they do not interfere with the like liberty of others. A further limitation on the right to liberty is given by the harm principle. This principle says that the liberty of one person should be restricted only to prevent harm to others (Feinberg, 1973; Mill, 1859). The right to property is fundamental to the libertarian theory, and it determines both the role of the state and the rules of individual conduct. When a person finds or "mixes labour with" an unowned item, there is initial acquisition of property. The owner of the property may sell it on the free market or give it away as the owner pleases.

Rawls (1952, 1972) is a defender of *justice as fairness*. This theory contains three principles: Each person is to have an equal right to liberty (greatest equal liberty), persons with similar abilities and skills are to have equal access to offices and positions (equality of fair opportunity), and social economic institutions are to be arranged so as to benefit maximally the least well off (fair differences).

Inspired by the ethical theories of utilitarianism, libertarianism, and justice as fairness, three value premises may be identified:

- *The principle of beneficence* states the moral obligation to benefit others, especially not to harm them (utilitarianism).
- *The principle of autonomy* states the moral obligation to respect each other's right to self-determination (libertarianism).
- *The principle of justice* states the moral obligation to act fairly in the distribution of burdens and benefits, especially not to discriminate against anyone (justice).

These principles, which are commonly accepted in medical ethics (Beauchamp & Childress, 1994; Gillon, 1994; *International Guidelines for Biomedical Research*, 1993; *International Guidelines for Ethical Review*, 1991; Stanley, 1989), are rather vague and do not themselves provide a method for balancing them against each other when making moral decisions. They do provide, however, a potentially international and intercultural basis for a common moral commitment that requires that transgression of any one of them can be justified only by pointing to the overriding application of one or more of the others (Gillon, 1993).

IDENTIFICATION AND ANALYSIS OF ETHICAL CONFLICTS

An ethical conflict is a situation where there is at the same time, a moral obligation to adopt each of two alternatives, and the agent cannot adopt both alternatives together (Gowan, 1987; Sinnott-Armstrong, 1988). When paternalism and smoking behavior modification is the issue, the ethical conflicts often (but not always) arise because principle of beneficence and the principle of autonomy cannot be satisfied at the same time.

Examples of measures suggested (and often implemented) to change smoking behavior are (1) health education in schools, via the mass media, for people using health services, and by voluntary organizations (Flynn et al., 1992, 1994; Gregorio, 1994); (2) price policy, such as regular price revisions and differential taxation (Townsend, Roderick & Cooper, 1994; Yach, 1994); (3) premarket licensing, such as quality control, health warning on packages, ban on brands exceeding the upper limits of hazardous substances, and classification of products as "harmful" and "very harmful" (Benhamou, Benhamou, Auquier, & Flamant, 1994); (4) total ban on advertisement and sales promotion—so far only on the national level (British Airways' response, 1994; Fulop, & Mckee, 1994)—or at least on campaigns with special appeal to teenagers (Hastings, Ryan, Teer, & MacKintosh, 1994); (5) sale restriction (Leppo & Verio, 1986); (6) restriction on smoking in schools, nurseries, public transport, and other public locales (Moore, Wolfe, Lindes, & Douglas, 1994); (7) restriction on portrayal in films and television of smokers as successful and attractive (Hazan, Lipton, & Glantz, 1994); and (8) research, planning, and evaluation of consumption levels and trends and their distribution and of the health effects of smoking (Gritz, 1994; Wynder & Hoffmann, 1994). It has also been suggested that smokers (as a group) should be held accountable. Revenues from cigarette taxation should be placed in a specific trust to pay for heart disease costs (Kaesemeyer, 1994).

A model that combines ideas from Hermerén (1986) and Francoeur (1983) facilitates the identification and analysis of ethical conflicts raised by such measures. The model—which is more fully discussed in Nilstrun (1990), Haglund, Nilstun, Westrin, and Smedby (1991), Westrin, Nilstun, Smedby, and Haglund (1992), and Nilstun and Westrin (1994)—has two dimensions. The first dimension specifies the relevant ethical principles (in this chapter, the three principles of beneficence, autonomy, and justice are used) and the second dimension specifies the different groups of individuals involved in or affected by the attempts to modify smoking behavior.

Each group should consist of persons who, in relation to antismoking policies, have similar interests. The groups should be exhaustive; i.e., all those who are involved in or affected by the policy should belong to at least one group. But the groups are not necessarily exclusive; i.e., one individual may belong to more than one group. The groups involved in or affected by antismoking policies are:

- Smokers (many of whom want to go on using tobacco).
- Adult nonsmokers (most of whom don't want to be exposed to tobacco smoke).
- Children (who should be protected from passive smoking and prevented from using tobacco).
- Fetuses (all of whom should be protected from maternal smoking).
- Pets (which should be protected from being exposed to tobacco smoke).
- Tobacco industries and trades (which want to manufacture and sell their products).
- Employees in tobacco industries and trade (who don't want to lose their jobs).
- Employers (who want to reduce their costs due to smoking).
- The state (which gets revenue by taxing tobacco products but pays for health care).
- Health care professionals (who want to reduce the use of tobacco).

The task, when applying the model to assess attempts to modify health behavior, is to identify ethical costs and benefits to those involved or affected. Since the words "costs" and "benefits" here are used in a rather wide sense. some clarification is needed. To identify and assess the rightness or wrongness of attempts to modify health behavior with reference to the principle of beneficence is to determine their tendency to produce good or bad consequences. Within the utilitarian tradition, it is natural to call fulfillments of the principle of beneficence (i.e., the good consequences) ethical benefits and violations of the principle (i.e. the bad consequences) ethical costs.

In the literature on medical ethics, the words "costs" and "benefits" are not used in connection with the principle of autonomy. To assess a health behavior modification policy with reference to this principle is not to determine any good consequences. The rightness or wrongness of the policy is assessed by reference to the obligation to respect the right to self-determination of the persons involved (no matter what its consequences might be). Though less common, in order to facilitate comparison, the expression "ethical costs" is used to denote violations of the principle of autonomy and the expression "ethical benefits" to denote fulfillments.

In the same way, violations of the principle of justice are called "ethical costs" and fulfillments "ethical benefits."

The official smoking policy in the 1960s (in this chapter called the "liberal smoking policy") is used as a baseline, which means that this policy is treated as though it has no ethical costs and no ethical benefits. Given this simplifying assumption, the question to be answered is: What are the differences, in terms of ethical costs and ethical benefits, to the groups involved in or affected by an antismoking policy (as suggested by the different measures identified to reduce smoking) compared to a liberal smoking policy?

Ethical benefits related to the principle of beneficence consist of prevention of harm to smokers (who are induced to quit smoking or reduce their consumption), adult nonsmokers (who don't start smoking or are less exposed to tobacco smoke), children, fetuses, and pets. Reduced tobacco-related health care costs and absence due to illness are ethical benefits to the state and employers, respectively. The joy felt by many health care professionals when smoking is reduced might also be considered an ethical benefit. Not only ethical benefits, however, but also ethical costs fall upon smokers. Most of them really enjoy smoking and many are not harmed. Nevertheless, they are forced to abstain, e.g., at work, due to antismoking policies. (Many health care workers seem to take for granted that the benefits always outweigh the costs to smokers. But is this assumption correct?) In addition, there are costs to the tobacco industry, both employers and employees. The costs and benefits related to the principle of beneficence are indicated in the first column of Table 2.

Ethical costs related to the principle of autonomy consist of interferences with the right to self-determination. Smokers' freedom to act on their desire to smoke is limited by the antismoking policy. There are also autonomy costs to the tobacco industry and the employees in these industries. As to autonomy benefits, the prohibition of smoking in public premises favors the freedom of those individuals who want to avoid health risks posed by exposure to tobacco smoke. The costs and benefits related to the principle of autonomy are indicated in the second column of Table 2.

There are also ethical benefits and costs related to the principle of justice. A liberal smoking policy is to the advantage of smokers at the expense of non-smokers. But antismoking policies reverse the situation. Smokers, at least in Sweden, are now frequently treated in ways that can only be described as discrimination. A change from liberal to antismoking policy implies justice costs to smokers and justice benefits to nonsmokers. The costs and benefits related to the principle of justice are indicated in the third column of Table 2.

To make a complete ethical analysis of anti-

Table 2. Ethical Benefits and Ethical Costs of an Antismoking Policy Compared to a Liberal Smoking Policy[a]

	Ethical principles		
Persons involved or affected	Beneficence	Autonomy	Justice
Smokers	Benefits	Costs	Costs
Nonsmokers			
Adults	Benefits	Benefits	Benefits
Children	Benefits	—	Benefits
Fetuses	Benefits	—	Benefits
Pets	Benefits	—	—
Tobacco industries and trades	Costs	Costs	—
Employees in tobacco industries	Costs	Costs	—
Employers	Benefits	—	—
The state	Benefits	—	—
Health care professionals	Benefits	—	—

[a]The liberal smoking policy (premised on the principle of autonomy) is the baseline for comparison.

smoking policies (compared to a liberal smoking policy), all the costs and benefits in Table 2 should be taken into consideration. In this chapter, however, the purpose is only to discuss the two ethical conflicts raised by paternalism. For both of these conflicts, the requirement of the principle of beneficence (in relation to smokers and nonsmokers) comes into conflict with the requirement of the principle of autonomy (in relation to smokers).

Antismoking measures, the purpose of which is to benefit not only smokers but also nonsmokers, give rise to the first ethical conflict. This conflict arises because it is not always possible to satisfy both the obligation to respect smokers' right to self-determination and the obligation to prevent them from harming others (social paternalism). Antismoking measures that aim at benefiting smokers give rise to the second conflict because it is not always possible to satisfy both the obligation to respect smokers' right to self-determination and the obligation to prevent them from harming themselves (individual paternalism). The two most important benefits and the most important cost relevant to the assessment of paternalism that accrue to smokers and nonsmokers are indicated in Table 3.

BALANCING ETHICAL COSTS AND BENEFITS

So far, this approach has been descriptive and analytical and the objective has been to meet a minimal standard of intersubjectivity; i.e., competent persons, asking the same questions and using similar methods, should also reach similar conclusions (Hermerén, 1972, p. 121). The choice of value premises and the identification of ethical costs and benefits to those involved and affected are intersubjective in this sense. But when the ethical costs and ethical benefits are to be bal-

Table 3. Most Important Ethical Cost and Two Most Important Benefits Relevant to the Assessment of Paternalism of an Antismoking Policy Compared to a Liberal Smoking Policy[a]

	Ethical principle	
Persons involved or affected	Beneficence	Autonomy
Smokers	Benefits	Costs
Nonsmokers	Benefits	—

[a]The liberal smoking policy (premised on the principle of autonomy) is the baseline for comparison.

anced, it is difficult to satisfy the requirement of intersubjectivity.

The harm principle, as formulated by Mill (1859), justifies different solutions to the two ethical conflicts raised by paternalism:

> ... the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.

According to Mill, individual paternalism should be avoided; i.e., priority should in this situation be given to the principle of autonomy at the expense of the principle of beneficence. But social paternalism is sometimes ethically justified; i.e., priority should in such situations sometimes be given to the principle of beneficence at the expense of the principle of autonomy.

A similar position is defended by VanDeVeer (1986) and Feinberg (1986). According to VanDeVeer, individual paternalism is never justified when it is incompatible with respecting competent persons' right to direct their own lives within the sphere of acts that do not wrong others. According to Feinberg, the right to self-determination always takes precedence in the rare cases in which there is a conflict between promoting a person's good and respecting the personal right of self-determination.

If the harm principle is accepted, antismoking policies are justified only when they are aimed at protecting nonsmokers from being exposed to tobacco smoke. Consistent application of the harm principle implies that all public premises (including restaurants and other eating places) should have nonsmoking areas even if their having them may be inconvenient to smokers.

But antismoking policies cannot be justified by reference to the good of the person being coerced. At least some of the many restrictions placed on adult smoking in the workplace and in hospitals are hard to justify with reference to the harm principle. Pleasant smoking rooms, conveniently located and with adequate ventilation, would protect nonsmokers from the danger of passive smoking.

There are several problems, however, with the harm principle. The most important is that few if any find the principle acceptable without exceptions. Also, there is no consensus as to what particular antismoking policies should be considered as such exceptions. This lack of agreement makes the harm principle lose much of its force when ethical conflicts are to be solved. It also explains the popularity of "commonsense morality." According to this morality, to solve an ethical conflict raised by paternalism requires a determination, *in any particular case*, of which principle—beneficence or autonomy—is more important (Brock, 1994):

> The cost to the subject's well-being from respecting a particular choice of the subject can vary greatly in degree—from the loss of the subject's life at one end of a continuum to the most trivial of adverse effects at the other end. Likewise, the importance of respecting the individual's autonomy can vary substantially from case to case depending on such factors as how central and far-reaching the choice is within the particular individual's plan of life, how strongly the individual wants to make the choice in question for him- or herself, and so forth.

Ross (1940), an important source of inspiration for the theory of bioethics that emanated from the Kennedy Center in Georgetown in the late 1970s (Beauchamp & Childress, 1994), makes this problem with ethical conflicts explicit. According to Ross's theory, one enters into a decision-making situation equipped with a set of basic ethical principles that are used to identify and examine the problems at hand (Ross, 1940, p. 41):

> ... right acts can be distinguished from wrong acts only as being those which, of all those possible for the agent in the circumstances, have the greatest balance of *prima facie* rightness ... over their *prima facie* wrongness,... For the estimation of the comparative stringency of these *prima facie* obligations no general rules can, as far as I can see, be laid down.

By "prima facie rightness or obligation" is meant that the act is right or obligatory unless it con-

flicts with an equal or stronger right or obligation. A prima facie right is binding unless overridden or outweighed by competing moral rights (Ross, 1940, pp. 18-22; cf. also Beauchamp & Childress, 1994, p. 33).

One can agree with Ross that no such general rules can be laid down. That they cannot be does not imply, however, that ethical principles are useless. On the contrary, the effort to formulate such principles and identify the ethical costs and benefits to those involved or affected not only improves knowledge about the alternatives and their probable consequences, but also counteracts the human tendency to "forget" ethical costs and benefits. When it is believed that the right solution to an ethical conflict has been found, the capacity for unbiased assessment of counterargument is easily lost.

The use of principles to identify ethical costs and ethical benefits is therefore essential to ethical analysis. But when one has to decide how to solve an ethical conflict, the use of analogy is often more convincing (Winkler, 1993, 1994). That it is can be illustrated by comparing the ethics of data utilization in epidemiology and in journalism (Westrin & Nilstun, 1994).

Much of the available knowledge about the harmful effects of smoking derives from epidemiology, often using case registers and record linkage. The purpose of such studies is to prevent harm to unidentified individuals. But the large number of individuals investigated often makes it practically impossible to obtain individually informed consent, and without such consent there is infringement on personal autonomy. This means that epidemiology is almost inconceivable without some element of social paternalism.

In the European countries, there is at present a strong antipaternalistic trend. Legal controls over data collection have adversely affected the prospects for epidemiology, especially in countries with previously favorable conditions for epidemiological research, such as Sweden. Far greater damage to environmental epidemiology is likely if a recent proposal by the European Commission is implemented. Its key paragraph states that "member states shall prohibit the automatic processing of sensitive data—for example, regarding health—without the expressed and written consent freely given of the data subjects." This restriction reflects a desire to give priority to respect for individual autonomy at the expense of benefits to the whole population. According to this paragraph, paternalism is not justified in epidemiology.

By contrast, journalists have been allowed far greater freedoms. One reason is that the aims and tasks of journalism—with its emphasis on an open society—are not compatible with strict adherence to the principles of respect for individual autonomy and of doing no harm. Hence, infringements on both the principle of beneficence and the principle of autonomy by journalism are unavoidable ethical costs in an open society. This means that paternalistic acts sometimes are justified with reference to journalism.

But is this difference between journalism and epidemiology justifiable? One can argue that it is not. In epidemiology, which also aims at benefits to the open society, there is no need to harm research subjects. But it is not possible to carry out case-register research and record linkage without some infringement on individual autonomy. Compared with the ethical costs of journalism, however, the ethical costs of epidemiology are very modest. So if social paternalism is justified with reference to journalism (and in my opinion it is), it should also be accepted with reference to epidemiology.

CONCLUDING REMARKS

Any attempt to resolve the ethical conflicts related to paternalism in the context of health maintenance, health restoration, and health improvement is dependent not only on personal values and factual assumptions but also on the choice of analogy. Since people differ over values, many assumptions about health behavior modification are questionable; further, since the force of reasoning by analogy is highly dependent on

cultural affiliation, different conclusions as to paternalism may be equally rational or irrational. Competent persons, facing the same ethical conflicts and using similar methods, do not always reach similar conclusions; i.e., the requirement of intersubjectivity is not always satisfied.

If the authority of science ends where intersubjectivity ends (which seems reasonable), medical ethicists do not have any special mandate to solve these ethical conflicts. Thus, the task of setting limits on the use of paternalism in health behavior modification falls outside the scope of medical ethics and into the realm of politics.

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The ethical challenge of genetic testing for breast cancer

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The identification of BRCA1[1] and BRCA2[2] as the genes associated with some hereditary breast and ovarian cancers has major scientific value, but also raises many dilemmas.[3] Genetic testing for BRCA mutations has no value in general screening, and it is most often uninformative even in women with high-risk families.[4] Its ability to predict the development of cancer in mutation carriers is still under evaluation,[5] and available treatment options - such as lifestyle changes, close follow-up, chemoprevention, and even prophylactic surgery - do not yield complete protection against breast and ovarian cancer.[6] Despite these major limitations,[7] the test is now commer-

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cially available. Most often the public is mislead by the press raising false hopes for effective prevention, and thus tends to perceive genetic testing for breast cancer as a reliable screening tool. Therefore, major educational efforts are needed for lay people as well as for health-care workers.

As part of the *Human Genome Project*, extensive debate has surrounded the social and ethical ramifications of genetics[8] and these have been acknowledged in recently published guidelines for health care workers.[9] The most pressing issues presently are: information and informed consent;[10] rights in access to genetic information[11] – including rights of the person tested (and whether or not testing should be limited to high-risk populations only), rights to know the results of someone else's test, rights to have a fetus or a child tested,[12] rights of the research community to use archived material from deceased patients or to process samples for anonymous research;[13] privacy[14] and confidentiality – including the privacy interests of the deceased – risk of discrimination in health insurance, at the work place, in adoption and possibly in access to education;[15] pre-

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natal susceptibility testing[16] – including counseling, abortion, embryo selection[17] and eugenics;[18] and justice in the allocation of resources – both in the Western context and in a worldwide perspective that includes less affluent areas. Despite ample debate in the medical and ethical literature,[19] most of these issues are still unresolved: this illustrates the complexity of the subject, and leaves us with the unsettling conclusion that, as the secrets of our genome unravel, something more fundamental is at stake, which we have not yet fully explored. In analyzing many dilemmas of women who consider genetic testing for breast and ovarian cancer, it clearly emerges how medicine, culture, normativity and philosophy are complexed. It is such connection which needs our attention. The scope of this paper is to illustrate this thesis, by exploring some recurrent themes of the discussions with my patients who consulted me not as a genetic expert, but rather as their treating oncologist. In those conversations patients were openly expressing their concerns for themselves and their female relatives in the context of a well-established patient-doctor relationship. Fascinated by the complexity of the issues raised by my patients, I took notes and later organized them in five recurrent main themes, which I present here in the format of open questions. Can genetic knowledge affect our concepts of diversity and responsibility? Is the risk of discrimination increased by gender biases? Does genetics affect our views on autonomy and trust? Does genetic knowledge increase control? Rather than pretending to give an answer to such questions, this paper wishes to stimulate the moral debate which is central to solving

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the dilemmas of genetics, in Rilke's spirit of 'loving the questions first'.

Can genetic knowledge affect our concepts of diversity and responsibility?

Philosophers have long considered the nature of knowledge: knowledge is never neutral, never abstract from the 'knower' and from the context. Knowledge is rather always 'situated', for it is produced by an individual in a specific context.[20] In addition, knowledge is instrumental: a means to enhance our ability to control the world. Knowledge has an epistemic, a pragmatic and an ethical dimension, which are always intertwined since it is not possible to think profitably about cognition without thinking about practice.[21] This applies particularly to science, which is not only the abstract pursuit of 'truth', but primarily a social enterprise never independent of its applications and their consequences, nor of the context.

Genetic knowledge differs from other types of knowledge, insofar as it is predictive, probabilistic and individual.[22] Thus, in genetic knowledge the practical and contextual aspects assume a unique and peculiar relevance.

The interplay of scientific and social issues is particularly manifest in the heated debate on genetic manipulation, where the social and political consequences and the moral implications are strikingly apparent. Yet the more subtle dilemmas of genetic testing are equally important to uncover and to analyze. When women ask: 'Is testing worthwhile if there is no guarantee of effective prevention?' they raise complex epistemic and ethical questions. The more traditional medical view holds that a test should be performed when some

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forms of therapeutic intervention is available; otherwise a medical test is not offered outside of research purposes. With respect to genetic testing, however, there is no consensus now on whether or not should genetic testing be limited to pathologic entities for which preventive or therapeutic measures exist. This is due to our lack of a proper definition of what is 'therapeutic' vis-à-vis the novelty of genetic knowledge. In the case of genetic testing for BRCA1 and BRCA2 mutations, for instance, sensitivity, specificity and reproducibility are sufficiently high to provide accurate information regarding what the test purports to measure -the presence or absence of certain mutations. However, the ability to predict the future development of breast and ovarian cancer is still uncertain, particularly when considering the impact of allele-specific penetrance.[23] In other words, genetic testing for breast and ovarian cancer predisposition provides us with an accurate, yet only probabilistic information. Hence, the determination of the worth of the test stems primarily from a social agreement between test subjects, the research community and society at large on 'what is worth', and this may be found outside the limitations of immediate therapeutic results. For the research community, for instance, the test is worthwhile even in the absence of direct therapeutic benefits because, through the study of BRCA-associated cases, the biology of breast and ovarian cancers can be studied and better understood.[24] Also among test subjects, some persons value the possibility to make more informed choices about their health so highly, that the test appears worth even in the absence of definite prevention strategies. This illustrates how genetic informa-

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24 KINZLER K.W., VOGELSTEIN B., *Gatekeepers and caretakers*, Nature 1997, 386: 761-763; MILNER J., PONDER B., HUGHES-DAVIES L. ET AL., *Transcriptional activation functions in BRCA2* (letter), Nature 1997, 386: 772-773; SHARAN S.K., MORIMATSU M., ALBRECHT U. ET AL., *Embryonic lethality and radiation hypersensitivity mediated by Rad51 in mice lacking BRCA2,* Nature 1997, 386: 804-810; GARCIA-PATINO E., GOMENDIO B., PROVENCIO M. ET AL., *Germ line BRCA1 mutations in women with sporadic breast cancer: clinical correlations.* J. Clin. Oncol. 1998, 16: 115-120; JOHANNSSON O., RANSTAM J., BORG A. ET AL., *Survival of BRCA1 breast and ovarian cancer patients: a population-based study from southern Sweden.* J. Clin. Oncol. 1998, 16: 397-404; LYNCH H.T., WATSON P., *BRCA1, Pathology, and Survival* (editorial), J. Clin. Oncol. 1998, 16: 395-396.

tion may carry benefits to the individual and to society, which go beyond those contemplated in traditional medical dogmas. To face genetic knowledge and its dilemmas, a new conceptualization of the world is required, which challenges our traditional epistemic approach to science and medicine.

Genetic knowledge relates to genetic diversity, and carries the risk that people will be identified with their genes, if misleading and excessive weight is given to the predictive value of genetic information. This process of identification of human being with their genome is know as "geneticization", whereby genetic models are increasingly used to explain disease and thus influence drastically the medical practice as well as individual and societal attitudes towards a broad spectrum of issues (from reproduction, to prevention, to disease control to exquisitely moral issues).[25] Here again the scientific and the social levels overlap. In fact, it is through the research community that we know our genome and face genetic diversity, but it is through society that we attribute values. Society colors the meaning of normalcy and diversity. Society at large - hence all of us - often attaches a negative connotation to diversity and determines the acceptability of sickness and disability. Disease has both an objective and a subjective dimension, and has both a 'meaning' and a 'value', which are established through social agreement. Disease is not only a pathologic entity: disease is also a social construct, at times accompanied by a change in the "ontological status" of the ill person.[26] Suffice to consider what happens when the symptom experienced (fatigue, for instance) is labeled as a disease (the flu versus a form of leukemia). In the genetic era, this ontological change may happen on the basis of genetic information alone. When our genome is known, will we be 'healthy' if we have no organ dysfunction or only if we do not carry a predisposition to a disease? If we do carry such a predisposition are we going to be called 'sick'? Will we rather have to fit into a new category of the 'asymptomatic ill' and what would this exactly entail? (May we be reminded that

25 HOEDEMAEKERS R., TEN HAVE H., *Geneticization: The Cyprus paradigm.* J. Med. Philos. 1998, 23: 274-287.

26 ROLLIN B., *On the nature of illness.* Man and Medicine 1979, 4: 157-172.

certain groups of people such as HIV positive persons are already part of such category). How will genetic diversity affect the lives of those who carry a genetic predisposition to cancer and those of their relatives? Clearly, how genetic risk is perceived depends both on how society faces diversity and on how the scientific community will deliberate as to whether genotypic or phenotypic information should be privileged. If society accepts diversity as an objective element of life, and hence 'normal', there will be 'little incentive to misuse genetic data'.[27] However, there is something that distinguishes genetic from other types of diversity: its apparent inevitability, as both the personal and the social consequences of it seem to escape from our control. Mystery surrounds genetics in our collective imagination, and makes us perceive genetic risk as more drastic than others in life. Recognizing that genes never act alone is the first step to put genetics into proper perspective. Cancer is a polygenic genetic disorder involving the interaction of many genetic mutations and multiple – largely still unknown – environmental cofactors. BRCA1 and BRCA2 mutations are only two factors for the population at risk for breast cancer, and they may turn out to be among the least important. This is already the case in the general female population (the role of BRCA1, and BRCA2 mutations being proven only in high-risk families, where pedigrees show a high incidence of first and second-degree female relatives affected at early ages by both breast and ovarian cancers). Thus the recommendation for genetic testing for breast cancer as a screening tool in the general female population is misleading if not fraudulent at present; while even its recommendation in high-risk families outside of research studies may still be premature (and pedigree analysis may remain more meaningful). The whole scientific community – including basic scientists, health care workers, pharmaceutical industries, scientific and medical press – thus has the primary responsibility to study the interactions of genetic and environmental factors and to clarify the proper role of BRCA testing.[28] Media also play a major

27 REILLY P., *ASHG statement on genetics and privacy: Testimony to United States Congress.* Am. J. Hum. Genet. 1992, 50: 640-642.
28 PYERITZ R.E., *Family history and genetic risk factors. Forward to the future* (editorial), JAMA 1997, 278: 1284-1285.

role in the education of the public, and the public itself has a responsibility to seek accurate information. Because of the profound resonance that misleading information in the field of genetics can have on all our lives, we are reminded of how much humility and sense of proportions is required in medical research as well as in the dissemination of medical information.

The various but limited roles of genes in disease causation suggest that responsibility towards our genes does not differ from health-related responsibility as we presently see it. In fact, it is from the balance – or lack of – in attributing the proper place to genetic and environmental factors that the answer to a major question can be found. The question is: do we – as members of society – have any special responsibility because of genetics? There is no additional responsibility that we owe to society because of our genome, since genetic diversity in no way changes our positions in society. Hence, any form of eugenic pressure should be strongly opposed. Moreover, we remain responsible to care for ourselves, our community and our environment. A test for intelligence, or susceptibility to heavy metals, or predisposition to breast cancer is not to be used for discriminatory purposes or as a shortcut in our responsibility to further education, keep a safe environment, and research the cofactors involved in disease causation.

Is the risk of discrimination increased by gender biases?

If we fail to understand properly the meaning of genetic diversity, discrimination will easily arise from genetic knowledge. Cases of discrimination based solely on genetic predisposition have been reported in the medical literature. Legislative efforts to protect against genetic discrimination have been made in the United States and worldwide,[29] often to go beyond the mere litigation of particular cases. The issue of discrimination, in fact, can not only be addressed

29 NATOWICZ M.R., ALPER J.K., ALPER J.S., *Genetic discrimination and the law*, Am. J. Hum. Genet. 1992, 50: 465-475; MASOOD E., *Gene tests: who benefits from risk?*, Nature 1996, 379: 389-392.

on the level of individual cases in legal proceedings and the fight against discrimination should address the discriminatory process itself.[30] If we consider the possibility of discrimination against women who test positive for BRCA1 and BRCA2 mutations, it is clear that the successful strategy is to foster true equality at a societal – not only legal – level.

Women are still often exposed to gender discrimination. As cancers associated with germline BRCA1 and 2 mutations are predominant (though not exclusively) in women, there is justified concern that discrimination against a female heterozygote carrier will be enhanced by gender biases. It is noteworthy that men can also be carriers of BRCA1 and BRCA2 mutations and transmit them to their offsprings, but somehow this is rarely the subject of public discussion and awareness. This contributes to enhance the gender bias associated with such mutations.

In considering genetic testing, therefore, women's attitudes differ with respect to the relevance that they place on the risk of discrimination. Members of high-risk families may see a way to possibly alleviate their concerns, if the test is negative, or to render them more active with respect to preventive measures, if the test is positive. Although informed and aware of the risk of discrimination, they may consider it almost trivial in comparison with the suffering of breast or ovarian cancer.

On the contrary, other women perceive the risk of discrimination as too high, and its potential consequences as too disruptive for their lives, to be ignored. For them genetic biases would only compound already existing gender biases in employment, health care[31] and other aspects of life. Social biases with serious consequences have already appeared in the disguise of health concerns: unfortunate examples include sexual discrimination with respect to HIV testing and racial discrimination with respect to sickle cell testing. Women's concerns are therefore justified in view of the past, and many pa-

30 WOLF S.M., *Beyond "Genetic Discrimination": Toward the Broader Harm of Geneticism*, J. Law Med. & Ethics 1995, 23: 345-353.

31 MILES S., PARKER K., *Sounding board: men, women, and health insurance*, N. Eng. J. Med. 1997, 336: 218-221.

tients already feel that not only they can vertically transmit the disease to their daughters, but they may also be vertically transmitting an increased risk of discrimination. Thus, some women feel forced to choose between knowledge as the power that they could acquire, and knowledge as the power that could be used against them by society. Clearly, this is a major unresolved issue, awaiting the active participation of all women in defense of their equal rights.

Does genetics affect our views on autonomy and trust?

Concern for one's children and family, as well as debate over rights, imply that we consider ourselves both as autonomous independent individuals and as relational individuals connected to one another. One of the main reasons for persons to request genetic testing is a concern for their offspring and relatives. Genetic testing for breast and ovarian cancers has been demonstrated to have a profound psychological impact on the entire family, including those members who do not carry a mutation.[32]

Large debate in the ethical literature has surrounded issues of personal autonomy versus community goods. Occasionally, extreme positions have absolutized autonomy, but this scarcely reflects the reality of our existence, where from birth we are connected to one another. This connectedness at times conflicts with our desire to be completely autonomous and infringes on our personal rights. Recognition and respect for human rights founded on personal liberty is the foundation of our democratic societies, and medicine accordin-

32 BREO D.L., *Altered fates-Counseling families with inherited breast cancer,* JAMA 1993, 269: 2017-2022; HOSKINS E.F., STOPFER J.E., CALZONE K.A. ET AL., *Assessment and counseling for women with a history of breast cancer,* JAMA 1995, 7: 577-585; LERMAN C., NAROD S., SCHULMAN K. ET AL., *BRCA1 testing in families with hereditary breast-ovarian cancer. A prospective study of patient decision making and outcomes,* JAMA 1996, 275: 1886-1892; BOTKIN J.R., CROYLE R.T., SMITH K.R. ET AL., *A model protocol for evaluating the behavorial and psychosocial effects of BRCA1 testing,* J. Natl. Cancer Inst. 1996, 88: 872-882; STIEFEL F., LEHMANN A., GUEX P., *Genetic detection: the need for psychosocial support in modern cancer prevention,* Support. Care Cancer 1997, 5: 461-465; GENERAL ASSEMBLY OF THE UNITED NATIONS, *Universal Declaration of Human Rights,* Geneva: UN, 1948.

gly must place a particular emphasis on autonomy to protect patients' dignity and their right to self-determination. Emphasis on personal rights does not, however, change the relational essence of our being human, and genetics now, by increasingly revealing the links that unite mankind,[33] comes as a reminder of our connectedness.[34] There is, in fact, a rediscovered sense of belonging together, if only through our genes, which is one of the most positive and promising messages of genetics. The protagonists of today – the patients – say that when they enter the difficult path of genetic testing they are not alone nor do they wish to be so, and that their being a part of a community does not mean abdicating their autonomy, but merely redefining it.

This process of redefinition of autonomy involves also the rapport between patient and doctor, where relational aspects have always been essential. In the patient-doctor relationship genetics makes these aspects even more important as patients facing genetic testing rely on "trust". Trust is an essential ingredient in the patient-doctor relationship, an important ethical principle[35] and the basis for certain modern ethical theories.[36] Trust is increasingly important as one moves from the isolation of the autonomous moral agent (where the individual is alone) to the connectedness of a more relationally understood moral agency (where the individual is part of a society). In one realm responsibility arises out of contracts, most often among peers, and is limited to symmetrical relationships, where power is equally distributed.[37] There the language is that of autonomy, self-determination and contractual obligations. In the other realm, responsibility often arises from asymmetrical relationships, where re-

33 LENOIR N., *UNESCO, genetics and human rights*, Kennedy Inst. of Ethics J. 1997, 7: 31-42.

34 BYK C., *A map to a new treasure island: The human genome and the concept of common heritage*, J. Med. Philos. 1998, 23: 234-246.

35 PELLEGRINO E.D., THOMASMA D.C., *For the patient's good. The restoration of beneficence in health care*, New York: Oxford University Press, 1988: 235-250.

36 BAIER A., *Moral Prejudice. Essays on Ethics*, Massachussetts: Harvard University Press, 1994.

37 KANT I., *Critique of practical reason and other writings in moral philosophy* in *Immanuel Kant*, (Translated by Lewis White Beck), Chicago: Chicago University Press, 1949.

ciprocity exists in asymmetry.[38] Here the language is that of vulnerability, dependability and caring. The patient-doctor relationship is at the same time a contractual relation based on mutual obligations and an asymmetrical relation based on the particular needs created by disease itself; thereby trust is an essential element of both.

As the responsibility of the scientific community with regard to issues in genetics is extremely high, the public needs and wishes to trust, for instance, that genetic knowledge will never be misused, whether for eugenic purposes (subtle eugenics can stem from increasing economical pressure in health care), or for more or less overt discrimination. In prenatal counseling, for instance, trust is especially needed for a woman who may have witnessed many of her relatives dying of breast and ovarian cancer, and may also feel pressured by a society with low acceptance of sickness. Trust is essential when facing decisions about prevention. An example would be the choice to perform a prophylactic mastectomy in a 25 year old woman carrying a BRCA1 mutation: is surgery at that age less expensive than long-term measures, such as strict follow-up, or prevention trials or possible treatment for a later breast cancer? Women need to trust that their doctors will stand against economical pressure if necessary; and never make treatment decisions dictated by costs only. Whether it is the preliminary counseling about undergoing genetic testing, or subsequent personal and family counseling, or counseling about prevention and treatment options, trust is paramount for the person facing any decision-making based on genetic risk assessment. In this perspective, genetics itself is a potent reminder of how the connectedness of our moral agencies reflects also in the patient-doctor relationship and calls for a reappraisal of trust as an indispensable tool.

38 LOWENSTEIN J., *The midnight meal and other essays about doctors, patients, and medicine*, New Haven: Yale University Press, 1996; SURBONE A., *The patient-doctor-family relationship: at the core of medical ethics* in BAIDER L., COOPER C.L., DE-NOUR A.K. (Eds.), *Cancer and the family*, Sussex (England): John Wiley & Sons Ltd., 1996: 389-405.

Does genetic knowledge increase control?

The fundamental philosophical issue in genetic testing – and genetics at large – is whether genetic knowledge expands or restricts the control that we have on our lives. Clearly, we are not our genome, and only in part is genetics helping us predicting our future; yet we seem to see genetic data as more fundamental and more inalterable than any other in the equation of life and to rely excessively on predictions based on genetic knowledge. Thus, for some women the knowledge of a very high-risk to develop breast cancer has a profound and limiting effect on their personal choices: the haunting specter of cancer appears as the final negation of freedom, and their life is determined by the expectation of a dire future. On the contrary, some women who have already been breast cancer patients feel that the quality of their life in terms of its intensity and depth has improved after they have confronted the disease, and they consider genetic risk as no different from any other risk in life - something to be dealt with and to possibly overcome. Finally, other women hold a more abstract belief that knowledge in itself always contributes to control and freedom.

Philosophers have long debated the meaning of freedom, and have either stressed the importance of free will or followed more deterministic views of causation of life events. The case of genetic testing does not differ philosophically from any other type of predestination. However, traditional philosophical thinking has been centered around principles that tend to underestimate relational aspects, especially in regard to what is perceived as controllable not only by 'me', but also by a common "us". The repercussions of testing positive for a genetic cancer predisposition, for instance, do not depend only on individual reactions, but also on society's attitudes towards disease, and on our collective perception of genetic abnormality. Control is thus more than a personal issue, since the normative standards for what can be controlled presuppose a shared understanding, which is in turn supported by various social practices. The concept of genetic predisposition to cancers or to other major diseases is indeed one in which scientific and philosophical understandings intersect, as statistical distributions and projections intersect with norma-

tive standards of acceptability, health and well-being. We will likely never find a common agreement as to whether genetic information increases or limits our control, for the answer involves our deepest personal selves. However, as a society, we can strive to create and share social practices that support a non-discriminatory approach to the advancement of human genetics.

Conclusive remarks

Major economical interests support the development of human genetics and interfere with the choices of both health-care providers and patients. Genetic testing is an area particularly exposed to the interference of economical interests, as even the professional motivation for offering such tests is often based on the monetary interests of physicians, laboratories and pharmaceutical industries. Thus the ethical implications of genetic testing can go unnoticed or can be clouded by an indiscriminate use founded on less than ethical reasons. Is genetics with its moral and social ramifications only an issue for the élite or can a deeper understanding of the philosophical and social implications of genetics really contribute to the progress of mankind? Genetics and its dilemmas are clearly exclusive of certain privileged societies and groups, while other major health concerns such as poverty, malnutrition, infant and childhood mortality, infectious disease epidemics and lack of basic medical support still remain the dominant reality in some parts of the West and in far too many other parts of the world. Yet the philosophical issues surrounding genetic testing may be generalizable, and the interest and the debate over genetics, far from clouding other important issues in science and in medicine, may stimulate a better understanding of the concept of diversity and foster a higher level of connectedness among all human beings. By so doing, the contribution of genetics to human progress may go beyond its limited medical aspects by deeply challenging our medical, moral and social engagement.[39] Yet,

39 SASS, H.M., *Introduction: Why protect the human genome?,* J. Med. Philos. 1998, 23: 227-233.

thousand of years ago the Chorus in Antigone sang: 'Future things: not our domain. But in this today which unravels in front of us, what shall we do?'[40] To this question genetics still provides no answers.

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RIASSUNTO

La recente scoperta di un test genetico, che permette di verificare una predisposizione ereditaria ai carcinomi mammari e ovarici, è di grande importanza scientifica e di eguale rilievo sul piano sociale ed etico. Molti dilemmi etici caratterizzano i tests genetici, ed assumono particolari sfumature in questo caso. Infatti, per la sua natura aggressiva e perché l'incidenza è in aumento, il carcinoma mammario è diventato un problema centrale nella salute delle donne. Le pazienti affette dal cancro al seno, e le donne in generale, sono spesso profondamente interessate a capirne l'eziopatologia e i possibili trattamenti, così come a discuterne le ramificazioni psicologiche, sociali e morali.

Questo articolo offre una riflessione sugli aspetti qualitativi del dibattito, così come sono emersi negli incontri con le pazienti prima della loro decisione finale di sottoporsi al test genetico. Benché i cinque temi ricorrenti nella pratica clinica non siano necessariamente rappresentativi di altre situazioni cliniche, essi illustrano alcuni fondamentali aspetti filosofici, etici e morali che sono al centro della nostra essenza umana e del nostro essere agenti morali, e che riflettono l'inestricabile connessione di medicina, cultura, normatività e filosofia di fronte alle questioni di genetica.

Nell'esposizione sono stati evitati i casi clinici particolari, per mantenere la confidenzialità, e non si è fatto uso di questionari, in quanto possono apparire riduttivi rispetto all'entità e complessità del problema.

La conclusione è che le sole risposte corrette ai dilemmi posti dai tests genetici per il carcinoma mammario sono quelle che nascono da una analisi insieme medica, sociale e filosofica.

40 SOPHOCLES, *Antigone*, in *Greek tragedy*, Torino: Einaudi, 1980.

SUMMARY

The ethical challenge of genetic testing for breast cancer.

The scientific importance of our recently acquired ability to test for heredity predisposition to breast and ovarian cancers is paralleled only by its social and ethical relevance. Dilemmas are common in all genetic testing, but they assume particular nuances in the setting of breast cancer. Due to its devastating nature and to its increasing incidence, breast cancer is a central issue in women's health. Breast cancer patients and women in general are often deeply involved in understanding the disease process and the treatment options, as they are in discussing the psychological, social and moral ramifications. This paper is a reflection upon some qualitative aspects of the debate that surrounds genetic testing for breast and ovarian cancer, as they have emerged in my encounters with breast cancer patients prior to their decision to consider genetic testing. The five recurrent themes identified in those conversations may or may not be representative of other practice situations, but they illustrate some fundamental philosophical, ethical and moral questions which exist at the core of our human essence and of our moral agency, and which point to the unavoidable intertwinement of medicine, culture, normativity and philosophy, *vis-à-vis* the many questions raised by genetics. The Author has intentionally refrained from questionnaires, which could betray the complexity of our thinking process, and from the vignettes, as they could betray confidentiality. The paper concludes that the correct answers to the dilemmas posed by genetic testing for breast cancer predisposition can only arise from a blend of medical, social and philosophical analysis.

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DIFFICULT DECISIONS IN CANCER SURGERY

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Most of the decisions of the surgeon's everyday professional life are related simply to the indication for a diagnostic procedure or a treatment option. The nature of cancer is however very complex. Therefore, unless a surgeon has a good knowledge of oncology, even simple decisions might become "difficult". Nevertheless, very often the surgeon is confronted with a patient whose situation is particular and cannot simply be solved by following the written guidelines. Reasons for this can be numerous, e.g. extent of disease, age, general condition, patient's beliefs, religion, family situation and many others. This is when really difficult and responsible decisions have to be taken with all the consequences for both the patient and the surgeon. Most of the "strictly surgical" decisions are related to the technical planning of the procedure, or need to be taken during the surgical procedure itself. All the other decisions are related to the diagnostic procedure, adjuvant treatment, rehabilitation and many other factors. Decisions which have to be taken along with all these steps might also carry significant ethical implications. Today a surgeon is very active in clinical research and is often leading it.

For all these reasons we can conclude that the role of a surgeon in treating a cancer patient goes far beyond simple surgical skill. In the decisions a surgeon makes, as a member of a multidisciplinary team, a broad spectrum of different factors has to be considered, and he is often put into a position when a clear border between "yes" and "no" is blurred. Three case reports will be presented for further discussion.

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DIFFICULT DECISIONS IN MEDICAL ONCOLOGY

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More and more patients with malignant diseases are being treated with drugs (cytostatic agents, hormonal agents, immunotherapy), either in the adjuvant setting or for metastatic disease. The treatment is usually of longer duration, most often about six months, and most of the drugs have side effects that the patients have to cope with. In view of all these, it is essential that the patient understands and agrees with the treatment procedure and is informed of possible side effects.

The aim of my presentation is not to talk about difficult decisions a medical oncologist has to make when choosing appropriate drugs or drug schedules. I would like to point out some situations (in form of case reports) I have encountered in my practical work and that still seem to me difficult to deal with. I would like to discuss them with you and with your help possibly find the best solutions to these problems.

Case No. 1.

Male, 33-year-old, father of three children, presenting with a large, deeply infiltrating painful tumour in the iliac-femoral region on his left side; aspiration cytology - high grade liposarcoma. Treatment options: hemipelvectomy (refused), radiotherapy or chemotherapy before definite surgery. Instead, he decided to starve the tumour (40 days starvation). Because of excruciating pain, he needed intensive analgesic support in order to continue with his "therapy".

Q: Do we support him in his "therapy"? We know it is ineffective (he wants to be cured!)?

After 32 days he stopped starving, a hemipelvectomy was performed, some months later, he developed multiple pulmonary metastases; at first, they were unsuccessfully resected, later, a complete remission was achieved by chemotherapy. He also developed a cerebral (parietal) metastasis which was removed. At the moment, he is asymptomatic.

Q: Would starting the treatment with chemotherapy give him the possibility for a better quality of life? Should we be more aggressive with our proposal at the beginning of treatment? How could we do that?

Q1: DO WE SUPPORT THE PATIENT WHO DECIDES TO START ALTERNATIVE TREATMENT, WHILE STANDARD TREATMENT OPTIONS ARE STIL AVAILABLE?

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Case No. 2.

Female patient, aged 50 years, with inflammatory breast cancer of her left breast. She has been living in an asylum because she is mentally retarded (mentally developed as a six years old child) and has no relatives. Treatment in this case: chemotherapy, surgery, radiotherapy, treatment duration app. 8 months - five year survival 30-40%. She could not understand the treatment and side effects. When we were trying to explain the treatment procedure to her, she started crying. We started treatment (**Q: Agreement of official guardian?)**, but after a couple of cycles, she absolutely refused to continue (aggressive behaviour). She died later with locoregional and disseminated disease.

Q2: DO WE START TREATING ADULT PATIENTS, WHO CANNOT UNDERSTAND THE TREATMENT PROCEDURE THAT IS COMPLICATED AND LONG AND WHERE COOPERATION OF THE PATIENT IS ESSENTIAL?

Case No. 3.

Female patient, aged 35 years, with metastatic breast cancer (the bones, lung, pleura, neck lymph nodes, liver, retroperitoneal lymph nodes, in the pelvis). She has received all standard therapy and has been irradiated at multiple sides. Her life expectancy is short. She has developed bilateral hydronephrosis (more on the right side) due to the compression of the ureters with elevated serum creatinine (600 mmol/l) and potassium (6,4 mmol/l). She has pain mainly in her right flank, spreading also to her left flank. Morphine is effective for her pain, she is a little drowsy but otherwise she does not seem very ill. She is informed of her disease.

Q: Insertion of nephrostomal cateters (Right?, Left?, Both?)?
Continue with morphine only (her creatitine is rising constantly)?
Let her choose the two options?

Q3: HOW AGRESSIVE SHOULD WE BE WITH PROCEDURES AND INFORMATION IN THE TERMINAL STAGE OF MALIGNANT DISEASE?

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ETHICAL ISSUES SURROUNDING THE USE OF QUALITY OF LIFE QUESTIONNAIRES IN CLINICAL TRIALS

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There is growing international consensus towards the use of quality of life (QOL) questionnaires in clinical trials. The UK Medical Research Council (MRC), European Organisation for Research and Treatment of Cancer (EORTC) and the National Cancer Institute of Canada (NCIC) all recommend assessment of QOL or justification for not doing so (Lancet 1995).

The whole ethos of research is based on the theoretical principles of beneficence and non-maleficence (Ford & Reutter 1990). Subsequently, ethical dilemmas arise with the use of QOL questionnaires in clinical trials. In the poster we intend to explore these issues in the following areas: -

- Protocol Design
- Data collection
- Analysis
- Publication of Results
- Treatment Management

We hope to raise awareness of the factors that are involved in the use of QOL questionnaires. For the protection of patients, we intend to make recommendations, which will encourage ethical exploration at an every stage of the research process.

- Editorial (1995) Quality of life and clinical trials *The Lancet* July 1 Vol. 346 (8966) pp 1-2

- Ford JS and Reutter LI (1990) Ethical dilemmas associated with small samples *Journal of Advanced Nursing* 15 pp 187-191

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THE PROBLEM OF AUTONOMY IN MODERN MEDICAL ETHICS

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Modern medical ethics is based primarily on four basic principles: on autonomy, on non-maleficence, on beneficence and on justice. In modern medical ethics, they arouse very strongly only after Nürnberg codex. Before the era of the mentioned codex, the medicine was leaded by paternalism. However in modern world, where more and more population is getting older and older and where we are dependent from each other, the concept of autonomy as a leading right in traditional liberal theories must be at least questioned. In our hospital, at the Department of Vascular Surgery, a study was performed which statistically compared two groups of elderly patients. There were 43 patients in the first group (25 men, 17 women, age 63-78) and 56 patients in the second group (28men, 28 women, age 59). In the first group were patients who stood only day or two before an amputation of leg. In the second group were patients without serious problems with legs. Both were asked if they could decide alone for operation. There was not a single patient that was willing to undergo operation without talking with his or hers relatives. Patients with a forestaying amputation of the leg were included into study with only one reason: this particular operation puts them into devastating social position. This raises again the question of the role of mutual interdependence in relationship between physician, patient, his famility and society. And on this point, a women philosopher Annette Baier must be introduced. She claims that in contemporary philosophy she hears a little bit different voices as others. She deplores the near exclusive emphasis in modern moral philosophy on universal rules and principles, and she sternly rejects Kantian contractarian models with their emphasis on justice, rights, law and particulary autonomous choice among free and equal agents. The conditions of social cooperation, especially in families and communal decision-making are, as Baier observes, typically unchosen and intimate, and they involve unequals in relations. Her thesis is not that traditional ethical theories are false or even, but that they capture only a piece of the larger moral world. Baier strongly envisions smaller scale system that pulls together few strands (she proposes "appropriate trust") to make them a bridging concept. She does not recommend that we should discard categories of obligation, but that we make a room for an ethics of love and trust, including an account of human bonds and friendship. Although Baier's philosophy was mostly criticized, because she is a woman and was called a woman philosopher, it has a great impact on relationship and emotions. Mutual interdependence and relationship ethics is basically the ethics of medical care which maintains that many human relationships - for example in health care and research - involve persons who are vulnerable, dependently, ill and frail and that the desirable moral response is attached attentiveness to the needs, not detached respect for the rights. Accordingly, this approach features responsibility that the right-based account could be ignored in the attempt to protect persons from bring invaded by others. Four basic principles of the modern medical ethics -autonomy, non-maleficence, beneficence and justice - strongly need the fifth companion: be it named appropriate trust or mutual interdependence. Although both concepts were many times criticized by communitarians, as Alysdair McLean, or philosophers, as Gilligan, who recommend coherent view, both concepts as we would say, simply give up too much in the moral life in hospital.

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DO WE STILL NEED ETHICS IN THE AGE OF NEO-CANNIBALISM?

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One of Nietzsche's postulates was "God is dead". And it would seem that it was Nietzsche himself who was most afraid of the ultimate consequences of his own postulate.

The present-day individual is in the same situation as Nietzsche, asking him- or herself the question, "Who or what can take the place of the dead God?" and dreads the inevitable reality that nothing but the deified or idolized human can take the place of the dead God.

In the last thirty years individual resisted regimentation and fought against dogmas and absolute truths but modern man or woman now assumes the infallibility that he or she used to oppose and demands immortality of the "dead God".

The demand of "nil nocere - to do no harm" stands or falls with the idolized human being and the question of the value of life. This leads to the question: "How can the individual demand solidarity from others of his/her kind with the sick, weak and handicapped, if he/she is not willing to protect life?"

We who enjoy the "advantage of late birth" accuse our parents and grandparents of inactivity vis-ŕ-vis the Nazi regime. But are we not likely to have the same blind spot when we vehemently defend those things that are done in the name of "freedom for science and research"?

If we enter the question "Where can I purchase fetal tissue" in a search engine like www.ask.com we will receive something like a million links in reply. Is life - born or unborn - worth so little that we accept manufacture of vaccines from the products of abortions? In a welfare state where medical treatment is supposed to be cost free for the individual, is there not a danger due to the economic pressure produced by lack of resources and subsequent rationing, of removing seriously ill patients earlier from life-support systems? This is all the more important in view of the fact that just before Christmas 1999 the media were full of the story of a woman who awoke from a coma after 16 years. In The Netherlands, a law is being prepared that would reduce the age for euthanasia to 12 years and relieve the parents of the right to object or act on behalf of their children.

Even in this immoderateness of demanding man the claims for ethics in medicine, politics, environment etc. are based and demand the correction and renewal of medical curricula. When Virchow reformed the medical curriculum in Germany in the second half of the 19th century, the obligatory philosophical studies were deleted. But under the contemporary situation probably he will hinder and resist with all his reputation and efforts to do so.

Ethics is concerned with the demand to do good and avoid evil while economics determines what can or may be done. But economy must subordinate themselves to ethics, which is not subject to trial and error. Ethical decisions must be applied appropriately but application does not change the truth of ethical norms.

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Ethical issues in healthcare prioritization: a medical viewpoint

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Introduction

To a clinician, prioritization in medicine is not a new issue; we have always been forced to make difficult choices when resources (money, manpower, technical facilities, etc.) have been limited. What is new is that the discussion and the decisions have become more open, to which this series of articles testifies. This paper is partly based on the author's personal clinical experience as an internist. In addition, the author has been involved, together with politicians, health administrators, other physicians and healthcare personnel, in work on guidelines for priorities in healthcare, both at local and national level in Sweden, work that has compelled the author to reflect on issues of prioritization more than before.

Clinical decision making that is not based on a solid ethical platform is likely to be difficult, inconsistent and erratic. However, the four ethical principles stemming from ancient Greece and still used by clinicians (do good, do no harm, be fair, respect the patient's autonomy) are not very helpful when making decisions that concern priorities. The first two of these principles are too general to act as guidelines; fairness may be an important goal but needs to be defined more precisely; and, as discussed below, priority decisions sometimes violate the autonomy of the individual.

In Sweden, a government commission, including politicians and professionals in medicine, ethics and healthcare administration, has presented guidelines for priorities in healthcare [1]. By analyses and discussions, it was surprisingly easy to reach a consensus on an ethical platform that could be applied both on the political/administrative and the clinical level. This paper presents the three components of the ethical platform and discusses the possible implications for clinical decision making.

The principle of human dignity

When discussing the issues of fairness and the distribution of healthcare resources, it is natural to link them to ideas of human dignity and universal human equality. This view is deeply rooted in Western humanism and is expressed in the United Nations Declaration of Human Rights and, in some form or another, in the constitutions of many countries.

According to the principle of human dignity, each human being has a unique value and all individuals are valued equally. Human dignity is not geared to any personal qualities or functions in the community, but to the individual's very existence.

The principle of human dignity may not be controversial as such, but its implementation in clinical medicine is often complicated. For instance, it implies the following.

1 Age cannot be the determining factor when a choice between patients must be made (provided that 'medical factors' are equal). If, for instance, resources for dialysis are limited, it is not self-evident that a 25-year-old man should be given priority over a 75-year-old man. Due to their very existence, they are valued equally.

2 Social values cannot be used as a basis for choosing among patients. For example, a woman with young children has no priority over a mentally retarded patient with no children.

3 The patient's ability cannot be used as a basis for setting priorities. Thus, an inability to understand instructions or follow a prescribed lifestyle does not, in itself, constitute a reason for giving the patient a low priority when choices are made.

These are examples of how one basic ethical principle is applied. When a decision is made in clinical practice, it must be weighed against other ethical principles. The principle of human dignity is most easy to apply in priority decisions when 'medical factors' are equal.

The principle of need and solidarity

The first principle, that of human dignity, does not provide enough guidance on prioritization when resources are limited; it rather defines the grounds on which decisions should not be based. The additional basic principle of need and solidarity is much more useful when setting priorities. It can be worded very simply:

Resources should be channelled to those fields (activities, individuals) where the needs are greatest.

How can medical resources be distributed justifiably? It could be that everyone is entitled to the same share of the common resources. This is illustrated on the left in Fig. 1. The paradox here is that equal distribution of resources will inevitably lead to unequal health. This is

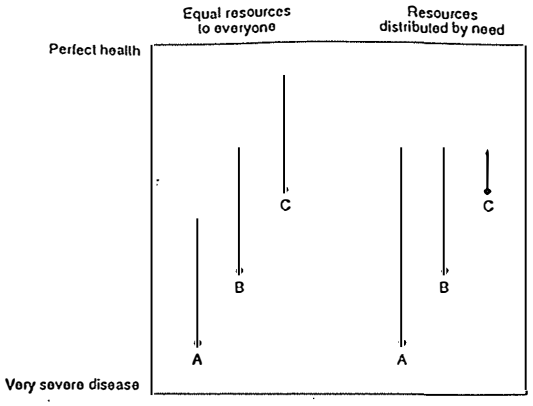

Fig. 1. Justice in allocation of resources may be based on equal distribution to everyone (left, individuals A–C) or a larger share to those who have greater need (right, individual A) involving a sacrifice by those with lesser need (individual C).

fundamentally different from a situation when most is given to those who have the greatest need (Fig. 1, right), which is what the principle of need and solidarity implies. Those who are in less need will have to forego some possible improvement in health to provide for those in greater need. This principle is closely related to the fundamental reason for medical care at large, i.e. to assist those who are in severe distress and need help. The crucial question here is: what is need? This is discussed below.

An alternative to the principle of need and solidarity would be a principle of demand. It would imply that, when choices are made in medical care, one should opt for those fields (activities, individuals) where demands are the greatest. It would be in line with the basic ethical rule of respect for the patient's autonomy. Care is usually demanded when it is needed, so often there is no conflict with the principle of need and solidarity. But not all needs are explicit and, in many clinical situations, there is a demand for medical care with no real need for it. When allocating public resources, the principle of need and solidarity will occasionally be in conflict with the principle of autonomy; the patient cannot always define what the need is.

The principle of efficiency

In an orthodox form, this principle has been expressed as:

When choosing between different fields of activity or different measures, one should opt for that which, all other things being equal, has the greatest cost-efficiency.

This principle is most useful when choosing among different possible diagnostic and therapeutic procedures in the same patient. Then it is not controversial and provides little additional guidance when making priorities. The principle is difficult to apply in clinical practice when choosing among individual patients or groups of patients, because 'all other things' are never equal; patients always differ. Attempts to compare the cost-effectiveness of procedures from different medical domains, e.g. haemodialysis with coronary by-pass surgery by estimation of quality-adjusted life years (QALY), are subject to severe criticism on both ethical and theoretical grounds [2].

On the other hand, priority-setting that does not take costs and effectiveness into consideration is detached from the realities of the world. To solve this dilemma, this principle is perhaps best expressed in more relative terms:

When choosing between different fields of activity or different measures, one should opt for a reasonable relationship between costs and effects, measured as improved health and quality of life.

Thus, cost-efficiency considerations have a fundamental role to play in priority-making. They are, however, subordinated to the first two basic ethical principles, those of human dignity and need–solidarity.

What is need?

Need, like disease, has both a subjective and an objective side. The seriousness of a disease can be rated according to various dimensions; the suffering experienced by the patient, the extent of functional impairment caused by the disease, and the medical prognosis in terms of survival or risk of permanent disability. Each of these dimensions is difficult to assess in the individual patient, and comparisons between patients are even more difficult.

Needs do not always have to be conscious or verbalized. When setting priorities, the whole population must be taken into account, not only those spontaneously seeking medical treatment. In a priority system based on solidarity, special attention must be paid to people who are less able to express their needs, for instance young children, confused or senile patients, and those with severe mental disorders.

What is benefit?

Benefit is closely related to need. Therefore, it has the same dimensions as need; it involves reduced suffering, less functional impairment caused by the disease and better medical prognosis in terms of improved survival or reduced risk of permanent disability.

For medical care to be beneficial it must have both purpose and meaning. Prolonging life in a terminally ill patient who has renal cancer, by total parenteral nutrition or intensive treatment of an infection, achieves

its purpose, life is prolonged, but it is hardly meaningful and, thus, it is of no benefit to the patient. In such a patient, palliative care would instead be both purposeful and meaningful.

Advanced age

The use of medical resources increases rapidly with age. It has been estimated that, in Sweden, an 85-year-old person consumes on average 40 times as many hospital bed-days as a person below the age of 65 years. The proportion of all healthcare costs that goes to dying patients is reported to be 10–12% in the USA [3] and 16% in Sweden [4]. Many elderly persons fear that, as resources of the healthcare system become more limited, their access to healthcare may be jeopardized. Daniel Callahan, Director of The Hastings Center (devoted to studies in medical ethics) has discussed the goals of medicine in an ageing society [5,6]. He has suggested that public resources should not be spent on prolonging life in people who have reached 'the natural life-span', which he seems to set at around 75 years.

This does not, in the present author's opinion, agree with the principle of human dignity discussed above, where the individual's value is connected to his or her very existence; the value is the same whether the patient is 10, 40 or 80 years old. Chronological age is not an issue that can be used when choosing among patients. Advances in biomedicine have improved the possibilities to help elderly people with disease, e.g. cataract, fractures, severe arthritis, urinary incontinence and problems of prostatism. Strategies for geriatric rehabilitation have greatly improved in recent years.

The distinction between chronological and biological age is important. Reduced physiological reserves in elderly people limit their possibility to tolerate advanced diagnostic or therapeutic interventions. Therefore, a more comprehensive medical evaluation often results; the focus of medical management differs between elderly and young patients. In younger patients, the emphasis is on prolongation of life, whereas in many elderly patients with reduced physiological reserves it is on improving the quality of life. It does not mean that the elderly person's access to medical care is more limited compared with that of the young, and strict age limits are not compatible with the basic principle of human dignity.

Financial and social position

When the two basic principles of human dignity, and need and solidarity are applied, there is clearly no reason for giving higher priority to a person just because he or she is important to the society from an economic or social point of view. Straightforward as this standpoint may seem, it is not without complications.

Loss of income and production when an injury or a disease affects a person during their working years would perhaps be a reason for giving high priority to early treatment and rehabilitation. In fact, it is common that private or public insurance agencies pay for healthcare services to speed up the return to active work. However, if this is done at the expense of other patients' access to medical care, it does not comply with the priority principle of need and solidarity. If, on the other hand, it is achieved by adding new resources into the public healthcare system and no-one is set aside, it is less challenging to basic ethical principles (although it may still increase health inequalities). The same applies if the treatment is entirely financed and provided outside the public healthcare system.

In many European countries, it is generally accepted that position in society should not be a basis for choosing among patients. It is less self-evident that social function should be disregarded. A commonly used example is that of a mother with several young children: is it not reasonable that she should have a high priority? However, this question can be rephrased: is it fair that anyone who has not succeeded in getting children should be further stigmatized by not having the same access to medical care? The priority principle of need does not refer to social value but to the severity of disease, with special attention paid to individuals who cannot speak for themselves. Therefore, a mother with several children does not take precedence over a childless man or woman.

Self-inflicted disease

Many disorders are caused by, or aggravated by, lifestyle factors such as smoking, excessive alcohol drinking, over-eating and dangerous leisure-time activities. Among healthcare personnel and laymen, a common opinion is that patients with self-inflicted disease should somehow have a lower priority than those who are not responsible for their disease. When the Federation of County Councils in Sweden, a co-ordinating agency for public healthcare in the country, made an inquiry among politicians, health administrators and physicians, it became evident that physicians were more reluctant than politicians and administrators to reject a patient because of lifestyle factors. An example is given in Table 1.

There are many reasons why lifestyle cannot be accepted as a rule on which to base prioritization. There is presently a very rapid increase in our understanding of the genetic basis for disease, including alcoholism, severe overweight and lung cancer. In an individual patient, it is often impossible to decide to what extent genetic rather than lifestyle factors have contributed to

Table 1 Responses to the question: 'If an unequivocal connection between smoking and a certain type of lung cancer has been established, then he who quits smoking should have priority to treatment before he who does not make a corresponding promise. Do you agree?' [adapted from ref. 12]

Category	*% agree entirely*	*% agree partly*	*% do not agree*	*% other or no responses*
Politicians	26	47	25	2
Administrators	29	41	29	1
Physicians	19	33	44	4

the disease. Many detrimental lifestyles (smoking, alcohol abuse, low physical activity, etc.) are closely associated with low education, economic deprivation and low social status. If low priority is given to people with unhealthy lifestyles, there is an obvious risk that inequalities in health distribution in the community will increase. This would be in contradiction to the basic principle of needs and solidarity. Furthermore, the definition of a harmful lifestyle and self-inflicted disease is liable to be arbitrary. Smoking and alcohol abuse for obvious reasons come under this definition. But what about lack of leisure-time physical activity? And, if physical exercise is beneficial, how does one judge injuries related to excessive physical activities?

Whereas the concept of self-inflicted disease is reputed to influence prioritization, it does not mean that lifestyle factors cannot be taken into consideration in clinical decision-making. The result of a medical or surgical treatment may be jeopardized if a detrimental lifestyle continues. Obvious examples are persistent smoking after vascular surgery for peripheral artery disease, continued excessive drinking after a liver transplant, or heavy physical exercise too soon after an operation for a sports injury. In selected cases, it is in accordance with basic priority principles to insist on lifestyle changes for the intervention to be appropriate and meaningful.

Positive selection?

There are many groups of patients who have acquired a disease and an injury under conditions that seem particularly tragic. It has been advocated that these patients deserve special attention and thereby get a particularly high priority; it may be a person who has been infected with human immunodeficiency virus (HIV) within the healthcare system, a patient with a severe drug-induced injury, innocent victims of traffic accidents caused by drunken drivers, military staff wounded in United Nation peace-keeping assignments, etc.

However pitiable these patients are, they do not, a priori, have a greater need than anyone else with the same disease but incurred under different circumstances. The conclusion is that there is no ethical basis for 'positive discrimination' in clinical practice. Admittedly, political decisions may sometimes overrule this standpoint. In Sweden, persons infected by HIV during medical treatment have recently been entitled to special favours, including free medical treatment.

Case history: a series of choices

A 74-year-old man who is a smoker, slightly demented and had a myocardial infarction 2 years ago, undergoes prostatectomy. On the same evening, he complains about slight chest pain. This is aggravated on the following morning, and an electrocardiogram shows an anterior wall infarction. The coronary care unit of the hospital has no empty beds; it is a six-bed unit and this is the seventh patient. A 43-year-old woman, mother of three teenagers, who has been under observation for 6 hours with only moderate suspicion of a myocardial infarction is transferred to a general medical ward to make room for the 74-year-old man.

Was this a right choice? If the principle of human dignity is applied, prioritization must not be swayed by age or social value, i.e. the fact that the woman is a mother of three teenagers. The medical benefit from care in a coronary unit is as great for a 74-year-old patient as for a 43-year-old, so the principle of efficacy does not favour the younger patient. From the standpoints of 'need' as well as 'efficacy' the patient with a definite myocardial infarction has a higher priority than the patient with an unconfirmed possible diagnosis of infarction free of complications over 6 hours of observation.

Should the patient have thrombolytic treatment? When he arrives at the coronary care unit, the infarction is at least 9 hours old. He cannot be treated with streptokinase because it was used 2 years ago and there is a risk of an anaphylactic reaction; therefore, the expensive alternative, t-PA, has to be used.

To what extent should the doctor consider cost-effectiveness when deciding on whether to use thrombolytic treatment or not? Should his or her obligations be confined to the patient lying in front of him or her at that very moment, or does the physician also have an obligation to future patients who cannot receive adequate treatment if the department's financial resources are depleted?

The use of an expensive therapy may be restricted by regulations imposed by the hospital and department management. Within such a framework, however, the individual physician should not provide suboptimal treatment for the individual patient. This would, in the present author's opinion, represent an undue form of prioritization. If, on the other hand, several methods of

similar efficacy are available, it is more ethical to use the least expensive one.

The patient survives, and the question of coronary by-pass surgery is raised. He says that giving up smoking is beyond him. Should the fact that he has a disorder that is at least partly self-inflicted be an issue when deciding on whether to operate or not and when putting him on the waiting-list for operation? Continuing an unhealthy lifestyle should not, in itself, discriminate against the patient. However, persistent smoking is expected to jeopardize the result of the operation and, if this elderly man is judged to have reduced physiological reserves, surgery may be declined for medical reasons unrelated to the issue of prioritization.

Priority grouping

On the national level, models of prioritization have been presented in Norway [7], the Netherlands [8], New Zealand [9] and Sweden [1]. The Norwegian and Swedish models rate a number of priority groups with examples given, whereas the Dutch and New Zealand models define a core of health and medical care to be publicly funded. Among more local models, the Oregon list has attracted the most attention [10,11] and comprises a detailed ranking of 688 diagnostic/therapeutic pairs and is meant to be applied to the minority of patients covered by the public Medicaid programme.

The Swedish model is the only one that includes lists both on the political/administrative level and the clinical level. The priority groups to be used in clinical work are presented in Table 2.

This list is similar but not identical to the list suggested for political/administrative purposes. An important difference is that population-based prevention is excluded from the clinical priority list, because decisions on such prevention strategies are seldom taken by an individual clinician.

Diagnostic procedures are not covered by the priority list. The Swedish Commission emphasizes that a diagnosis is a prerequisite for assigning a patient to a priority group. Therefore, everyone who feels ill is entitled to a basic clinical examination.

To illustrate how various disorders may be grouped according to the clinical priority list, some examples are given in Table 3. The examples are the author's own interpretation of the priority grouping, with an emphasis on urological disorders.

In the opinion of the Commission, the main financing of treatment of disorders in groups I–III should be from public sources. In practice, these three groups differ in that patients in group I should have immediate access to care of the highest standards. It is acceptable that those in lower priority groups have more limited access, if resources are limited. They may have to wait for an elective surgical procedure, their hospital stay may be shortened, etc.

Public resources should not be allotted to treatment of disorders in group V, whereas group IV constitutes

Table 2 Priority groups in clinical practice as presented by the Swedish Health Care and Medical Priorities Commission

Priority group	*Content*
IA	Treatment of life-threatening acute diseases which, if left untreated, will lead to disability or premature death
IB	Treatment of severe chronic diseases
	Palliative terminal care
	Care of diseases that have caused reduced autonomy
II	Habilitation/rehabilitation
	Individual-based prevention
III	Treatment of less severe acute and chronic diseases
IV	Care for reasons other than disease
V	Self-care sufficient
	Minor ailments

Table 3 Examples of disorders grouped by priority

Priority group	*Examples*
IA	Acute myocardial infarction
	Stroke
	Acute urinary obstruction
	Testicular torsion
IB	Renal, bladder or testicular cancer, including palliative care
	Renal failure with dialysis
	Psychotic disorders
II	Rehabilitation after severe trauma
	Prevention of diabetic complications including nephropathy
	Prevention of nephrolithiasis
III	Moderate chronic bronchitis
	Gastritis
	Migraine
	Hernias
	Urinary incontinence
	Lower urinary tract infections
	Benign prostate disorders
IV	Assisted conception, including *in vitro* fertilization
	Cosmetic plastic surgery
	Growth hormone treatment for shortness of stature
V	Common cold
	Simple sprain
	Occasional headache
	Occasional sleep disturbances

borderline cases that could be publicly funded if economic resources are sufficient but omitted if they are limited.

This priority grouping agrees reasonably well with attitudes expressed by politicians, health administrators and physicians in general in Sweden [12]. Figure 2 shows priorities among these categories relative to how resources are allocated today. The attitudes were similar in the three groups of respondents (politicians, health administrators and physicians).

One of the most controversial points concerned the issue of assisted conception. Most respondents feel that less public resources should be allocated to this area, which agrees with the low priority given to assisted conception by the Medical Priorities Commission (Table 2). Fierce criticism against this standpoint has been raised by obstetricians and lay organizations supporting infertile couples. One line of argument has been that infertility most often is caused by defined medical disorders, and should be regarded as a handicap often leading to severe psychological suffering. A counter-view is that childlessness is not, in itself, a disease and that the criticism against the proposal of the Commission is an example of how strong groups of patients can express their claims very clearly, whereas others, perhaps in greater need (abused children, demented people, stroke patients, etc.) are less able to make their voices heard in the public debate on priorities in the healthcare system.

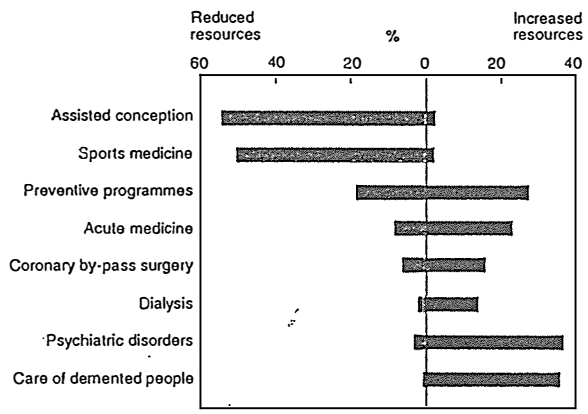

Fig. 2. Responses by 481 politicians, health administrators and physicians in Sweden to the question 'What areas should receive increased and reduced allocation of resources?' [adapted from ref. 12].

The Swedish priority grouping agrees well with guidelines presented by the government committees in Norway [7], the Netherlands [8] and New Zealand [9], a reflection of the common values in medical ethics, based on Western humanitarian traditions.

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Elderly patients with cancer: an ethical dilemma☆

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Contents

Abstract

Longevity is the greatest risk factor for developing cancer. However, despite the increasing focus placed on cancer in the elderly, a prominent discrepancy relating to the age of the patient persists, with elderly people often receiving less than optimal treatment and care. There is no doubt that ageism has a profound impact on health care received by elderly people. Incorporating ethical principles into their clinical practice could facilitate health professionals in the provision of optimal treatment and care for elderly patients with cancer. This article explores some basic ethical assumptions regarding the needs of this patient group in relation to the ethical dilemmas of truth telling, consent and relationships, and power.

Keywords: Cancer; Elderly; Ethics

1. Introduction

The elderly population of the developed nations is currently growing at 2.5% per year with a doubling of the number of elderly expected in many countries by the year 2025. In western Europe a quarter of the population is over 70 years of age [1] and in the USA and Australia approximately 12% of the population are elderly [2]. Such dramatic changes in life expectancy mean that while people over sixty currently constitute a fifth of the British population, by 2030 they will constitute a third and those aged over eighty are the fastest

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growing section of the population [3]. There are a number of factors responsible for this ageing population including high birth-rates, an increase in public health programmes, improved nutrition, improved scientific knowledge and new drug development [4]. As a consequence of longevity it is certain that in the next 20 years the number of people with cancer will increase. There is now little doubt that cancer is a disease of the elderly albeit the indicative factors are yet to be determined [5]. Consequently, if cancer incidence rates remain as they are, and there are no significant prevention or therapy breakthroughs by the year 2030, a notable increase in the number of people alive with cancer and in the total number of new diagnoses is expected [6]. Given then that Government bodies and health care professionals alike are aware of this situation can one expect a rational approach to the care of this growing cohort of individuals with cancer? It is clear, from an ethical perspective, that it is important to ensure adequate provision of care for this population therefore one assumes that in readiness for this so called 'oncologic timebomb' health care professionals are prepared to provide optimal care to elderly patients with cancer.

2. Delivery of cancer care

The ethical debate surrounding the delivery of healthcare is not new and adding an aged population into the equation will only serve to further complicate the argument. There is no doubt that ageism, the stigmatising effects of society's negative attitudes towards the elderly, does have a profound effect on the health care the elderly receive. Rationing of health care is a dominant feature in health care delivery as we approach the new millennium. In this cost conscious era one could question whether treatment for the elderly person with cancer is a priority, given that their contribution to society is perceived as limited, whilst the death of a young person reputedly represents lost potential for society.

It would seem therefore that contemporary society presents us with a paradox whereby longevity is something we strive for yet simultaneously old age is not glamorous and is often disregarded. Even though old age is something most of us will experience, ageism is much less discussed than racism or sexism [7]. In relation to cancer care there is evidence that age is a real factor in determining access to services with health care professionals entering, perhaps unknowingly, into the ethical dilemma of ageism in cancer care.

3. Ethical dilemmas of providing cancer care

Ethics is a strange and ambiguous word with a number of connotations and it is utilised extensively in the field of cancer care perhaps as a means of deluding ourselves into believing that we are providing appropriate care to patients. The practice of nursing demands that we are familiar with and competent in the use of numerous tools and without many of the tools we use in daily practice such as thermometers, infusion pumps, nursing records, our care would be sub-optimal. Yet not many nurses consider ethics to be a vital tool used in the delivery of patient care. This is despite the fact that in clinical practice we face a variety of ethical dilemmas every day. That ethics are not considered integral to care delivery may explain current practices of health care for elderly patients.

This article will consider from an ethical perspective, the delivery of cancer care to the elderly and question if nurses are behaving in an unethical manner towards this patient population. Structuring this paper around three common ethical dilemmas commonly faced by nurses and indeed most health care professionals will contextualise the discussion within the practice of caring for elderly patients with cancer. These ethical dilemmas are: truth telling, consent and relationships and power.

4. Truth telling

Nursing is imbued with a sense of duty, a notion which was much proclaimed by Florence Nightingale and perpetuated through subsequent generations of nurses. Part of this duty is to tell the truth when caring for patients and one could contend that the suggestion of lying to individuals would be abhorrent to us all.

Truth telling is a central theme in all human relationships and, it could be argued, finds particular relevance in the complex situation of caring for people with cancer. For centuries people have used a variety of ethical methods when seeking to clarify issues which have a moral dimension. Two of the most common are deontology and utilitarianism.

Based on Kantian theory, Deontology claims that being moral and truthful involves acting from a sense of moral duty, respecting others rights and honouring obligations. Whilst Utilitarianism argues that actions are morally right when they result in happiness for the majority of people.

Within each of these is the sense of duty which nurses feel towards patients. How can it be then that with regard to the elderly we can somehow disregard the notion of duty and deliver care that is far from being based on truth or reality and in fact compromises their chance of survival? This discrepancy could be explained by the attitude of health care professionals towards the elderly.

There is no question that ageist attitudes prevail in much of modern society. Even in countries that traditionally revere their elderly, young people are now moving away from their sense of duty in caring for elderly

members of the family. Unfortunately ageist attitudes are not just a factor of a changing society world-wide but they also appear to be evident in the majority of healthcare providers. Several researchers have highlighted the effect negative attitudes of health care professionals has on the care and treatment afforded elderly people. However not only does wide spread discrimination against older people exist in the provision of healthcare, they are also the victims of restricted assumptions about the quality of healthcare expected in old age. The series of targets set in the UK Governmental White Paper, The Health of the Nation [7], provide little comfort for older people as they emphasise reducing premature death and specify upper age limits, for example, reduction of heart disease and stroke among those aged under seventy-four despite these being major causes of death among people over seventy-five [8]. Indeed in seeking to achieve these targets, one could question whether an already under-resourced health service would give even less attention to older people.

Rational decision making regarding resource allocation is fraught with difficulty. Approaches based on quality adjusted life years (QALYs) are inherently discriminatory for the elderly. Counting extra years as benefit of medical procedures risks shifting resources away from older to younger age groups Similarly, those judged to have a low quality of life, predominantly elderly people, will be disadvantaged [8]. Moreover, the lack of medical knowledge resulting from the elderly's exclusion from clinical trials [9], results in inappropriate clinical decision making and is especially concerning as the elderly stand to gain more from technological advances than their juniors [8].

In relation to truth telling then it would seem that current delivery of cancer care to the elderly is not based on sound ethical judgement. Rather, truth seems to be somewhat distorted to suit policy makers and the attitudes of health care professionals.

5. Consent

There are ways in which ageist attitudes are seen in everyday practice and in many ways cancer care epitomises these through the various stages of the disease. If negative attitudes towards the elderly are institutionalised as part of our cultural beliefs, it is unlikely that our ways of caring for older people will have satisfactory outcomes [10]. That elderly patients with cancer are refused an opportunity to participate in appropriate health care demonstrates a clear lack of an informed consent process that is such a dominant feature in contemporary cancer care. Consent to treatment underpins the delivery of care and conforms to the Declaration of Helsinki. It can be asserted then that by not informing elderly patients of all the opportunities available to them that we are indeed practising unethically. In terms of treatment for elderly patients there is substantial evidence to demonstrate that age alone is the factor that determines what treatment individuals will receive.

Despite the magnitude of cancer in the elderly, a concentrated approach to overcome barriers to screening and early detection in this population is, to a large extent, non-existent world-wide with the elderly singularly underrepresented in most studies of cancer screening and early detection [2]. When recommendations for screening are placed alongside epidemiological data, screening policies seem at best illogical and at worst a misplaced opportunity to encourage long-term health awareness.

In recent years there has been a growing realisation that the management of older individuals with cancer was not organised on a rational basis applying sound scientific information from clinical studies but rather treatment was decided on the whim of the treating clinician. As a consequence there is an increasing representation in professional journals citing evidence of poor referrals, inadequate diagnosis and under treatment of elderly patients.

Fentiman and et al. [1] were among the first to draw attention to several important areas where it was felt care to this group of patients fell short of the optimum:

- indifference on the part of oncologists,
- lack of attention to treatment of the elderly in major oncology conferences,
- exclusion of subjects over 70 years of age from clinical trials,
- lack of pharmacokinetic studies in elderly subjects,
- underestimation of life expectancy,
- misconceptions that the elderly are always poorly tolerant of chemo/radiotherapy,
- cancer is more indolent in the elderly,
- lack of criteria for elderly specific treatments,
- lack of attention to attitudes of the elderly with cancer,
- lack of opportunity for elderly to express their own opinion about cancer therapy.

In addition to this Monfardini and Yanick [12] have also identified a number of problems:

- misinterpretation of signs and symptoms because of concomitant conditions,
- masking of symptoms,
- delay in seeking medical attention,
- patients' lack of awareness of cancer signs and symptoms.

The rigours of therapeutic intervention for the elderly have been debated and authors such as Fentiman et al. [1] note that many physicians arbitrarily decrease the dosage of conventional chemotherapy regimes, use single agent chemotherapy or withhold chemotherapy on the dubious ground of unsuitability. Burklow [13], following a large study involving 5400 patients, reported that older patients receive appropriate treatment less often and are less likely to be referred to specialist cancer centres than younger people are. These findings were further supported by Bain et al. [5] and are especially concerning when one considers them in conjunction with the report, 'A Policy Framework for Commissioning Cancer Services' [14] which advocates both population wide equality of treatment and care and specialist referral. In their review of 699 patients with an array of different cancers, Goodwin et al. [15] concluded that the percentage of elderly people receiving definitive treatment declined with age. When age was considered in conjunction with other extraneous determining factors such as access to transport, performance status and mental state, it transpired that all of these factors predicted for non-receipt of radiation therapy but not surgery. In breast cancer care there is similar evidence of lack of appropriate delivery of cancer treatment. Despite the widely held view that breast cancers in elderly women are less aggressive there is little evidence to support this [16] however, elderly women have often been excluded from breast cancer clinical trials [17]. Bergman et al. [18] found that women over the age of 75 were less likely to receive adjuvant radiation therapy following surgery, receiving hormone therapy as their sole treatment more often than their younger counterparts. However, as elderly patients with breast cancer should receive treatment that effectively controls disease long term, the unselected use of hormone therapy alone is clearly no longer acceptable [17]. Additionally, addressing the issue of screening for breast cancer in elderly women, Haigney et al. [19] highlighted that although older female patients have a positive attitude towards breast examinations, this is not reflected by the attitudes and practice of hospital doctors. This indicates the need for change in attitudes and training to ensure older women do not miss out on diagnosis and treatment

In terms of consent then, is this the sort of treatment patients with cancer wish to receive? Whilst empirical research in this area is limited there is evidence to refute the suggestion supported by clinicians that older patients would not want to be treated as aggressively as younger patients. Results of a study by Yellen et al. [20] involving patients of varying ages indicated that older adults were as likely as their younger counterparts to agree to chemotherapy for both curative and control of disease purposes. There was neither an effect of disease stage on treatment decisions nor an interaction between disease stage and age. Such data supports the assertion of Newcomb and Carbone [21] that physician's attitudes rather than patients preferences influence treatment decisions. When one compares these results with those of Slevin et al. [22] who found that patients with cancer tend to unconditionally accept the physician's recommendations for treatment, one could question whether physicians' attitudes influence the way they explain the risks and benefits of treatment to older patients. Indeed, it is concerning that there is also growing evidence that nurses are equally paternalistic towards elderly patients with regard to treatment with some nurses believing that elderly patients should not be considered for aggressive cancer therapy [23]. If informed consent is a fundamental ethical right of all individuals, why are older individuals who require treatment for their life threatening illness not receiving it?

6. Relationships and power

The three key individuals most often portrayed as central to the health care equation are the doctor, nurse and patient. However the power which is held by each of these differs considerably. Chadwick and Tadd [24] discuss this in relation to the doctor-nurse-patient relationship and state

> Characteristically the doctor has been portrayed as 'all knowing' the nurse as caring, unselfish, obedient and obeying and the patient as helpless and utterly trusting.

That patients are perceived as passive recipients of health care is perhaps changing in some cultures but it remains that most treatment related decisions are taken by medical doctors. In doing so, they exercise the ethical principles of beneficence and non-maleficence. That is they have a duty to do good and a duty to do no harm. It is clear however that elderly patients with cancer receive sub-optimal care and as a consequence their life expectancy is compromised. As the average life expectancy for 65 and 85 year olds is longer than the survival for most untreated malignancies, failing to provide adequate antineoplastic treatment can be seen as denying the older individual the opportunity to fulfil his or her life expectancy [25].

Even when patients have the same stage of disease, performance status and treatment tolerance, age inequalities are apparent. Such paternalism averts survival and questions the ethical reasoning of health care professionals. If the rationale for such behaviour is

non-maleficence then one can argue that health care professionals responsible for the majority of patients with cancer are somewhat misguided and are practising unethically. Surely open and informed discussion with elderly patients would go some way to ensuring equity of treatment and address the misguided approach to treatment decision making which guides current practice.

In many ways the power imbalance which exists in cancer care is perpetuated by nurses as they fail to act as advocates for patients in their care. From an ethical standpoint one can question whether nurses can in reality function as an advocate for individuals for whom they already hold preconceived ideas. Lookinland and Anson [26] clearly illustrated the existence of negative attitudes of qualified nurses towards elderly people highlighting nurses' strong feelings of discomfort and ill-ease in the presence of old people. Yet in failing to fully inform elderly patients of treatment options available to them nurses are failing in their duty to do no harm to individuals in their care.

If nurses are really to act as advocates for elderly patients then they first have to have respect for older people. So it is concerning that negative attitudes towards the elderly are not only evident in qualified nurses but also in young people generally [11,26]. Indeed, one could suggest that it is one's experience as a member of society rather than as a professional that moulds one's beliefs about ageing and the elderly. Nevertheless, professional socialisation appears to negatively influence attitudes further. These results give cause for concern when considered in relation to the expected rise in future need for geriatric care providers and also when considered from a socio-political context, for these young people represent future voters who will establish policies that affect older people. The principle of 'respect for persons' is central to Kantian ethical theory. By this Kant claims that duty demands that persons be treated as ends in themselves and never merely as means to an end. As health professionals then we need to consider the respect we have for the individual patients in our care and question the motives for treatment employed for the elderly in contemporary cancer care.

Traditionally the training of nurses and doctors contains large elements of apprentice-like training and nurses are quickly socialised into a particular role which is subservient to doctors. If we consider Aristotelian principles then we can see how such socialisation is detrimental to ethical patient care. In terms of becoming morally good or virtuous, Aristotle stresses that it is by learning the habits of the virtuous that is important yet there is a general failure in nursing and medical education to identify role models in clinical practice who are ethically competent [27]. An Aristotelian approach to health care ethics could help focus the mind of the nursing profession and the professions educators to the need to identify ethically sensitive role models so that desirable habits of practice are encouraged. In so doing we may begin to see a shift in attitudes which would positively impact patient care.

7. Conclusion

Consideration of ethics in health care practice raises our awareness of some of the most fundamental questions surrounding human interaction. Knowledge of ethics would make us more aware of issues concerning the appropriate balance between respect for persons and individual autonomy and the beneficent paternalism which is enshrined in not only health care provision but also mirrored in normal human existence with regard to the elderly.

If we are to improve the care elderly people with cancer receive we must begin to explore some of our basic assumptions regarding the needs of this patient group. Ensuring that we provide an equitable service to older people with cancer is indeed an ethical challenge and the justice of providing optimal care to these patients should not be considered a dilemma.

8. Reviewers

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THE MEANING OF EUTHANASIA AND PHYSICIAN-ASSISTED SUICIDE

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Introduction

It is not uncommon that ethical debates over the controversial issue of help in dying are marked by people talking at cross purposes as well as misunderstanding each other's statements. This, I think, is mainly due to unclearity at the conceptual level. In this abstract, I propose what I take to be precise, definite, clear and unambigious definitions (or interpretations) of the terms «euthanasia» and «physician-assisted suicide» – definitions it should be possible to agree upon by all or most people, regardless of their ethical stance on the two practices.

Euthanasia

The word "euthanasia" originates from the Greek eu; good, and thanatos; death. As has often been pointed out, literally speaking, euthanasia means a good or gentle death. From two Dutch national surveys carried out in the years 1990-91 (the Remmelink Report) and 1995, there is available a wealth of information about the Dutch euthanasia practice, data and findings that are unique in the world. It has been pointed out in the literature that, euthanasia in the strict – and in the Dutch context the only proper – sense refers to the situation in which a doctor kills a person who is suffering 'unbearably' and 'hopelessly' at the latter's explicit request (usually by administering a lethal injection). There can be no doubt that the intention of the doctor who performs euthanasia is to kill. This is also seen clearly in the use of medication, which most often involves an intravenous injection of a barbiturate to induce coma, followed by an injection of a neuromuscular relaxant to stop respiration. Thus the physician, in taking these steps, aims for a speedy death in the person having requested euthanasia. It should be underlined that the person's explicit request must be voluntary for the killing to count as an instance of euthanasia. One should add the standard Dutch substantive requirement that the voluntary request be made repeatedly; no doctor may, it would seem, act upon just one request for euthanasia.

Euthanasia – definition (interpretation) of

- A doctor's intentionally killing a person who is suffering "unbearably" and "hopelessly" at the latter's voluntary, explicit, and repeated request – usually (but not exclusively) by administering intravenously a lethal dose of (different) quick-acting drugs/medication.

Note that this definition does not entail that the person be terminally ill, nor that he or she has a somatic disorder. Hence it would cover cases of medicalized killing of both chronically and nonsomatic, mentally ill persons – cf. recent developments within medical and legal practice in the Netherlands. It also would cover a situation in which a doctor kills a person who is tired of living due to old age, physical detoriation, loneliness and dependency. Such a person is not a patient in any traditional sense.

Physician-assisted suicide

The Dutch State Committee on Euthanasia of 1985 defined physician-assisted suicide as a doctor's «helping someone to take his life after an explicit request.» With physician-assisted suicide, too, the request must be made repeatedly. The element of voluntariness should be underlined since a person might request such help under coercion or duress. It is required that the person voluntarily expresses his or her wish to die and

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makes a (preferably but, in the Netherlands, not necessarily written) request for medication for the purpose of ending his or her life. Physician-assisted suicide thus involves a person's self-administration of deadly drugs that is supplied by a doctor. Most often the prescription is for a barbiturate that suppresses respiration when taken in large doses.

Physician-assisted suicide – definition (interpretation) of

- A doctor's intentionally helping/assisting/co-operating in the suicide of a person who is suffering "unbearably" and "hopelessly" at the latter's voluntary, explicit, and repeated request for the doctor's participation – usually (but not exclusively) by prescribing, preparing and giving a lethal dose of (different) drugs/medication to the person for self-administration.

Like with the above definition of euthanasia, this definition (or interpretation) of physician-assisted suicide does not preclude cases of nonterminal, nonsomatic or even existential suffering (cf. the famous Chabot case in the Netherlands). Also notice that the definition allows for the use of so-called "suicide machines" by which a person releases the deadly dose, which is then given intraveneosly in a mechanical way, thereby killing himself (dr Jack Kevorkian; dr Philip Nitschke).

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Editorial

End-of-life decisions

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Several papers in this issue of the journal and an important, though to some controversial, set of guidelines from the British Medical Association (BMA) warrant a return to the issue of withholding and withdrawing life-prolonging treatment - including artificial nutrition and hydration (ANH) - in contexts where though they may prolong life they are judged incapable or highly unlikely to provide any health benefit to the patient concerned; *or*, in contexts where the patient has previously and competently refused such treatment. The Greek case described in this issue by Drs Garanis-Papadatos and Katsas tells of an 82-year-old woman in semi coma after a severe cerebrovascular accident (CVA) who in her first six weeks of hospitalisation repeatedly expressed her wish to die both by signs and a few uttered words, and by trying to remove the nasogastric feeding tube.[1] Her children, aware of her lifelong aversion to hospitals asked the doctor about the possibility of withdrawing treatment. He was totally opposed, but after the patient's further deterioration into complete and irreversible coma the physician agreed to withdraw artificial nutrition while insisting on maintaining intravenous hydration. It was the most fundamental form of care and he as a doctor was obliged to provide it - and his personal stance was supported by both medical and religious tradition. The patient survived two more weeks and died from a further CVA. The authors tell us that this doctor's views accord with those of the majority of Greek doctors. They also add that were a Greek prisoner undertaking a hunger strike to refuse artificial nutrition and hydration the prisoner's refusal would be honoured. (In this context the paper by Dr Brockman about hunger strikes by prisoners provides fascinating insights.[2])

Although they do not specifically address the issue of ANH Dr McHaffie and colleagues report on the considerable variation that exists across Europe in legislation and practice relating to withholding and withdrawal of life-prolonging treatment in the case of neonates who are either highly likely to die whatever treatment is given, or, (the source of more controversy) are likely to have severely impaired lives if they do survive. Among their important if unsurprising findings is that whether or not life-prolonging treatment is to be continued, all the countries studied agreed about the importance of maintaining high-quality compassionate care for the patient.[3] Well *is* ANH to preserve life as long as possible a caring and compassionate thing to provide, regardless of whether or not any benefit to the patient's health will result, regardless of the patient's views or, where these are unclear, regardless of the views of those who know the patient well enough to be able to say what the patient is likely to have thought? The Greek doctor referred to by Drs Garanis-Papadotos and Katsas clearly thought so in relation to artificial hydration, while somewhat inconsistently allowing withdrawal of artificial nutrition.

The BMA guidelines, at one with UK law, are at pains to reject this point of view. Keeping someone alive by ANH is not "basic care" it is medical treatment for patients who one way or another are unable to swallow. Furthermore the primary goal of medicine is *not* to keep patients alive as long as possible but rather "to benefit the patient by restoring or maintaining the patient's health as far as possible, maximising benefit and minimising harm". Usually, but not always, prolonging a patient's life who would otherwise die is a benefit for that patient. But if treatment, including life-prolonging treatment (LPT), would fail, or ceases, "to give a net benefit to the patient (or if the patient has competently refused the treatment) that goal cannot be realised and the justification for providing the treatment is removed".[4]

The BMA emphasises that such an approach has nothing to do with euthanasia in the sense of intentionally killing a patient. Instead the intention of such withholding or withdrawing is to refrain from providing treatment that is not benefiting the patient. In this the BMA explicitly accepts that foreseeing the almost inevitable death of the patient if LPT is withheld or withdrawn

does not entail intending that death. Instead it involves acceptance (by doctors, relatives and society more broadly) that we are all mortal and that in some fatal conditions no treatments - including ANH - are of any benefit to the patient. And the BMA also emphasises this does not involve any judgments about the value of a patient's life - but does involve judgments about the value to a patient of a proposed or current treatment.

Opponents argue that nutrition and hydration, no matter how they are supplied to a patient, are never medical "treatments" - they are basic care and basic rights. The BMA, in line with UK law, rejects this claim. Some forms of providing food and water to those who are for some medical reason unable to swallow require medical techniques and skills for their implementation and/or provision and are properly classified as medical treatment. While the offering of food and water is basic care and should not be denied to those who can swallow food, for those who can't (or for whom normal feeding is unpleasant, for example because of choking) the issue should properly be: is the provision of ANH appropriate? And the answer should then properly turn on the question: will such ANH be beneficial to the patient's health?

Recognising the emotive and for some contentious nature of decisions to withhold - and particularly to withdraw - ANH, the BMA guidelines recommend additional precautions over and above those it recommends generally for decisions to withhold and withdraw LPT. These additional precautions include formal clinical review by a senior clinician who has experience of the condition from which the patient is suffering and who is not part of the treatment team; careful recording of the case, to be retained for further clinical review, and mechanisms for ensuring that all cases where the patient's wishes were not known are locally reviewed to check that appropriate procedures and guidelines have been followed.

And for all cases of withholding or withdrawing LPT - whether or not ANH is involved - the BMA guidelines recommend careful assessment of each individual case to ascertain whether the treatment in question will benefit the patient. In such assessment the patient's own views, preferably contemporaneous but when these are not available, previously established when competent, are preferable. When these are not available parents' views are especially relevant for children. For adults who have previously been competent to make their own decisions the role of family members and close friends is seen as providing evidence about what the patient is likely to have considered to be beneficial. For those who have never had capacity to make their own decisions "the primary factor will be the clinical benefits and burdens of the treatment" assessed as far as possible from the patient's point of view (as distinct from the preferences for themselves of the health care team or the family). "The views of those responsible for the continuing care of the patient, which would include those close to the patient, should form an important part of that assessment".

In assessing whether provision of a LPT would benefit a patient who is unable to advise the doctors either directly or indirectly, various factors should be taken into account by the doctors who are ultimately responsible for making the decision. These include, so far as can be ascertained: the patient's own wishes and values; clinical judgment about the effectiveness of the proposed treatment; the likelihood of unmanageable pain or suffering; the level of awareness the patient has of his or her existence and surroundings as demonstrated for example by the ability somehow to interact with others, and the capacity for self-directed action or the ability to take control of any aspect of his or her life; the likelihood and extent of anticipated improvement in the patient's condition if LPT is provided; the degree of invasiveness of the LPT; the views of the parents if the patient is a child, and the views of people close to the patient, especially close relatives, partners and carers, about what the patient would consider to be beneficial.

The medical actions described by Drs Garanis-Papadatos and Katsas would surely be inconsistent with the BMA guidelines. It is difficult for this writer to understand how they could benefit or "care for" or be in the interests of the patient. Should the time come for European guidelines, which approach should be recommended? Debate is invited.

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ACCOMPANYING THE SICK TO FACE THE DEATH

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1. INTRODUCTION

There is nothing more important in life than being born and dying. At birth we know nothing about the world around us, while at the moment of death we start to know the unknown. To help patients at this ultimate phase of life, it is imperative that all health care doctors will "accompany" the dying not only with clinical care, but also with solidarity and compassion.

Cecily Saunders, foundress of the Hospice in England, says to the dying: "We care deeply for you, because you are very dear till the last moment of your life. We will do everything possible not only to help you to die, but to live your life to the full till the very end.

The sisters of the late Mother Theresa of Calcutta in her "Home for the Dying" (formerly a hindu temple), receive daily the "Dying" from the streets and the slums. Mother Theresa used to say: "They have lived like animals, now they can die like angels".

2. Today in Italy, France and Spain about 75 to 80 percent die in hospitals. Very sadly many die alone and at times are buried alone.

3. In a study (Miles & Gomez 1999) in the Unites States 85 percent of deaths occur in health care institutions (hospitals, nursing homes, etc.) and about 70 percent involve electivity withholding some form of life-sustaining treatment.

A study in the Journal of American Medical Association (1990) claims that:

- 85-90 percent of critical care professions state they are withholding and withdrawing life-sustaining treatments from patients "who are deemed to have irreversible disease and are terminally ill".

- it is estimated that 1.3 million American deaths a year follow decisions to withhold life support.

All this is a very important stage of "bedside ethics", which calls for the accompanying of the dying with compassion. This is also part of the "humanization" of health care in hospitals. The aim of this presentation is not the discussion of euthanasia, but of the human caring of the sick facing death.

4. The position in the U.S. as presented by Margaret P. Battin (Health Care Ethics 1994):

"In the United States, we have come to recognise that the maximal extension of life-prolonging treatment in these late-life degenerative conditions is often inappropriate. Although we could keep the machines and tubes - the respirators, intravenous lines, feeding tubes - hooked up for extended periods, we recognise that this is inhumane, pointless, and financially impossible. Instead, as a society we have developed a number of mechanisms for dealing with these hopeless situations, all of which involve withholding or withdrawing various forms of treatment.

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Some mechanisms for withholding or withdrawing treatments are exercised by the patient who is confronted by such a situation or who anticipates it: these include refusal of treatment, the patient-executed DNR order, the living will, and the durable power of attorney. Others are about a patient who is no longer competent or never was competent. "Withholding and withdrawing treatment is the way we in the USA go about dealing with dying, and indeed "allowing to die" is the only legally protected alternative to maximal treatment recognised in the United States. We do not legally permit ourselves to actively cause death".

- "In our days the doctors affirm nearly as a sacred duty to remain passive near the bedside of the patient, once there is no more hope but, in my opinion, if they do not want to fall short in their professional obligation, as also their sense of humanity, they should not only know the techniques, but also provide a service to render more easy and light the suffering of pain and of all who are dying".

5. The situation today differs from country to country in Europe. In the Netherlands "voluntary active euthanasia" is also an available response to end-of-life situations. Although active euthanasia remains prohibited by statutory law, it is protected by a series of lower and supreme court decisions and is widely regarded as legal, or more precisely judged (legally "tolerated") as sick. This law is under heavy criticism.

6. Another different situation exists in Germany (where the painful memories of Nazism is still alive), there is a vigorous opposition to the notion of active euthanasia. Euthanasia is viewed as always wrong and the Germans view the Dutch as stepping out on a dangerously slippery slope" (Battin).

However, it is an artefact of German law that, whereas killing on request (including voluntary euthanasia) is prohibited, assisting "suicide" is not a violation of the law, provided the person is capable of exercising control over his/her actions, and also acting out of freely responsible choice.

In France there has been a very controversial debate in Parliament to legalise "death with dignity".

7. This is a brief overview of a rapidly changing transformation on dying and death, which will call for deeper empathy and compassion in our "bedside ethics".

However, I can summarise our reflection by focusing on the three different historical positions, which interact between them. All three need clarification to reach some kind of ethical position:

a) Francis Bacon (Advancement of Learning, published 1605) first developed his philosophical-medical perspective. Bacon proposes the "good death" or "the external euthanasia" in the chapter dealing with the body.

b) He underlines the deity of the doctor to:

- alleviate pain, anguish and suffering of the patient, when it is impossible to restore him to health. In this case the doctor may only offer him a more serene and easy death.

"The way F.Bacon dealt with the problem is different from how it is presented today, as being pro-euthanasia" (Manuel Cuyas S.J., Euthanasia, Piemme, 1989).

Bacon's approach is best described in his own words: " Ma ai nostri giorni i medici ritengono quasi come un dovere sacro il rimanere inattivi di fronte al malato, una volta che questo sia stato dichiarato senza speranza; ma, a mio parere, se non vogliono mancare al loro obbligo professionale oltre che ad un senso d'umanitŕ, non solo dovrebbero conoscere le tecniche, ma anche prestare il proprio servizio per rendere piů leggere e facili da sopportare le pene e le sofferenze di coloro che spirano".

Cuyas affirms "the dominating idea is the will to serve the person of the sick till death ... This is a positive conception of euthanasia, fully in agreement with the fundamentals of an individualistic and social ethics" (Cuyas p.101).

c) The often common abuses of "futile treatment" (prolonging life) has created a reaction of defence by pressure groups and active associations pro-euthanasia, who demand legislation in favour of a free choice of when and how to die. This is considered a right of the individual, which surpasses the doctor's decision.

This runs against the imperative ethical foundation which obliges doctors to provide every possible care.

d) The politics of convenience is also now developing, based on "cost and benefit" and the supreme value of not going against the sentiments of the citizens, who implore another person to end their suffering and life. It is ethics based on feelings and pity, the person who helps the patient to die should not be legally guilty of homicide or cooperation towards suicide.

Cuyas affirms "It is impossible to consider a decriminalised euthanasia, as it is impossible to extend it to cases which the minimum moral norms demand a condemnation to protect the rights of innocent life" (p. 102).

It appears on the level of personal rights that there is no substantial difference between:

- being able for pity's sake to end the life of a terminally ill patient;
- and the inclusion of a yet more painful and sad case of a non-terminally ill patient in similar situations.

8. I think here it is worth remembering some of the ethical principles which are embraced in a personalistic ethics:

a) The right for freedom of conscience (art. 18 Declaration of Human Rights):

"All people should be immune from cohesion ... this in religious matters none should be forced to act against conscience or hindered .... to act in conformity with his conscience privately or publicly" (Vatican Council Two).

b) The right to know the truth, regarding all matters which concern a person and the rights to have information about his/her condition. This is a right founded on the dignity of the human person, as a responsible "partner" in the doctor-patient relationship.

c) The right of consent to decide personally on any treatment or research to which the person is submitted. The patient is the chief actor in his health care, a right acknowledges by various codes and laws.

d) The right for dialogue between the patient and doctor. This should also include a dialogue into the family and all those close to the patient, and likewise with the proper environment and community.

9. The guidelines in the accompaniment of patients should aim at giving "the very best" (Don Verzé) of all health workers to the patient. This includes these norms:

a) "Quando non c'č piů nulla da fare, c'č molto da fare" (Lega Italiana contro i Tumori) "When there is nothing to do be done, there is a lot to do". All forms of palliative cares in a very honest way should be considered to alleviate suffering of 1000 patients in a Milan hospital none requested to end their life sustainment.

b) To be close to the patient in all the phases of his illness, those which Kubler-Ross describes as the phases of shock, refusal, anger, depression, compromise, acceptance and hope. The patient need support through empathy, listening, communication (verbal and non-verbal), presence of family, psychological help

Very often the patient, even if he/she does not affirm so, knows he has come to the end and even arrives through intuition of knowing when.

c) Believers, whether Christian and non-christian, desire also spiritual accompaniment. Dying, according to all anthropologists, in all cultures means giving a spiritual value and a social value to life. Even those who do not believe in my experience desire some kind of spiritual (not religious) comfort.

d) A person has the right to die with his family around and in privacy (e.g. in a private room).

e) The family needs also counselling, comfort and help to cope with courage when their beloved one passes away. The will of the dead need to be fully respected with regard to donation of organs, burial, etc.

10. As an "icon" of this reflection I wish to read to you an extract of the book by Rosemary and Victor Zorza (Un Modo per Morire, Ed. Paoline), which they wrote about the death in a hospice of their 25 year old daughter Jane.

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ADVANCE DIRECTIVES

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Operational definitions:

Advance Care Planning

Since clinicians must frequently make difficult decisions about life sustaining or death delaying treatments for patients about whom they know very little, advance care planning can protect patient choice even after the patient has lost decision making capacity. Central to this process is the clarification of values and the statement of general goals of care as well as specific treatment preferences that are the substance of advance care planning.

Advance Directive

More specific than advance care planning, advance directives are written or oral statements that describe patient preferences for care when patients cannot decide for themselves. An advance directive may include specific treatment preferences, a statement of general values, and or a designation of surrogate decision-makers.

Decision-Making Capacity (DMC)

Patients are generally believed to have DMC until proven otherwise. DMC includes the ability to understand the nature of the proposed test or treatment, the accompanying risks and benefits, the probabilities for a given outcome, and lastly, the ability to communicate a preference. DMC is determined more on a sliding scale and not an al or none phenomenon; patients with dementia or mental illness may still retain DMC.

Durable Power of Attorney for Health Care

A legal means of documenting a surrogate decision-maker in the event of lost DMC.

Living Will

A living will is a document that specifies treatment preferences to be activated when a patient loses DMC. Typically, living wills apply only specific scenarios, such as terminal illness or a persistent vegetative state.

Surrogate

A person designated to make decisions on the patient's behalf when DMC is lost. Sometimes this person is appointed by the court. When chosen by the patient, he or she may be referred to as the health care proxy or the attorney in fact for health care. The surrogate's task is to render decisions based on the previously expressed wishes of the incapacitated patient whom he/she represents. This process of proxy decision-making is termed substituted judgment.

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(Perceived) Best Interest Standard

When there are no advance directives and no previously expressed patient preferences that can be recalled by others, surrogates and health care providers decide together what they believe to be in the patient's best interest. Typically, this is not applied by physicians alone and if needed, a court-appointed guardian is utilized to protect patient interests from unbridled professional autonomy.

Advance Directives

Background

Historically, clinicians faced with treatment decisions for incompetent patients made the decisions themselves or consulted with family members who did their best to make what they believed to be the optimal decision. In an era of icon toppling and rampant distrust, this benign paternalism has given way to a new breed of doctor called a "provider" and a new breed of patient called a "consumer." Technology also has now been able to reverse and prolong chronic illnesses and the introduction of new and improved life-sustaining therapies has resulted in fates worse than death (as the Bouvia, Quinlan, & Cruzan cases argue).

Legal Cases

To establish whether competent patients could refuse application of life-sustaining therapies:

1). William Bartling, 70 years old with COPD and lung cancer; he developed a pneumothorax after a lung biopsy and became ventilator dependent. After two months he requested to be withdrawn from the ventilator but his doctors refused. In 1994, the California court ruled that "if the right of the patient to self determination as to his own medical treatment is to have any meaning at all, it must be paramount to the interests of the patient's hospital and doctors."

2). Elizabeth Bouvia, 26 year old with severe cerebral palsy asked for her tube feedings to be discontinued and that she be provided with pain and symptom relief while she starved to death. On appeal, the court stated, " We find nothing in the law to suggest that the right to refuse medical treatment may be exercised only if the patient's motives meet someone else's approval." Thus, idiosyncratic reasons for a decision must be respected if the patient possesses DMC.

The overwhelming majority (from 66-93 %) of Americans would like to discuss advance care planning with clinicians, but only 6-33% have actually done so. Other studies reveal that even when present on the medical record, advance directive forms are often unnoticed or ignored.

Ethical Principles

Respect for patient autonomy and nonmaleficence are the substrate of good ethical advance care planning. Respect for autonomy is manifest in advance directives since they empower patients to determine what is to happen to their body after they lose DMC.

Making It Happen

1. Introduce the topic
2. Information exchange/ intelligible communication
3. Listen for preferences
4. Proxies
5. Documentation
6. Provide Feedback, elicit questions, and recheck understanding/preferences over time

Resources for Advance Care Planning

Choice in Dying: http://www.choices.org

American Association of Retired Persons: http://www.aarp.org

Patient Decision Support: www.patientdecsions.com

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EMERGENCY DETERMINATION OF DECISION-MAKING CAPACITY (DMC): BALANCING AUTONOMY AND BENEFICENCE IN THE EMERGENCY DEPARTMENT

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Introduction

In most clinical situations, emergency physicians (EPs) have little difficulty determining a patient's implicit ability or competency to participate in the emergency medical (EM) decision making process. Sometimes, however, the boundaries between competence and impairment are blurred, depending more perhaps on toxicokinetics and less on I.Q. or baseline cognitive function. The assessment of medical decision-making capacity (DMC) is an important and basic skill in the clinical EM armamentarium since it both informs our diagnoses and is informed by our diagnoses. Thus, there is a bi-directional utility to mastering this clinically useful concept.

Definition of DMC

The multifaceted construct of DMC ultimately refers to a patient's ability to make an authentic choice. Genuine DMC reflects cognitive and affective functions, which are clinically manifest in intellect, memory, judgment, insight, language, attention, emotion, calculation, and expressive and receptive communication skills. DMC includes the ability to:

1. Receive information
2. Process and understand information
3. Deliberate
4. Make and articulate choices

Unlike the more static entity of legal competency, capacity varies, as a function of host and environmental factors over time. Thus, DMC is a dynamic, task-specific, and changing talent; in practice it may be assessed on a nondichotomous spectrum of capacity, pertaining to the particular healthcare decisions at hand. Often, impairment is situational; the same patient may be competent for one decision and not another, depending on the gravity and consequences of the decision and the potential for harm. In emergency situations, physicians must promptly assess whether a patient is capable of making an often-complex decision. The objective of this document is to describe standards for the rapid determination of DMC in the ED setting without compromising either patient autonomy or safety.

Bioethical Precepts of DMC

Honouring DMC in Emergency Medicine has important ethical and moral significance. The Code of Ethics of the American College of Emergency Physicians states that "patients with decision-making capac-

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ity must give their voluntary consent to treatment...Emergency physicians should be able to determine whether a patient has decision-making capacity and who can act as a decision maker if the patient is unable to do so." The SAEM Code of Conduct also underscores a promise of "Respect, securing the safety, privacy, and personal welfare of patients, and offering informed choice whenever possible."

Attention to bioethical principles can greatly inform a clinician's determination of optimal choice. Companion issues of informed choice and presumed DMC are both supported under the ethical principle of respect for patient autonomy. The principle of respect for autonomy is manifest in the doctrine of informed consent. Under the doctrine of informed consent, patients with adequate DMC are allowed to make autonomous choices abut their own health and healthcare. We must avert the twin harms of presuming intact or impaired DMC when they are not in fact present.

Respect for autonomy is not the only ordering principle, however, and to it clinicians must carefully add a blend of beneficence, nonmaleficence, and justice. Justice would have us respect the impact of a patient's decisions on identifiable others, and recognize that individuals have rights, to the extent that they do not materially harm others. The principle of beneficence dictates that the patient's welfare must be promoted while the principle of nonmaleficence exhorts us to avoid harm. These principles need not be seen as mutually exclusive. Indeed, it is optimal to both respect choice and protect from harmful choice, but sometimes this is not possible. When dealing with the mentally ill, for example, we may feel caught between the Scylla of abrogation of civil liberty and the Charybdis of allowing marginally competent patients to make potentially dangerous or unsafe choices. It is in these difficult situations that every effort should be made to carefully assess the DMC of the patient, much as one would do a neurological exam on any patient with an altered mental status. To assess DMC clinicians must be astute, using exemplary diagnostic, treatment, and communication skill to bridge the gaps in cognitive understanding whenever possible.

DMC Determination

Although a thorough discussion of all medical decisions in the ED is impossible, patients participate more fully in the therapeutic ED encounter and in the decisions that affect their health when they possess an adequate level of DMC. In most clinical scenarios, DMC is easily and implicitly ascertained. In others, the EP may utilize a more standardized approach to DMC determination, particularly when the decisions involve potentially grave or serious consequences. We suggest the use of the following steps:

"8 Steps to Determine "D-E-C-I-S-I-O-N" Making Capacity"

- **D**etermine need to establish DMC.
- **E**nsure expressions of choice are possible.
- **C**orrect reversible environmental, metabolic, mental & physical challenges to DMC.
- **I**nvestigate affect and cognition using standardized tests.
  - Affect: "Are you depressed or anxious?" Memory: 5 minute recall of 3 words Language:
  - Receptive: "Cover your right eye with your right hand."
  - Expressive: "Name all the animals you can think of in one minute."
  - Visuospatial: "Draw the face of the clock when it is 1:30."
  - Judgment: "What would you do if you found a stamped envelope on the ground?"
  - Understanding: "What does it mean that 'A stitch in time saves nine.'?"
  - Attention: "Spell your name backwards."
  - Calculation: "Count down from 100 by seven; what is 100 minus 7?"
- **S**urvey patient goals and values using open-ended questions about the choices, alternatives, and consequences at hand.
- **I**ntegrate the information gathered and analyse the "DREAM" to determine DMC.
- **O**penly share the results with the patient and their health care advocates, if present.
- **N**ote legibly the DMC determination on the ED chart.

Patients with Impaired DMC: The "DREAM" Acronym

Authorities variously characterize dream as "an illusory mental image." Moreover, the dreamer is defined by the Oxford English Dictionary as "A habitually impractical person." Similarly, a dream world is defined as

"the world of imagination or illusion, rather than of objective reality." Those lacking DMC may be thought to be living in such a dream world in which illusion eclipses the reality of the immediate clinical situation. Those asleep or occupying a dream-like state with respect to present clinical decisions are unlikely to be decisionally competent. The following mnemonic, "DREAM" may aid in assessing whether the patient's ability to exercise authentic choice is in fact, diminished. If one or more of the following five elements is present, then DMC may safely be said to be impaired at some level. This does not necessarily imply that the patient lacks competence for all decisions, however, such patient's must be protected from making choices that would reasonably appear to be at odds with their deeply held values and goals. Thus, DMC is forestalled by the following conditions:

- **D**ecisions - that are Durable & Data-Driven cannot be made during ED visit.
- **R**easoning - rational or otherwise is absent.
- **E**xpressions - of choice are unrealisable for whatever reason.
- ž• **A**lternatives - and their foreseeable consequences (including the consequences of no treatment) cannot be appreciated.
- **M**adness, **M**isunderstanding, **M**ental imbecility, **M**etabolic derangements, and other obstacles render **M**eaningful **M**anipulation of information impossible.

Threats and Barriers to DMC

Numerous clinical settings provide challenges in the determination of DMC. Although an in-depth review of causes of altered mental status is beyond the scope of this document, some examples of challenging clinical settings may include minors, elderly patients, intoxicated patients, psychiatric patients, patients in extremis, patients of other cultures or languages, patients with physical communication impairments, severe pain, organic disease states, research subjects, and numerous other clinical settings. Even in such circumstances, where some impairment of DMC may be suspected, a sliding scale approach should be used, remembering that most barriers are relative, rather than absolute. EPs must be aware of potential barriers to DMC, but must make an individual assessment of DMC relevant to the specific clinical setting and decision at hand. Even individuals who have some impairment of DMC may demonstrate adequate understanding of the decision at hand, and its ramifications, to make an appropriate informed choice.

When DMC is Impaired

Although adults are generally presumed to be competent to make decisions, sometimes they are unable or unwilling to make certain medical decisions in the ED. If DMC is reversibly compromised, then all efforts to restore DMC should take place before ultimate DMC is established. Once treatable conditions such as hypoxia, dehydration, hypoglycaemia, fear, or opiate intoxication are corrected, DMC may need to be reassessed. If DMC cannot restored in a timely manner, other attempts should be make to identify and protect the patient's perceived best interests. This may include consulting family, surrogates, advance directives, the courts, or another clinician expert, to assist in the determination of the most appropriate actions. Clinician bias must give way to the primacy of patient dignity and patient-centred values. Honouring these suggests that once the course that optimises patient safety and interests is identified, it should be initiated, despite possible objections from either the decisionally impaired patient or noncustodial others. However, even when clinicians must act in loco parentis, they should strive to share decision-making power by involving the patients and their representatives as much as possible.

Conclusions

While the stepwise approach may prove a helpful adjunct to the determination of DMC, it is not a substitute for sound clinical judgment. When DMC determination is challenging, or the ramifications of a decision serious, the assistance of a third party (such as a surrogate, a consultant, another clinician, etc.) may be valuable in discerning the most appropriate action.

In addition to the obvious clinical utility of DMC assessment, the steps taken in the very establishment of DMC provide an excellent opportunity to promote communication, dialogue, and interaction, which may nurture the physician-patient relationship. While DMC is conditional, the compassion and respect we have for our patients must be unconditional. Even those lacking a coherent rationale for their words and actions deserve to have their dignity protected, and to be granted a fair chance to share in the therapeutic decision making process.

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Appendix

Evolution Of The Concept Of Patient Autonomy

By Gregory Luke Larkin, MD MSPH FACEP

Autonomy = auto (self) + nomos (goveming) - persons should be able to make decisions based on their own beliefs, values, and prejudices.

Synonyms: Self-determination - to consent to or refuse any form of medical treatment.Respect for Autonomy: a core tenet of Western medical ethics and one of the four principles (Beauchamp).Belmont Report: respect for persons; caveat: not all are capable of self-determination Modern notion in medical ethics although concept is in Kant

Contrasts with the old paternalism; i.e. "doctor knows best"

Unknown in Ancient Codes of Ethics and thru Percival vs. other Principles, which have been around for millennia.E.g. Non-maleficence: primum non nocere (first, no harm) (Hippocrates in Epidemics)Beneficence: to do good (Hippocratic Oath, Pythagoreans)Justice:fairness (Plato's Republic)Ancient Codes were largely more etiquette than moral principles.

Modern Codes: Gregory, Hume, Percival, in England; Rush, Hayes, Davis in US.Respect for Autonomy evolved outside of medicine (Kant, Mill, Emerson, Cordoza)Kant: see persons as ends in themselves, "never as a means only."

Mill: On Liberty

Emerson: rugged individualism

Legal derivation of respect for autonomy came from the right of privacy under which adults of sound mind are considered to be in control of their own bodies, and by extension, their own fate.

E.g. Schloendorff vs. Society of New York Hospital (1914), Judge Cordoza famously stated, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

E.g. Griswold vs. Connecticut 381 US 479, 1965. Right of privacy to use contraceptive devices.Modern Western Medical Ethics in the 20th Century

Growing need for a new ethic

WWII: Nazi Doctors-Nuremberg-hypothermia, etc.

Tuskegee Syphilis Experiments 1932-1972 (28 died by 1969)

Jewish Chronic Disease Hospital Studies (Sloan-Kettering)-cancer cells; 1963Willowbrook State School for retarded children with hepatitis 1965-71Atomic Energy Commission and the Department of Defense

1947-1974;Ur/Pt

New Technology e.g. dialysis rationing by "God Committee" in Seattle 1962

Bioethics Timeline

parallels explosion in biotechnology & reaction to rampant distrust1954:Morals and Medicine by Joseph Fletcher

Patient rights to use contraception, artificial insemination, euthanasia, and to have full disclosure of all information and options to patients

1964:World Medical Association Declaration of Helsinki Research consent1966:Beecher HK. Ethics and Clinical Research, NEJM 274;

1354-60.Unethical studies.

1969:Founding of the Hastings Center in by Willard Gaylin & Dan Callahan1970:The Patient as Person by Paul Ramsey

1971:Founding of the Kennedy Institute of Ethics, Georgetown Univ., Wash. DC;

1976: Karen Ann Quinlan, not an auto accident

1978-83:Presidents US Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1978: Encyclopedia of Bioethics;

1979:Principles of Biomedical Ethics; Beauchamp and Childress; Belmont Report, 1979-published in response to Beechers work by the National Commission for the Protection of Human Research Subjects; called for ethical guidelines for research and the establishment of Institutional review Boards to evaluate all research in institutions that receive federal funding to guarantee protection of research subjects.1982: Baby Doe, Down's syndrome case with esophageal atresia parents refused surgery1983: Presidents Commission calls for the establishment of hospital ethics committees to "promote effective decision making" for mentally incompetent patients and handicapped newborns.1984: Baby Doe Regs, 1984. C Everett Koop, MD & DHHS

1986:US Supreme Court overturns the DHHS "Baby Doe regs";

1988:Joint Commission on Accreditation of Hospitals requires formal DNR policies; 1990: Cruzan vs. Directot, Missouri Dept of Health, US Supreme Court. Persons have a constitutionally protected liberty to refuse unwanted medical treatment including "lifesaving nutrition and hydration." But it is up to the states.1990: Patient Self-Determination Act (PSDA); solicit, inform and advance directives1991: Helga Wanglie. Husband found to be right surrogate; no futility1991: Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying. Hemlock Society's Derek Humphreys1993: Baby KI: anencephalic futility case1994: Measure 16 passes in Oregon permitting PAS

1995: Gilgunn v Massachusetts General Hospital; futility and DNR placed in spite of daughter's wishes.

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DETABOOING OF DEATH- AN ESSENTIAL CONDITION FOR A BETTER QUALITY OF LIFE OF THE DYING

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Every person should have the right to decide where, how and with whom he would like to die. This is also comprised in the document on the rights of the dying passed by the General Assembly of the United Nations in 1975. Human rights in the period of dying are often grossly violated because all too frequently others, the patient's relations or his doctor, decide on where the patient will spend the last period of his life. The patient's relations act in this way since they wish to do for him everything feasible, especially to prolong his life as much as possible. They are supported in these efforts by the doctor, who does not want to run the risk of being accused by the relations that the patient's death was his fault; besides, he may himself find it difficult to accept the fact that patients also die. Only too rarely anybody listens to the dying person and hears his wishes and does everything so that he might spend the last period of his life as he wants to, possibly quite differently from what the ideas of his environment are.

The doctor's personal attitude to life, illness, handicap, old age and death is often of decisive importance. This personal attitude of his may also affect his professional decisions concerning diagnostic methods and therapy. When a doctor who is terrified of death and considers it just a failure is confronted with a patient who has already been taking leave of life for quite some time, he will continue working on him and ordering examinations and therapies that might not be of any use or even unnecessarily put a strain on the patient. On the other hand, a doctor accepting death as a natural event will respect the life that is running out and will treat the patient only to make his life easier and to improve the quality thereof and at the same time he will also be able to reassure the patient's relations. For behaving in such a manner the doctor needs a good professional knowledge on the subject, but also a great deal of human maturity and courage to accept responsibility.

If we want to improve the quality of life up to the last moment thereof, much work for the detabooing of death in all strata of the population has to be done. Even the most modern medicine will not bring the desired results if we do not accept life as a whole, death included.

Slovenian Hospice Association is a part of the international Hospice programme, which can be summed up as an integral care of a dying patient and his family. The Association places special emphasis on the following activities: caring dying patients and their relations, the latter also after death in the period of grieving, detabooing death in all strata of the population, endeavouring to create more favourable conditions for the dying in medical institutions (hospitals and nursing homes), and assisting medical staff. Every year the Association organizes numerous lectures, workshops, seminars and other events at all levels: for medical staff, for teachers in schools and nursery schools, for students, in parishes etc. In the last academic year we have also been present at the Faculty of Medicine of the University of Ljubljana with seminars at the department of family medicine and in the Medical Students' Club with monthly discussions of topical issues. We also appear in mass media and publish pertinent literature.

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SICKNESS AND TIME IN A SEPIK COMMUNITY

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ABSTRACT

In this short article about the association between time, health and sickness in Ambonwari village, East Sepik Province, Papua New Guinea I examine people's practices and introduce their own concepts as they are axpressed and thought about in their own Karawari vernacular. I argue that it is the relationship between *kay* (habit, manner, way of doing things) and *wambung* ('insideness', understanding) – both being extended to the past and the future, both involving many individual and collective dimensions – which with its processual multidimensional nature – every process includes tempo, rythm, temporal strategies, etc. – produces multidimensional time as it produces itself. The relationship between "way of doing things" and "understanding" is the most important for Ambonwari conceptualization of their life-world, including health and sickness.

In one of his most influential books a social phenomenologist Alfred Schutz wrote that "*the problem of meaning is a time problem* – not a problem of physical time, which is divisible and measurable, but a problem of historical time" (1972:12; italics in original). Filled with physical events and having the nature of "internal time consciousness" (Husserl 1964), historical time is always related to one's own life. "It is within this duration that the meaning of a person's experience is constituted for him as he lives through the experience" (Schutz ibid.).

In this short article about the relationship between time, health and sickness in Ambonwari village, East Sepik Province, Papua New Guinea, I would like to present my views as clearly as possible. First of all I would like to introduce people's own concepts as they are expressed and thought about in their own, Karawari vernacular. This concepts are not simply inherited but are continually reconstructed and comprehended anew. Once this is understood, Ambonwari conceptualization of life can be depicted and confirmed through the careful observation of their practices. Only then I will be able to outline what do I mean by temporality, by sickness and by the relationship between health, sickness and time.

Ambonwari village has just over 400 inhabitants. It is probably the largest of eight main villages in which about 2000 people speak Karawari. This language is a member of the Lower Sepik Family, belonging to the larger group of Papuan languages (Foley 1986; Telban n.d.). There are 12 totemic clans and 35 patrilineages, including six with no present members. Residence is patri-virilocal. Introduced respiratory diseases – tuberculosis, pneumonia, influenza – along with malaria, take a heavy tool of Ambonwari people. Though there is an Aid Post in the village and though people visit hospitals in Angoram and Wewak when necessary, the practices of the two village healers reflect people's understanding of their world – that is their cosmology – and their well-being.

Many societies, including Ambonwari, do not even have a term which can adequately translate the English term "time" with its multiple and often measurement-oriented meanings. I have shown elsewhere (Telban 1998) that their "time" is not an abstract idea but an integral part of their life: the ways activities are performed, the manner in which people behave, the ways the village functions, as well as most significant rituals, are all subsumed under the term *kay* which refers to "embodied" processes, both collective and individual, both past (*kupambin kay*, "the way of the ancestors/elders") and present (*imnggan kay*, "the way of the village"). The past as represented in *kay* is not just automatically reproduced, but requires an active

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process which is reflected upon and guided by people's understanding, i.e. *wambung* (lit. "insideness"; see Telban 1993, 1998). As a verb *kay* captures several meanings: to be, to exist, to remain, to stay. As a noun it is used for being, habit, way, manner, as well as ritual, custom and law. As Ambonwari do not have a term for an abstract concept of "body", *kay* is not necessarily embodied in material flesh, in the case of spirits, for example (see Telban 1998a).

In this paper about the temporality of sickness I would like to show that it is the relationship between *kay* (seen as habit, manner, way of doing things) and *wambung* (understanding, "insideness") which is the most important for Ambonwari conceptualization of health and sickness and which with its processual nature produces time as it produce itself. One could say that both health and sickness are intrinsically defined by their *tempo* (cf. Bourdieu 1977:8).

The main sign that someone is sick is that her or his *kay* is not as it should be, as it is habitually expected. A person's breathing is different from usual, their skin is hot or cold, she or he sleeps more, or does not perform their usual activities. People say that a person is "with sickness" (*min mari ngandikin*), that is, she or he "has sickness" (in Karawari language – just like in many other languages – there is no verb "to have"). Sickness "has taken hold of a person" (*min mari yan sarinyan*). By holding and "using" a person, the sickness and person become one; they share the same body/being. To get better a person has to remove (cut off) "sickness" as a part of the body/being. Only in this way will she or he rehabilitate their previous *kay* (way of life). But to cut off the sickness one cannot just take medicines (if tablets, pills and so on work people say that they were not really sick) but has to look at one's past and address those issues which caused the sickness. People say that those healing practices which are part of medical treatment in Hospitals and Health Centres are powerful. But they cannot help Ambonwari people when they are seriously sick, that is when they have so-called "custom sickness", because medical doctors do not share and do not address the Ambonwari life-world of the living and spirits. Only by restoring the causes (wrongdoings; and here a patient's and his relatives' understanding comes into the play) the *kay* of a sick person will return to normal and the sickness will be cured.

In healing ceremonies, the specialist tries to find the cause and remove the objects which are the embodiment of sickness. A healer tries to restore the *kay* to its previous condition. As *kay* of an individual incorporates different collective *kay* the sickness also becomes a collective issue (of household or lineage, for example), incorporates past and present relationships (ongoing, those who are producers and are produced by time), including with their own familiar spirits. What is apparent from the practices of the healers is that they are able to perform an intermediate role, creating a temporary link between people and spirits. To become a healer one has to come in contact not only with spirits of the dead, but also with bush spirits, in particular those of the patient's own clan and land. The spirits supervise the healers' practices and guide them on their healing paths. I asked one of the healers, Tobias, how he could hear the voice of the spirit. He answered: "Just in the same way as you are talking to me now and I can hear you. The spirit talks into my ear and I hear him." Still curious, I asked him whether in fact the voice simply occurs in his head? He answered:

"No. The voice comes straight into my ears. When I chew ginger, my eyes turn around and my ears become blocked. I am unable to understand what people around me say. I hear only spirits. So I say to everyone: "Shut up, I want to hear what they have to say. Why are they angry? Their answer will come straight into my ear. I tell those around that I did not get these answers inside my own head but that I have heard the voice of the spirit. So I would know the cause and would ask a child's father, or a husband if his wife is sick, or her, if her husband is sick. I would tell them when the spirit had asked for matters to be settled and tell them how this can be done. If they do not listen, the sick person can die."

The wrongdoers then have to "cut themselves off" from the practice which caused the sickness by following the practices such as payment of compensation, seclusion, washing, food presentation, and so on. Ambonwari people often say that they have to look after their skin properly, which includes their acts. In regard to sickness we can make some common observations: a healthy person is defined by visible healthy skin and her or his habitual activity; a sick person is defined by unhealthy skin and the aberrant activity. Thus, a healing ritual is concerned with the extraction of invisible stones, shells, teeth, bones and thorns from beneth the unhealthy skin, the restitution of *kay* by identifying the cause of sickness in wrongdoings, and finally by addressing the spirits of the household, lineage or clan who share collective identity with the sick person.

Godfried Yanggus from Eagle-1 clan and his wife boiled some ginger plants in a pot and sprayed and treated their sick daughter with the aromatic mixture. As Kambianma, who was approximately six years of age, did not recover that day Godfried asked Tobias Yangi, one of the two village healers, to visit them. Late that evening Tobias entered the house. He held six or seven ginger plants with leaves. He chewed ginger with betel nut and rubbed ginger over the forehead and chest of the sick child. He made sure to spray her

under her finger- and toe-nails, and inside her ears and nose. Every orfice is a place where spirits can enter the sick person and carry the spirit from the body. While doing this Tobias inquired about any wrongs in Godfried's family and lineage. Godfried confessed that he had been to a sago forest which was not part of his clan's land. A few years ago two children had died after their father, Godfried's classificatory brother, had cut some palms in the same forest. They had decided then to leave the bush unused for five years. Tobias said that it was Godfried's mistake to cut sago palms in this forest and that this was also the reason for his own previous sickness. Tobias also commented that the Eagles had arrived in the village following others and that the village spirits were angry. But the sickness was given to both of them by the spirits of the house because he had used land which was not his. After massaging her for some ten minutes Tobias removed a stone from Kambianma's belly. Everyone chewed betel nut and Tobias was given sago pudding to eat. Kambianma went to bed and Tobias left after a couple of hours of chatting and chewing betel nut.

The focus of healing ceremony as well as ritual in general is *kay*: either its transformation or its presentation. In either case what matters is that "embodied" *kay* is not something that on simply possesses (like knowledge), but something that one *is* (Bourdieu 1990:73). So one could say that temporality of sickness is indispensable for a healer who, in many different ways, explores the patient's or their relatives' past in his search of a possible cure. Therefore temporality should not be equated with a simple duration, but should be understood in terms of its many individual and collective dimensions, such as body-time, space-time, narrative-time (each of which as a process includes tempo, rhythm, temporal strategies, and so on), to mention some of well known word compounds often used by those who wrote and still write about time. Only in understanding temporality as a multidimensional, which achieves its wholeness and integrity in an individual person and which both unites and differentiates individuals and groups, we can better understand people's experience of their existence.

As I noticed that some of the papers in this section address children I would like to look at temporality of sickness in the case of Ambonwari children. In an article entitled *Being and 'Non-Being' in Ambonwari Ritual* (Telban 1997) I argued that healers in healing ceremonies treat uninitiated children as "non-beings". From the perspective of Ambonwari "selves" or "beings", children belong to this domain. They exists as extensions of their parents or carers, from whom they cannot be separated conceptually. The wrongdoings of adults can bring sickness both on themselves and on others who share the houshold with them. In the case of children, however, the healer looks only at the wrongdoings of the parents. The healer has to "see" into the "insideness" of people, either with the help of spirits or through people's own confession. But, as Ambonwari say, children do not have "insideness" or understanding; they still lack Heart (*wambung*). Children are not conscious beings as they do not understand their actions. They do not know how to do things, they do not mourn at funerals, they eat food by themselves and do not think about its distribution. Children do things wrong all the time. Their activities are not the shared habits of Ambonwari people. Their ways of doing things are often not in accordance with the dictates of village life (*imnggan kay*, "the way of the village"). Lacking the collective and ancestral *kay,* and not being able to reflect upon them, they have no properly formed *kay* either. In other words, Ambonwari *kay* (being) is not simply given by birth, but has to be formed through the awareness of selfhood and by forcibly impressing "proper personhood" (Poole 1982:103). Selfhood, however, goes beyond consciousness. It captures "the awareness of an individual *as an individual*: as someone who can reflect on her or his experience of and position in society, of 'being oneself'" (Cohen 1994:65). In Ambonwari this means the awareness of oneself as an Ambonwari male or female who is not an extension of his or her parents anymore but a fully responsible individual. Lacking both selfhood and personhood children are not yet individual Ambonwari beings, and from this point of view, we could say, they are "non-beings" (Telban 1997).

Children who have not passed through initiation or first menstruation rituals are not yet regarded as beings in their own right. At birth and while a mother is still breastfeeding, it is the parents who observe certain prohibitions, not their children. By being conscious ("with understanding") a person can not only perform different activities but can understand them and can form, preserve and transform his or her distinctive habits. Children's "insideness", however, is not yet formed. Children's daily activities are an inseparable part of the activities of their parents. Children are extensions of their parents' beings. Even when they play, they are watched by their parents, older siblings or other relatives. Children help their parents with their daily tasks. The tasks are those of the parents and not those of the children. When playing, they often imitate the practices of adults. By learning the "ways" (*kay*) through practices children construe their understanding; to have understanding then means that they know how to do things. *Kay* and *wambung* are united in their association (Telban 1993, 1997, 1998, 1998a).

At the beginning of my paper I emphasized that it is the relationship between *kay* and *wambung* which is the most important for Ambonwari conceptualization of health and sickness. Through their processual nature they produce time as they produce themselves. Temporality of sickness in children (whose being and

understanding are not yet formed) is temporality of their parents' wrongdoings. Their parents' aberrant *kay* (wrongdoings) is visible in their children's (who are their extensions) aberrant *kay* (sickness). Only by correcting the former can te latter be restored. If only the latter is restored people do not recognize the former as the cause but say that a child was 'sick nothing'. Another question which reminds to be answered is how can someone's wrongdoing become the cause of sickness in someone else. When people live in the same household they share their practices, habits, ways of doing things. *Kay* of a husband and a wife are intertwined and controled by the spirits of the house. Their social relationships are 'embodied' ('embeinged'), that is, they are inseparable from their *kay*. *Kay* is a concept which broadens the narrow concept of 'body' to a temporal, social and cultural life-world embeded in every individual person. That is how, then, the problems in social relationships disturb *kay* and the well being of a person who belongs to the closest group of those who share the wrongdoer's *kay*. One's aberrant *kay* affects the *kay* of the other. Of course one could lie and pretend, but the spirits of the house see even the most hidden activities. And that is where their role as the regulators of relationships comes into the forefront and where the temporality of sickness recognizes most strongly not spirits as the beings of the past but the life-world in which both people and spirits dwell as consociates who share their intersubjective time.

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MEDICAL RESEARCH ON PERSONS UNABLE TO CONSENT IN THE CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: THE OVIEDO CONVENTION[1]

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The rapid development of science has opened new ways in which biology and medicine can interfere with human life and the human body. In many areas, this development is welcome, and has resulted in new possibilities to combat different diseases, prolong life expectancy, promote health, and improve the quality of life.

At the same time, however, it has opened new possibilities of producing significant harm to both individuals and society, either accidentally, when the new knowledge is applied in good faith but with harmful results, or intentionally, when it is abused for the interests or benefit of others. In both instances, human rights of individuals are violated in an inadmissible way.

The recent developments in biomedical sciences, in particular in human genetics, medically assisted procreation, organ transplantation, and in the rapidly expanding biomedical research on man in these and many other fields, have given rise to increasing public concern. It is this concern and fear of abuse of science and its achievements that prompted the Council of Europe nearly ten years ago to embark on one of its most ambitious projects ever: to produce what was initially known as the Convention on Bioethics. The task was entrusted to the Ad hoc Committee of Experts on Bioethics (CAHBI), and to its successor, the Steering Committee on Bioethics. At the beginning, the task appeared formidable, and, considering the vast, seemingly insurmountable, differences among the prevailing views and practices in the Member States, few of the experts believed that it could ever be accomplished. However, in contrast to the rather reserved expectations, the effort, which took nearly six years, finally resulted in a text which on the 4th of July 1996 was adopted by the CDBI with only 3 abstentions and a single vote against. Later it was adopted with some minor changes also by the Parliamentary Assembly and the Council of Ministers. On the 4th of April 1997 it was opened for signature to the Council of Europe Member States and other States who participated as observers, in the Spanish town of Oviedo.

The 1st of December 1999 can be considered a landmark in bioethics in Europe, when the Convention finally entered into force, after having been ratified by the first five member States of the Council of Europe (among which was also Slovenia). This unique document is the first international convention of its kind, having the status of a legally binding instrument, and is thus of eminent importance, comparable to the Convention on Human Rights. It will have far reaching consequences for the further development and protection of human rights in the context of modern medicine and biology.

The Convention represents not the smallest common denominator, but rather the highest possible common European standard for the protection of the human being in the field of biomedical sciences. It will fill a lot of the legal vacuum that still surrounds bioethics. It touches on most major ethical problems in the field of human health, except abortion and euthanasia (these two topics were excluded in the very beginning, as it was not considered possible to reach a European consensus on the extremely sensitive and controversial

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ethical questions involved). Among other things, the Convention should ensure that ethically bad medicine, e.g. ethically objectionable research, is not exported across boundaries between countries. Indeed, the Convention with its protocols will not only establish limits of ethically acceptable behaviour in science and medicine for the European countries, but will also set the rules for international cooperation in biomedical research with other countries. Inside Europe, it will be particularly important for the so-called new democracies, where bioethics often is not supported by any legislation or longstanding good practice, and is therefore particularly vulnerable to illegitimate pressure from various individuals and interest groups.

Specific ethical questions do appear in the individual branches of medicine, like oncology. However, most of the ethical problems are, at least at the principal level, shared by different medical specialties. Among these are many burning questions in biomedical research. The focus of this contribution will be on one of those, which is particularly sensitive:

Biomedical Research on Persons Unable to Consent

An important change in medicine over the last decades is the increasing recognition of patient's right to autonomy. Informed consent to any medical intervention or procedure, including even the use of personal medical data, is at the heart of an ethically sound relationship between the doctor and the patient. A special kind of relationship develops when a patient or a healthy persons is recruited to serve as a subject in biomedical research. Respect for the rights and dignity of human beings involved represents the most important limitation to freedom of research in biomedicine. It may be of interest to briefly refer to some of the landmarks in ethical thought regarding involvement of persons unable to consent.

The Weimar law on medical research, the Code of Nuremberg and the Helsinki Declaration

In Germany, research on children and persons unable to consent was prohibited as early as 1900. Germany, under the Weimar republic, was also the first country in the world to legislate on ethical rules in medical research. The law of 1931 required consent of the "research subject" and prohibited research on minors as well as dying persons and persons with no capacity of understanding. Unfortunately, already during the first few of the tragic 12 years that followed the coming of the National Socialist Party to power, the noble ethical tradition was pushed aside and many German physicians gradually stepped on a path leading towards the darkest period of medical "science without a conscience" (Rogers and Durand de Bousingen, 1995).

The Nuremberg Code of 1947, the first international code on biomedical research on man, permitted no experimentation on human subjects without their "voluntary consent". Thus it effectively ruled out any research on minors, mentally handicapped or unconscious patients. Although the code with its ten basic principles laid down the basis of modern ethical attitude in medical research, it has never gained wide acceptance and has certainly not been much observed in practice. Nevertheless, many still agree with its first principle, i.e. that research on persons unable to give a valid, free and informed consent should be prohibited.

The Declaration of Helsinki (Recommendations guiding physicians in biomedical research involving human subjects) with its four amended editions (World Medical Association, 1964-1996) has actually set the modern ethical standards for biomedical research on man. Perhaps the most important principle in the Declaration is that "in research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject".

In contrast to the Nuremberg code, the Declaration of Helsinki permits research on persons who are unable to consent for reasons of legal incompetence and physical or mental incapacity. In such cases, the informed consent is replaced by permission or authorisation from responsible relative or guardian.

The Oviedo Convention and the Additional Protocol on Biomedical Research

The latest international set of ethical standards is the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine, also known as the Convention on Human Rights and Biomedicine, or the Oviedo Convention (Council of Europe, 1997). Biomedical research is one of the areas covered in this document, which has an unprecedented status of a legally binding set of ethical rules, to be imposed and sanctioned by the internal law of the States who ratify the Convention.

In the Oviedo Convention, the category of therapeutic research of the Helsinki Declaration is replaced by the concept of research that has the potential of producing real and significant benefit to the patient in-

volved, as opposed to research which does not have that potential, and the Convention enshrines stricter protective provisions in case of the latter.

Research on man is associated with a basic ethical dilemma: Is it right to subject a patient incapable of consent to research from which he or she cannot benefit, for the sake of benefit of others?

In the view of the crimes committed in the Nazi concentration camps, it is not surprising that the greatest sensitivity to any impingement upon human rights and dignity of this kind nowadays exists in Germany. Germany's greatest concern regarding the Oviedo Convention was precisely the ethical doubt that research on persons unable to consent and not benefiting from it can ever be considered justified. In fact, this may be the main reason why Germany hesitates to sign the Convention.

At one stage during drafting the Convention, the opinion prevailed that when no direct benefit for health of the person involved can be expected, research on persons unable to consent should not be allowed, unless the risk incurred is negligible. If such prohibition were enforced, this would put an end to much of the presently permissible research in paediatrics and in psychiatry. Children and psychiatric patients as groups would be deprived of many important advances in the diagnosis and treatment of serious diseases. In fact, ban on research involving anything in excess of negligible risk to such persons would in itself be unethical. It would render meaningful research, for example, in paediatric oncology, on Alzheimer's or on Creutzfeld-Jacob's disease close to impossible. Research that has lead to successful treatment of childhood leukaemia in over 75 % of the cases would have been prohibited. In the light of this deliberation, the notion of negligible risk was replaced by that of minimal risk.

The Oviedo Convention is to be supplemented with more detailed texts expanding on its basic provisions. One of those is the Protocol on Biomedical Research (Council of Europe, 2000). The Protocol, which is presently in the final drafting stage, will be a comprehensive, self-contained, legally binding set of rules, which is expected, in the years to come, to guide researchers in most European and possibly other countries.

The Protocol further elaborates the principles of the Convention. One of these is that the risk and burden imposed should never be disproportionate to the expected benefit of the research. This general rule naturally also applies to situations where the person involved cannot benefit. However, it is emphasised that, in case of research on persons unable to consent, the acceptability of the risk and burden involved should never be weighed against the benefit for others. Furthermore, research on such persons is only allowed if research of comparable effectiveness cannot be carried out on persons capable of giving consent.

Another important principle is that research on a person without the capacity to consent may only be undertaken if he or she does not object. Furthermore, as has been said above, both the risk and the burden to which a person unable to consent may be exposed, may only be minimal. The notion of minimal risk, as defined in the Protocol, means that the intervention will be associated, in individual case, with very slightly detrimental and only temporary effects on the health of the person concerned. Examples serving for an orientation as to what the acceptable minimal risk might include the taking of an additional X-ray or MRI image, or drawing of a small sample of venous blood. A minimal burden produced by the intervention would be the equivalent of a temporary and very slight symptom or unpleasantness, such as caused by an electrical stimulus while performing a nerve conduction study. Where appropriate, persons enjoying special confidence being a close relation of the person concerned shall be called in to evaluate the burden.

Additional rules apply in emergency situations where consent or authorisation cannot be obtained. Whenever possible, the relatives of the patient or persons close to them shall be consulted, or other reasonable steps taken in order to ascertain the wishes of the patient. If there are indications that the patient would object, the research shall not be undertaken. The patient shall be informed, when it becomes possible, of his or her participation in the research, and consent for its continuation should be sought.

Conclusion

All ethical questions and dilemmas concerning the protection of persons without the capacity to consent have not yet been settled. It is probably unrealistic to expect an international consensus that would please everyone. It is also unlikely that a legal document alone can provide a guidance suitably covering all possible situations. It is encouraging to see that the various documents containing ethical guidelines as official policies or legal instruments, both those in current use and those still under development, are increasingly comprehensive and show remarkable convergence. A lot, however, still needs to be done. Great emphasis should be given to adequate teaching and training medical students and doctors and nurture their sensitivity to the needs, rights and dignity of both sick and healthy persons under their care. A practice guideline

should be developed on how to obtain valid informed consent, and particularly, authorisation in case of persons unable to consent. Finally, independent ethics committees reviewing and supervising medical research should most carefully ponder on what represents limits of acceptable risk and burden to which persons unable to consent may be exposed in any individual research study. It is their responsibility to always keep in mind the basic guideline in both the Declaration of Helsinki and the Oviedo Convention protecting such persons: The interest of society or science should never take precedence over interests and welfare of the human being involved. Ensuring a proper balance between the one and the other may be a most difficult task and responsibility.

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IMPLICATIONS OF EVIDENCE-BASED MEDICINE FOR THE METHODOLOGY AND ETHICS OF RANDOMISED CLINICAL TRIALS

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ABSTRACT

Evidence-based medicine may influence our approach to clinical trials. When preparing a systematic review, the quality of individual trials is of far greater importance than their individual results. Unbiased randomisation, attention to the treatment protocol and to the rules of good clinical practice and honest evaluation of experience are essential; less important are the power of an individual trial and statistically significant difference between the treatment arms. The recruitment period should be short and preferably not longer than three years, followed by timely publication of a report. Since systematic reviews and meta-analyses include and quote all available information, clinical researchers and editors should be less influenced by publication bias. These changes in methodology open clinical trials to new innovative ideas difficult to test in large multi-institutional trials, rend clinical investigators less dependent on commercial sponsors and might bring more patients into clinical research. Greater respect of the autonomy of individual physicians and less interference with the uncertainty principle could contribute to reduced ethical costs.

Key words: evidence-based medicine, ethics, controlled clinical trials

1. Introduction

In resolving dilemmas about the most appropriate diagnostic or therapeutic procedures, evidence-based medicine now occupies centre stage. Instead of relying on experience from individual trials or on narrative reviews with unclear methodology [1-3], evidence-based medicine seeks support from systematic reviews or from meta-analyses. Recommendations based on all available published and unpublished information will have a strong influence on our clinical practice.

Evidence-based medicine may change the role of individual randomised clinical trials. Whether a difference between the treatment arms is statistically significant or not, experience from any single study will be included in a systematic review or in meta-analysis and compared to other similar trials. Contribution of an individual study to new knowledge therefore depends more on a clear question and an appropriate approach to answer the dilemma, rather than on the power of the trial or on significant difference between the treatment arms. Such a shift in attention has important implications for the methodology of clinical research and also for the related ethical dilemmas.

I will start with a critical presentation of the current practice of randomised clinical trials. In an admittedly personal discussion, some weak points of the current practice will be presented. I will then offer some ideas where a change in methodology could lead to quicker generation of new knowledge and to lower ethical costs.

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2. A critical look at the practice of randomised clinical trials

2.1. LARGE MULTI-INSTITUTIONAL TRIALS

There is no doubt that randomised clinical trials bring important new knowledge into our daily practice of medicine. Hundreds of oncology cooperative groups worldwide are invaluable in the implementation of guidelines for good clinical practice and research and in promoting collaboration at individual and institutional levels. In this way, randomised clinical trials enrol patients who would not participate in research if left to the experience and initiatives of their physicians, hospitals or institutions. Thus, the current practice of wide collaboration alleviates the problem of insufficient participation of patients in clinical research.

We therefore need randomised clinical trials, we need oncology cooperative groups and we need large trials that only such groups can organise. However, we also need to recognise the limitations of performing research within such relatively cumbersome bodies. Since several hundred to a few thousand patients are needed for a definitive answer, adequate recruitment is the main problem of all concerned with the planning and conducting of a trial. Multi-institutional collaboration or cooperative groups are a logical response.

The three weak aspects of large cooperative trials are: 1) the smallest common denominator as the basis for formulating the scientific question; 2) statistics as the main factor for determining trial methodology, rather than a tool to analyse the results; and 3) the increasing dependence of large cooperative groups on commercial sponsors.

2.1.1. The scientific question

The scientific question is not: "What is the most promising new approach which we wish to compare against the standard treatment?" Rather, the question for those planning a trial is: "What kind of a trial would be acceptable for our group, could recruit a sufficient number of patients and would be interesting for sponsors?" Due to the policy of seeking the smallest common denominator among members of a group, important controversial issues or new provocative ideas are often avoided. The central idea is not the innovative potential of a trial but feasibility: in order to recruit a sufficient number of patients, a trial has to be acceptable for patients, clinicians and sponsors.

2.1.2. Statistical considerations

From the very beginning, a plan for a randomised clinical trial is governed by the need to recruit a sufficient number of patients. The investigators are required to specify the magnitude of the treatment effect with the related statistical significance and power of the study. The number of patients to satisfy these requirements is then determined. The role of statistics is therefore turned upside-down: instead of being a tool for analysis of the results, statistical considerations determine design of a trial. Eligibility criteria become inappropriately broad, pooling together heterogeneous groups of patients. Dilution of results is inevitable if the same treatment approach, or the same dilemma is applied to a heterogeneous population of patients.

Statistical considerations according to which only large trials are justified may be also the main reason for the virtual absence of controlled clinical trials for a number of relatively rare tumours or rare clinical conditions.

2.1.3. Dependence on commercial sponsors

Coordination of a multi-institutional randomised trial is a demanding task. Preparations for a trial, quality assurance and monitoring during the period of actual recruitment of patients together with the collection and analysis of data require expertise and considerable financial support. An increasing proportion of multi-centric trials depend on support from commercial sponsors. It is clear that sponsors influence the formulation of the scientific question addressed by a trial. The other negative influence of commercial sponsorship is seen when experience from a trial is analysed for publication. On one hand, companies have a clear interest for publishing positive experience in eminent journals; on the other hand, they have been found to suppress publication of negative experience [4]. Thus, commercial interests contribute towards publication bias.

2.2. SINGLE-INSTITUTION TRIALS

The advantages of single-institution trials are a relatively short time from design of a trial to its activation and the ability to test innovative ideas. While we need this type of pioneering research, we have to recognise its weak points.

The weak aspects of single-institution trials are: 1) their size; 2) vulnerability to systematic biases in patient registration, randomisation, eligibility for analysis and assessment of response; and 3) publication bias.

2.2.1. Trial size

Single-institution trials are usually small, enrolling from a few dozen to a few hundred patients. Due to their low power and to the publication bias favouring publication of positive small trials, calculation of confidence intervals and of statistical significance, they are of limited value. Each such trial by itself cannot prove anything; rather, it can show direction for further research and for confirmatory studies.

2.2.2. Systematic biases

In clinical research with little support in logistics and financing, the roles of the principal investigator, of the physician responsible for patient care and of the person responsible for registration and randomisation of patients often overlap. In such a situation, some investigators may succumb to a temptation to tailor the results by inappropriate randomisation procedure, by exclusion of some patients from analysis or by biased interpretation of the main outcome. This introduces a systematic bias and renders all experience misleading or useless.

2.2.3. Publication bias

There is no doubt about a bias against the publication of low-power negative trials, with shared responsibility of editors, reviewers and investigators [5-7]. Since most editors and reviewers share conventional views about the methodology of randomised clinical trials, the low power of such trials is a common reason for rejection of a manuscript. An additional responsibility for publication bias lies with the authors who have less interest in preparing a report if the results do not support the hypothesis [8].

3. Evidence-based medicine and the methodology of randomised clinical trials

While evidence-based medicine will continue to depend upon experience from large randomised trials, it can extract new knowledge also from small trials. The key to the value of information is the quality of research; the power of an individual trial is of lesser importance. I will list some practical ideas on the formulation of the scientific question and on the methodology of small randomised clinical trials.

3.1. THE SCIENTIFIC QUESTION

We will here discuss two issues. First, whether a trial should always simply follow the conventional pattern of changing a single parameter, or whether different treatment strategies could be also compared. Second, we will argue for phase II randomised clinical trials.

3.1.1. What to compare: a single difference or different strategies

Most randomised clinical trials compare two treatments that differ in a single parameter. However, due to the overlapping toxicity of anti-cancer treatments and to the fact that many optimal standard treatments are already at the edge of tolerance, it is rare that one could simply add another therapy to the best standard treatment. As an example, adding concurrent chemotherapy to radical radiotherapy with optimal fractionation and total dose is most likely to lead to excessive toxicity. Such a trial is often feasible only if patients in the standard treatment arm are under-treated. Therefore, what is actually compared is combined modality treatment against sub-optimal standard treatment. As an example, a trial comparing radical radiotherapy versus radiotherapy plus a radiosensitiser may be designed in two ways:

1. Standard radiotherapy alone vs. radiotherapy with the same fractionation and total dose and the addition of a radiosensitiser. In this case, patients in the standard-treatment arm will probably be under-treated. Such a trial may show that a radiosensitiser has an effect. However, it cannot prove that addition of a radiosensitiser is advantageous to optimal radiotherapy alone.
2. Radiotherapy in the optimal standard way vs. radiotherapy with a radiosensitiser and a modification of fractionation and of the total dose, aiming at approximately equal level of toxicity. Since more than one parameter has changed, experience from such a trial is open to interpretation. However, such a trial can prove that the new strategy as a whole did, or did not influence the main outcome.

The first approach offers a clear answer to a relatively narrow question; the second one may indicate a new promising avenue of treatment.

3.1.2. Randomised phase II trials

Phase II clinical trials usually serve as a basis for a randomised phase III trial. Phase II trials give an indication about the activity of a treatment for a certain clinical condition but are weak in providing quantitative information about the treatment effect. Due to the selection of patients, the results are virtually incomparable to any experience outside a particular trial. For the same reason, the new knowledge is of limited usefulness for evidence-based medicine.

When performing a phase II trial, the clinical investigator is often not under a pressure of the need for large recruitment. Quite commonly, the limitations of recruitment are more linked to logistics (such as the number of patients who can be offered twice-daily irradiation in a busy radiotherapy department) than to the number of patients who fulfil the eligibility criteria. In such a case, a randomised phase II trial may be an answer. As an example, 50 patients may be recruited to the new treatment and another 50 to the standard one within a period of 2 years. Although the power of such a study is low, it can be a valuable piece in meta-analysis and will contribute much more than a pure phase II trial reporting only the experience on 50 selected patients given the new treatment.

3.2. METHODOLOGY

3.2.1. Organisation of a trial

In comparison with large multicentric trials, small randomised trials are certainly easier to manage. Even if these trials may run without additional staff or financial support, the following steps are essential for preserving the scientific and ethical integrity of the research.

1. The protocol with presentation of the clinical problem, hypothesis, primary and secondary objectives of the trial, eligibility and ineligibility criteria, methods of treatment and follow-up should be both reviewed by an expert not involved in the research and approved by the Institutional Protocol Review Board and Ethical Committee.
2. Information for patients and informed consent forms should be prepared.
3. For most trials without substantial financial support, on-site external monitoring for quality control of research is not feasible. Still, some degree of external monitoring is highly recommended. Registration of patients for a trial and their randomisation should be done by an institution separate from the principal investigator's department. This external institution would later review the raw research data and issue a confirmatory statement that all patients registered and randomised for the trial are really reported. The costs for such a procedure should not be prohibitive and might be covered by an international anti-cancer organisation or by an oncology journal(s) publisher. External monitoring would diminish the risk of systematic bias in performing and reporting of clinical research.

3.2.2. Recruitment of patients

Once a trial is activated, it should remain open for new patients for a short period only. For trials in oncology, we recently proposed to limit the recruitment to three years [9]. This figure is based on the fact that one to two years usually elapse from the first draft of the protocol to its practical implementation; that due to new knowledge, five years seems to be the upper limit for the best standard treatment to remain unchanged; that over a longer period, substantial changes in diagnostics and staging, in detecting a relapse, and in supportive care introduce a bias for interpretation of the results; that conducting a trial over many years becomes difficult due to the diminishing interests of all participants and due to their mobility; and that ethical difficulties arise when interim results become available while the trial is still open for recruitment of new patients.

This proposal of three years as the upper limit for the recruitment of patients is clearly arbitrary. For some rare tumours and for those characterised by a prolonged clinical course, four or five years might well be acceptable. However, it is important that the plan for a trial includes a clear time frame for the recruitment of patients.

3.2.3. Presentation of results

The honest and timely preparation of a report according to the CONSORT guidelines [10] will contribute to a positive balance between the ethical benefits and costs of clinical research. When comparing treatments, point estimates with the appropriate confidence interval are preferred to testing for significance and p values.

Authors, editors and reviewers should understand that any individual small randomised trial cannot provide a definitive answer to the question addressed. The discussion section of the paper should be kept short and avoid far-reaching conclusions. With these limitations, publication of experience from small trials is justified.

4. Ethical considerations

The rationale for small randomised trials not aiming at a definitive, statistically significant answer for a particular clinical problem has been presented. From an ethical standpoint, a number of differences to the standard large multi-institutional trials can be seen.

First and above all, small trials are much more flexible in testing hypotheses for which a consensus within a large cooperative group would be difficult to achieve. Greater physicians' autonomy means that more ideas will be tested and, hopefully, new treatment approaches will be identified.

Clinical investigators and physicians in small independent clinical trials may be less influenced by commercial sponsors. Independent academic research could be a practical response to a series of systematic biases linked to the commercial sponsoring of medical research: a bias in formulating scientific questions, in trial design, in reporting results, in promotion of publications and in influencing the dominant topics of medical conferences.

Allowing greater physicians' autonomy is a net ethical benefit, provided it is not accompanied by other ethical costs. In small clinical trials, the over-lapping roles of the principal investigator and of the physician responsible for patient care may lead to sub-standard procedures of patient's consent. Regardless of the size of a trial, patients involved in clinical research should be given adequate information and should freely consent to participate. To protect the scientific and ethical integrity of the trial and prevent a systematic bias in the procedures of registration and randomisation, external monitoring is recommended.

One of the ethical concerns linked to large randomised trials is that interim results are not available to the participating physicians and to patients invited to join the trial. To include a large number of patients, the recruitment period is often long. In my view, patients have the right to base their decision on all available information, here including the information on what happened to previous patients in the same trial; depriving them (and their physicians) of this information is non-respecting of their autonomy. Small trials with a short recruitment - three years according to my arbitrary proposal - will be less susceptible to this ethical problem.

Finally, recognition of the value of small randomised clinical trials for evidence-based medicine means that it is the quality of research, rather than the size of a trial which is important for its inclusion in meta-analyses and systematic reviews. As virtually all published reports are cited, editors who strive to improve the journal's citation index will be less inclined to reject publication of a trial on the basis of its low power. This will alleviate the problem of publication bias.

5. Conclusions

Evidence-based medicine seeks information from all sources. Large trials will continue to be an important and reliable way of addressing common and relatively simple questions. However, we also need alternative, more flexible approaches. When properly conducted and monitored, small clinical trials can give a valuable clue to questions of greater originality. By combining experience from several similar small trials, evidence-based medicine can identify strategies worthy of further research.

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Communicatin with the Patient in Clinical Research

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INTRODUCTION

A discussion of communication with the patient in clinical research is often reduced to the practice and contents of informed consent. This is an unbearable oversimplification. There is no way to separate such a discussion from a more general discussion on the relations between a doctor and a patient. The patient in clinical research is still, and first of all, a patient. Similarly, a commitment to clinical research should not influence the physician's primary role as a physician. As far as their communication is concerned, the fact that the physician is proposing a clinical trial should not influence his relation to the patient. A discussion of communication in clinical research is therefore just one chapter of a general discussion of communication between physician and patient.

Starting any treatment is technically possible without much explanation. The danger of treating an uninformed patient can be compared to that of administering chemotherapy without checking blood counts and providing adequate support measures. Instead of tailoring the treatment to the individual, average tolerance is presumed, and average doses of drugs are given. The result may be a suboptimal effect on the tumor; in addition, unforeseen complications may arise that further intervention cannot alleviate. The same is true for the treatment of an uninformed patient: after a while, both doctor and patient may realize that the results of the treatment are different from what was anticipated and may find their relationship blocked in an atmosphere of mistrust.

The dangers and shortsightedness of concealing the proper information during routine treatment increases to become an unsurmountable obstacle when clinical research is concerned. Few of us doubt the benefits of clinical research not only for future patients but also for the actual patient enrolled in an exactly specified prospective trial and thence subjected to most rigorous quality assurance and control.[1] Nevertheless, the potential benefits of clinical research do not justify manipulating the patient for the purpose of obtaining his or her consent: no patient should ever enter a prospective trial without clear, thorough information, first on the disease and its implications, and then on the proposed research trial. Without much exaggeration, the practice of not informing the patient in a

trial about the diagnosis, and thence about the purpose, logic, and potential consequences of the procedures to which he or she is to be exposed, may easily be compared to experiments on laboratory animals, or to the sad experience with human experimentation in the not-too-distant past.[2,3]

After such a clear position regarding the necessity that a patient in clinical research be fully informed, what issues remain to be discussed? I have deliberately omitted some of the more frequently discussed questions on the ethics of clinical research or on the individual physician's preference versus collective equipoise[4,5] and have instead devoted more attention to those questions that profoundly influence communication. We will present the stage first, then the actors, and finally the play itself. The first section therefore presents the three phases of trials in clinical oncology, with special consideration of the issues of importance for the communication process. The second section presents the pressing dilemmas that the physician and the patient face when confronted with a research protocol. In the last section, an attempt will be made to describe the form and content of the communication process itself.

THE STAGE: THREE PHASES OF CLINICAL RESEARCH IN ONCOLOGY

Phase I Trials

A key moment when introducing a novel drug into clinical use is its very first application to humans. This is a phase I trial, which aims at establishing the pharmacokinetic parameters of the drug, its main side effects, safe dose range, and an acceptable—though not yet necessarily optimal—application schedule.

For most drugs, the research subjects in a phase I trial are healthy volunteers. The initial doses of the drug are only a percentage of the effective dose,[6] as predicted on the basis of animal testing. If no untoward side effects are noted, the dose is then gradually increased. However, anticancer drugs are invariably linked to severe acute side effects and potential late consequences such as carcinogenicity and organ dysfunction, and so research subjects in phase I trials of anticancer drugs are not healthy volunteers but patients with cancer that is not amenable to standard curative treatment.

If noted, an antitumor effect is recorded, but this is not among the main objectives of a phase I trial. Due to uncertain effectiveness of the drug, and especially due to the dose escalation schedule, which starts with extremely small doses, an objective tumor response is seen in less than 5% of patients in a phase I trial.[7,8] The subjects in a phase I trial appear to be used not for their own benefit, but predominantly for the

benefit of medical knowledge and of other, future patients; phase I trials may thus be regarded as ethically the most problematic type of clinical research in oncology.[9]

Phase II Trials

The aim of phase II trials is to identify tumor types for which the treatment appears promising. A phase II trial usually enrolls patients with a measurable tumor and in fair general condition for whom no effective anticancer treatment is known. The new drug is first tested as a single-agent therapy and later, if it is considered at least moderately effective, in combinations with other effective drugs.

Phase III Trials

After an innovative treatment has been tested in a phase II trial, a comparison with the best standard treatment is needed. To minimize the risk of a bias, random choice of the treatments to be compared is the rule for phase III trials.

The ethical issues linked to clinical trials with a random choice of treatment have not yet been resolved. For some, randomized phase III trials are a proof that clinical research—previously often a mixture of observations, unproved postulates, and wishful thinking—has become a true science. Other authors have expressed deep concern regarding this particular type of clinical research.[2,10] Utilitarian arguments about important past or future advances in medical knowledge as a contribution of randomized trials do not justify manipulating the individual patient with regard to his or her true interests and consent—a topic that will be discussed later. In addition, proper attention to the physician's personal preferences seem justified, and the methodology of other types of clinical research should also be further developed.[10,11]

THE ACTORS: THE PHYSICIAN AND THE PATIENT

Dilemmas of the Physician

Am I Primarily a Physician, or a Researcher?

Although it is frequently discussed,[11,12] this dilemma seems to me somehow artificial. After the physician has come to the end of questions about his readiness and competence to participate in the trial, and about

the appropriateness of inviting the particular patient into the trial, then he clearly has to accept both roles simultaneously. It would be bad science if coercion were used in order to rigidly follow the research protocol, with little respect for the patient's interests: the reader of such a report would underestimate the side effects of the treatment that is being advocated. It is in the interest of the physician and of the researcher—of the medical profession and of medical science—to produce a sincere report, including the difficulties in following the predetermined research protocol.

A good clinical investigator should always also be an excellent physician. Clinical competence and devotion to the physical and emotional needs of a patient, honest sharing of experiences with colleagues, and seeking their advice when needed are among those personal characteristics that are equally essential for the performance of good medical practice and of medical research.

Every rule has its exceptions. Our opinion that the physician and the clinical investigator should best be one and the same person is easy to defend for phase I and phase II trials, which represent the majority of clinical research; however, in some randomized trials, splitting the roles of the clinical investigator and the physician participating in the trial may be warranted. For statistical reasons, randomized trials will frequently enroll several hundred or even several thousand patients. When dealing with a trial of such dimensions, the organizational and statistical tasks become very complex and demand specific skills and experience that most physicians do not possess. The other reason for separating their roles is the physicians' preference for one of the treatment options. It is desirable that a randomized trial address an important dilemma; yet, in such instances, many physicians will have a clear preference for one treatment option or the other. In such a situation, splitting the roles of the clinical investigator and the physician participating in the trial may, indeed, be desirable: after full informed consent and after randomization, the patient would be treated by the physician with a preference for that particular treatment option. Not only would the technical performance of the treatment be higher, but also communication with the patient would be much easier if a physician who believes in adjuvant chemotherapy for non–small-cell lung cancer treats patients with chemotherapy, and a nonbeliever just gives good supportive treatment.

Yes or No for Participation in a Trial

When a research protocol is being prepared and circulated among potential collaborators, the really important question is whether to join a research group and promise to encourage patients to enter a specific trial. This question should not be reduced to just the scientific validity of the question formulated in the protocol, to the physician's competence and

technical experience with the proposed treatments, or to a feeling of a strong personal preference for one of the treatment options—questions that are beyond the scope of the present discussion and that have been extensively discussed.[13,14] If the answers to all these questions go in favor of joining the trial, further questions arise, and these further questions are linked to communication with the patient.

Unfortunately, it seems that the doctor's decision to join a research team is often taken very lightly. As a consequence, many, if not the majority, of trial protocols overestimate by far the expected dynamics of patient accrual. Of more than 1300 active clinical trials for cancer listed with the Physician Data Query service at the National Cancer Institute, it is most likely that the majority may never accumulate enough patients to allow a meaningful interpretation of the results and reach publication.[1].

The physician should know that a decision to participate in a trial means considerable additional time for explaining to the patients the purpose of the trial with appropriate and comprehendible explanations of the technical details, the expected outcome(s), and the alternatives. Although leaflets prepared in advance can be helpful, no written word can replace personal, customized, repeated explanation—and that is very time-consuming.

I have no experience in programs specifically designed to improve communication skills for the medical profession. However, two decades of observing my colleagues and their behavior with patients permits me to conclude that some physicians are simply unable to respond to the basic requirements for proper communication with a patient in a clinical trial. The ability to adjust to the level of understanding of each particular patient, the ability to present the current dilemmas and the need for continuous research, a proper balance between the two unacceptable extremes—coercion on one side and "it is totally your choice" on the other—accessibility for and patience with the patient's frequent additional questions, and compassion are among those personal characteristics that everyone discussing a trial with a patient should possess. Whether in research or not, the patient depends on the physician and cannot be considered as absolutely autonomous;[16] thence, he needs not only information but also help and friendly advice.

To Propose or Not Propose Entry into a Trial to a Particular Patient

The criteria for eligibility of the patient for a trial include parameters such as age, diagnosis and stage of the disease, performance status, or kidney function. After these criteria are met and after a thorough general discussion of the disease and its perspectives with the patient, the physician should realistically assess whether the particular patient will be able to understand the dilemmas that are to be resolved by the trial, together

with his own role in medical research. It is neither a favor to the patient nor a pleasant task for the physician to start a lengthy, embarrassing, and possibly even hostile discussion if the chances for a relatively smooth resolution of these questions are slim. An experienced physician will anticipate such an outcome and will not start a discussion about a trial, but rather propose the best available standard treatment. Therefore, not only the criteria of eligibility listed previously, but also the physician's assessment of the patient's capacity to accept his role in medical research should be considered before the proposal is formally presented to the patient and his consent is granted or refused.

Dilemmas of the Patient

For the purpose of this discussion, we will suppose that the patient has been properly informed about the diagnosis, natural history of the disease, and perspectives of the best available standard treatment. As we said above, no sincere discussion about the patient's participation in a clinical trial may start before these basic questions have been approached. Still, the scenario of the communication between doctor and patient is never written in advance: the patient will often come back to questions already discussed and seemingly resolved long ago—another reminder of the shortsightedness of the practice of concealing the truth.

Am I a Patient or a Research Subject?

This question is rarely clearly formulated, yet it lies behind the patient's dilemmas and hesitation in consenting to enter a trial. However altruistic some patients may be and no matter how they respect medical science and the need for clear and scientifically valid answers to the dilemmas of modern medicine, the patient is always still the patient, with his or her unique individuality and interests. The patient then may be expected to consent to a trial only if he is convinced that this offers him better chances, or at least no worse a chance than choosing one of the standard treatment options.

THE PROCESS OF COMMUNICATION

Thornton wrote that after the operation on her breast, she received a text prepared to explain her diagnosis, together with an invitation to enter a randomized trial of postoperative radiotherapy.[17] This report best illus

trates what the communication process with the patient should not look like. Communication is a bidirectional process, is continuous rather than once-and-for-all, and is based primarily on personal contact.

A message concerning a description of a health problem and the options for its management is never a simple process. The more complicated the problem is, the greater is the need for building close relations based on mutual respect and confidence. After the initial, introductory discussion, the patient will certainly need additional explanations and will try to adapt the information to his personal understanding of the role that a disease, with its consequences, may play in his life.

The patient's dilemmas will occasionally culminate in a crisis of adaptation to his or her changing position in relation to the social environment, and in relation to his or her ideal self-image. The physician should help the patient understand and overcome this often predictable, yet always unique, episodes.

All that has been said so far on the process of communication applies to an even greater extent to a patient in research. Apart from his normal demands as a patient, he has accepted participation in a clinical trial, with all the additional dilemmas that that may involve. It is more than just, then, that the patient in clinical research is treated as a partner to the medical profession. The practical implications of such a statement will be presented in the next section, in particular when discussing the patient's right to be informed about preliminary results of a study in which he is invited to participate.

Informed Consent

According to McKenna,[18] the elements of informed consent include:

- Adequate information about risks and benefits;
- An on-going process of communication between the doctor and the patient, rather than a one-time event;
- Comprehension by the patient of detailed explanations provided in appropriate language and reading level;
- Voluntary and uncoerced consent;
- Adequate documentation of the process used to obtain consent.

The process of informed consent should not only be specified in a research protocol, but should also be adhered to in clinical practice. A marked divergence between the declared policy and its practical implementation, as revealed in our recent study,[19] is a reason for serious concern and deserves more attention.

Oral or Written Information

Talking with the patient has always been the basis of our communication, and should remain so. Nothing can replace the physician's duty to repeatedly discuss with the patient the current knowledge about his or her disease, and future treatment options. A conversation can be only supplemented, never replaced, by written information such as leaflets describing a specific situation. I strongly believe that this is true not only for a patient in routine clinical practice, but also for a patient in clinical research: he also has the right to, and the need for, a caring physician with whom he can share his doubts, his fears, and his hopes.

It seems, then, that the difference between oral and written communication is somehow artificial. While some differences between the patient in clinical practice and the patient in research cannot be denied, the basic process of informing the patient and of obtaining his consent is very similar.[20] Fair, open, repeated conversation with the patient is always the basis of our communication. Written information, which is becoming indispensable in clinical research, is the supplement to oral communication.

The Patient's Signature

Should the patient sign his approval to enter a prospective clinical trial? Before we answer this question, two circumstances need to be mentioned. The first is that the consent always includes a statement that at any time the patient may withdraw from the trial. The second is that the responsibility for all elements of clinical research, from planning a trial to its practical implementation, always remains with the physician. In a randomized trial, it is the personal responsibility of the principal researcher that the trial really compare treatment options considered optimal for the entire time, until the last patient enters the trial. In the same way, it is also the personal responsibility of each participating physician that the treatment be delivered according to the highest standards of quality of patient care. Even if the patient lends his signature, he will never share the responsibility for the trial with the principal investigator or with his physician.

All this implies that signing a consent form is not to be compared to signing a contract between equal parties. The need for the patient's signature depends on cultural and legal circumstances, which may vary considerably from one country to another, and indeed even within the same community when patients with quite different educational and spiritual backgrounds are involved. The meaning of the signature can be only that he or she was informed about the research and does not disagree to participate in it. Never can the patient's signature be used against him or her

and interpreted as the patient's sharing the responsibility for eventual untoward events.

Detailed or Basic Information?

Should the written information really include a terrifying list of potential complications? My personal opinion is that the information should include all complications that are normally expected, but not those seen only exceptionally. Whatever happens, the legal and moral responsibility remains with the physician. If a consent form is more than one page of simple text and if it includes a lot of medical terminology, then it has been written for the protection not of the patient, but of the doctor or the sponsor of the research.

The Meaning of Words

We said that the researcher should do his best to prepare a text comprehensible to a lay person. In spite of all efforts, however, there may be a great gap between the understanding of the words, and the actual experience. No words can bring the experience of a disease to a healthy person. Likewise, a patient may not fully understand the real meaning of "febrile neutropenia." There is no remedy to this inadequate capacity of words, other than our responsibility to propose trials of true scientific value and to provide continuous psychological support to our patients, regardless of whether they do or do not participate in research.

Specific Aspects of Phase I, Phase II, and Phase III Trials

Phase I Trials

At first glance, there seems to be no conflict of interest between a clinical researcher and a patient consenting to participate in a phase I trial of a novel anticancer drug. After a thorough, compassionate presentation of their situation, patients with advanced cancer will usually consent to be included in the trial of a new drug: for most patients, uncertainty and hope linked to the new drug is preferable to the definitively grim prognosis that may be offered by supportive treatment alone. However, it is precisely this line of reasoning of a patient with advanced cancer that may offer an opportunity to manipulate the patient in order to obtain his consent: patients included in phase I trials rarely realize that the main objective of the trial is not to test the efficacy of the new drug, but to study its pharmacokinetics, preferred application schedule, and toxicity.[21] Consent

to participate in a phase I trial and to all the associated additional investigations, frequent visits to the clinic, and eventual side effects often stems from false hopes that the patient has a chance for a positive response—when this chance is really less than five percent.

It seems that a phase I trial would be much more acceptable to patients if the dose escalation schedule would permit a quicker, albeit admittedly more risky, testing of the drug in its anticipated effective dose range. When a patient consents to the trial, he should have some chance of winning. This would allow the clinical investigator to communicate with the patient with open cards, instead of hiding his real objective of testing the pharmacology and toxicity of the drug behind an unrealistic promise of therapeutic improvement.

Phase II Trials

From the ethical point of view, phase II trials are the least problematic type of clinical research in oncology. The interests of the researcher are very close to those of a well-informed, consenting patient.

Randomized Phase III Trials

Inherent in the performance of phase III trials are conflicting interests, possibilities for manipulation of patients' consent, and pressures for distortion of physicians' ethical principles.

From the patient's perspective, randomized clinical trials can be grouped under three categories:

- Trials comparing two treatments of approximately equal anticipated effectiveness and similar comorbidity. Numerous trials comparing different chemotherapy regimens fall into this category.
- Trials comparing radical treatment with a more conservative approach, stemming from a hypothesis that the less aggressive treatment is not less effective. Trials of radical versus organ-preserving surgery, of routine postoperative radiotherapy versus surgery alone, or of long-term adjuvant chemotherapy versus short-term perioperative chemotherapy may be mentioned in this category of randomized trials.
- Trials comparing the standard treatment of known low potential to influence the downhill course of the disease against an innovative treatment.

The patient should have relatively few problems in consenting to a trial of the first type. The patient's dilemmas with trials of the second and

third types stem from their misunderstanding of the difference between a hypothesis and the real role of a particular treatment that is still to be established.[22] Furthermore, patients also have their preferences regarding choice of treatment. The patients' preferences may be related not only to treatment of the cancer itself, as the most common end point to be evaluated in a study, but also to the acute and late side effects, long-term morbidity, and the expected interference with the patient's normal life. It is quite natural that patients look at the problem through their own eyes, not through the eyes of a scientist. When experts hide their opinion under "collective equipoise," patients' preferences should be considered.[23,24] Thus, Mrs. Thornton wrote that she would refuse postoperative irradiation if so many doctors feel that it is unnecessary and may be even harmful. Why should she offer her body to scientifically prove something that is very likely to be true?[17] Similar is the dilemma of that patient with inoperable pancreatic cancer who believes that someday an effective treatment for his condition will be found. As he has not much to lose, why should he consent to a randomized trial (and, thence, to a 50% chance of getting only supportive treatment) and not ask for some kind of innovative treatment right away?

Finally, months or years after entering the trial and completing the treatment, the patient's disease may progress. As a patient is often inclined to seek an explanation for his or her condition in the outer world, so also eventual progression of the disease may appear to be linked to the particular treatment option to which he or she had been assigned by random choice. The patient may feel that his well-being had been sacrificed for the sake of the progress of medical science. Whether expressed openly or in a more discrete mode, the patient will have even more grounds for such a statement in case he had actually been assigned to a treatment option that proved to be inferior in subsequent analysis. Therefore, the roles of the clinical investigator and of the physician do not end after the results of the trial have been made known to the scientific and lay community. Responsibility for the patient continues. The ground for potential conflict diminishes if the relationship has been based on sincere, humane mutual understanding rather than on hierarchy and the physician's professional superiority.

Has the patient the right to know the preliminary results of a study in which he was invited to participate? This question is particularly pressing in randomized clinical trials, in which patient accrual is usually protracted over several years and in which new patients are still entering the trial while the events (remissions, complications, or survival) from earlier patients have already been recorded. The present practice is that the cancer patient is not entitled to know the preliminary experience and the interim results. Indeed, some authors state that even the physicians participating in the study should not be told about the preliminary results. The reason for this is clear: when the interim results show an advantage

of one of the treatment arms, the uncertainty principle may be seriously compromised and neither doctors nor patients will accept further randomization.

Beyond the scope of this presentation are the practical implications of the idea that the patient has the right to be informed about the preliminary results of the trial he is about to enter. Here, I will say only that trials with a long patient accrual period very often become unethical. Many years of slow recruitment of patients into a trial will frequently lead to a situation with an obvious but statistically still unconvincing advantage of one treatment over the other. In such a situation, accrual of new patients cannot proceed without ignoring their right to be informed about the preliminary results. Completion of a trial in a short time is therefore highly recommended, not only for scientific but also for ethical reasons.

DISCUSSION AND CONCLUSIONS

Dissecting and analyzing the communication process may be both dangerous and artificial: such an attempt is not far from discussing what we mean by "love" through a detailed analysis of the motivations and actions of those involved. Being aware of the limitations of such an approach, I nevertheless have found no other way to present my personal view of the various general problems linked to communication with the patient, and in particular with the patient in clinical research.

In everyday communication, words can be an adequate medium only for very simple messages. Whenever emotions are involved—and this is the case in every decisive moment of our lives—movements and gestures, physical contact, silence, and the mere feeling of spiritual proximity are among the invaluable means for conveying messages.

Everyone responsible for another person is also responsible for his spiritual adaptation. Our roles are changing constantly: the physician of today may be a patient at the same time, or will certainly be a patient in the future. When it comes to clinical research, it is unacceptable that physicians involve patients in trials in which they themselves would not be willing to participate.[25–27] This is a clear sign of the erosion of moral principles among the medical community. The situation may be worse than just a predominance of utilitarian ethics over Kantian ethics, according to which a human being can never become a means. Professional ambitions linked to the fruits of clinical research, or even financial reimbursement offered as compensation for involving one's patients in research may have wider and more profound influences on the behavior of our profession than we would even wish to think.

The resolution of these dilemmas may be sought in true partnership with patients.[28] Some principles and practices of clinical research should probably change. Nobody should be forced to perform clinical research.

A physician should join a clinical research team only after all the implications of such a decision have been considered; sincere motivation for continuous communication with the patients in clinical research is not among the least important of these implications.

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Misconduct in Clinical Research

The Scandinavian Experience and Actions for Prevention

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The Nordic countries, Denmark, Norway, Sweden and Finland, started relatively early with the establishment of national committees dealing with scientific misconduct within the health sciences. They originally included slightly different parts of the dishonesty spectrum, when launching their independent control bodies, but have since then converged, with the end result that all four countries now include all aspects of the spectrum. In other words, the ranges now cover alleged fabrication and plagiarism on one side, and quarrels about authorship and terms of procedure within cooperating groups of scientists on the other. The Nordic experiences have made it possible to estimate a prevalence rate of 1–2 presented cases per million inhabitants, of which only approximately 1/5 is serious. The preventive actions have been publications of guidelines for: scientific co-operation; raw data storage; authorship. Further, educational initiatives include postgraduate courses for senior scientists; postgraduate courses for junior scientists; influence via inquiries and investigations. The Nordic experiences point strongly to the necessity of an independent national control body.

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Ethics related to biomedical research, with man as the subject, has developed rapidly after the disclosure of the World War II and preceding years' serious atrocities against prisoners, ethnic groups and political opponents, often in relation to medical experiments.

The Declaration of Geneva, the Helsinki Declarations and several other guidelines as a consequence focused primarily on the protection of human research subjects, their security and their free will to consent after thorough information. This aim is still central to all sets of ethical guidelines and implementing control bodies. However, in recent years the accumulated experiences with research in man have pointed to three other aspects of ethics related to research: the methodological standard of a project, the temporal responsibility of scientists towards the research subjects, and, finally, the scientist's own ethics, i.e. his or her moral standards reflected in his or her credibility. Before turning to this last condition for good scientific standards, two of the above-mentioned other conditions have to be briefly described.

The *methodological standards* of a biomedical project involving man are closely linked to the ethics of research, because even safe projects are considered ethically unacceptable, if methodological flaws prevent the results from ever being beneficial to patients, either the trial patients or the large group of other patients that usually might benefit from original research through *projective universality*.

The *temporal responsibility* of scientists involved in research on man is not totally new, but formerly was usually restricted to reporting on side effects and other unforeseen events during a study. Now it has been widened to the extent that scientists are obliged to secure that the introductory evaluation in a research ethics committee can rest on a *global* survey of the literature, and that they with a similar search technique follow the international development *during* the complete project period. The reason is obvious, that for instance a trial starting with a placebo group involved because of no known effective treatment at that time will no longer be ethically acceptable, if another trial elsewhere later demonstrates a new effective treatment, thus necessitating a re-evaluation of the whole project (1). The last part of the temporal responsibility is the clinical researcher's duty to inform all the participants of the results and the personal consequences after termination of the trial.

MISCONDUCT IN CLINICAL RESEARCH

The fourth component of ethics of research is the scientist's own ethics, i.e. his or her credibility and good behaviour. Owing to a number of scandals, reported in the international biomedical literature, the Nordic countries early on decided to set standards for good scientific behaviour, to establish national bodies to deal with individual cases, and to work for an effective prevention (2, 3).

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Table 1

Danish cases of alleged scientific dishonesty 1993–1997

	1993	1994	1995	1996	1997	Total
Treated	9	3	1	2	9	24
Dismissed	6	2	1	8	0	17
Total	15	5	2	10	9	41

The Nordic control systems

Five to six years' experience with the concepts of misbehaviour and fraud, and with figures for their absolute and relative representation of handled cases in the Nordic systems, based on inter-Nordic meetings (4), have made it possible to conduct an early survey. In what follows, committee structures and experiences will be mentioned country by country, in alphabetical order.

Denmark established its system in 1993 (5). The *structure* is a non-legally based, independent national committee with eight members representing the universities, the Research Council, the scientific societies, the hospital authorities, the research ethics committees, with alternates, covering all health sciences including dentistry and pharmacy. The chairman is a High Court Judge. At present the committee has no lay or industry representation. The secretariat is located in the Ministry of Science, together with the research councils and the Central Research Ethics Committee.

The Danish *definition of scientific dishonesty* is wide:

fabrication of data,
selective and undisclosed rejection of undesired results, substitutions with fictitious data,
- erroneous use of statistical methods with the aim of drawing other conclusions than those warranted by the available data,
distorted interpretation of results or distortion of conclusions,
- plagiarism of the results or entire articles of other researchers,
- distorted representation of the results of other researchers,
wrongful or inappropriate attribution of authorship,
misleading grant or job application

Other types of dishonesty concern the scientific message itself only to a small degree, but rather concern the attempts of researchers to distort the perceptions in the surrounding world of themselves and their relations with other scientists through exaggerations or omissions:

- covert duplicate publication and other exaggeration of the personal publication list,
- presentation of results to the public, thus by-passing a critical professional forum in the form of journals or scientific associations,
- omission of recognition of original observations made by other scientists,
- exclusion of persons from the group of authors despite their contributions to the paper in question.

These lists are not exhaustive but illustrate the wide scope of scientific dishonesty.

Cases handled by the Danish system can be raised by whistleblowers, institutions, or by the Committee itself.

The *sequence of handling* is:

- an inquiry,
- an investigation,
- reprisals, that are left to the scientist's institution, with an obligation for the institution to inform the Committee about reprisals or other reactions.

The *annual incidences* within the Danish system are: cases referred: 8/MIO inhabitants/year; cases treated: 5/MIO inhabitants/year; cases of scientific dishonesty: 1/MIO inhabitants/5 years.

Comments. The Danish system has come to stay. It will probably be extended to other research disciplines outside the health sciences, and will probably in the future include lay members and representatives from the drug industry. The reaction within the scientific society has initially been cautiously observant, but is now on the whole positive and loyal (6). In order to serve a comparative survey of all four Nordic national systems statistics from the Danish Com-

Table 3

Danish cases from 1993–1997 distributed on types of dishonesty

Fabrication	2	1
Plagiarism	3	0
Theft	2	0
Ghost authorship	2	
False methodologic description	3	1
Twisted statistics	2	0
Suppression of data	4	0
Unwarranted use of data	4	0
Authorship quarrels	8	1

Table 2

Danish ad hoc committees 1993–1997

	Internal membership	External membership	International membership	None	Total
Treated cases	14	2	2	6	24
Dismissed cases	2	0	0	15	17

Table 4

Deviations from good scientific practice

Unauthorized removal of biobank material	1
Unauthorized publication	1
Gift authorship	2
Exclusion of authors	3
Inadequate citation	2
Inadequate agreements between teams of scientists	5

mittee, which has the largest experience with concrete cases, will be reported *after* the complete Nordic survey (3).

Finland established its system in 1994. The *structure* is a number of non-legally based institutional committees, with an independent national committee (7).

The Finnish *definition of scientific dishonesty* is narrower than the Danish one and is not restricted to the health sciences. Cases are raised by the institutions.

The *sequence of handling* consists of the establishment of an institutional *ad hoc* group, yet with a majority of external members. Appeal to the central committee is possible after the *ad hoc* group's conclusion.

The *annual incidence* has been approximately: 1–2 cases/MIO inhabitants/2 years.

Comments. In the beginning, the Finnish system, too, has experienced some resistance among scientists and institutions.

Norway established its system in 1993 (8). The *structure* is an independent, non-legally based, national committee, serving the primary, institutional, *ad hoc* investigations. The chairman is a medical professor.

The *definition of scientific dishonesty* is wide, similar to the Danish scope, outlined earlier.

Cases are raised by institutions with a *sequence of handling* determined by the institutions. Thus, investigations are carried out locally and only if the results point to scientific dishonesty is a case referred to the National Committee.

The *annual incidence* is 1 case/4 MIO inhabitants/year.

Comments. There has been some resistance within the scientific society. The number of cases has been low, possibly due to the obligatory first-line handling of alleged cases within the institution.

Sweden established its system in 1997 (9). The structure is an independent, non-legally based, national committee, servicing the primary, institutional, *ad hoc* investigations.

The *definition of scientific dishonesty* covers a scope between, on the one side, Denmark and Norway, on the other, Finland.

Cases are primarily referred to the chief of the institutions involved, to the Dean, or to the Rector in university cases.

The *annual incidence* cannot at present be calculated owing to the short period of function.

Comments. Sweden was early in publishing a 'Note for Guidance on Good Scientific Research' in 1996, a kind of publication that is much needed in all Nordic—and other—countries.

The Danish experiences

At the Nordic meeting in 1998 for the national committees dealing with scientific dishonesty within the health sciences, Daniel Andersen surveyed the Danish experiences up until now (5). The number of cases from the period 1993–1997 is reported in Table 1. The establishment and type of *ad hoc* investigative committees are presented in Table 2. The cases distributed on kinds of scientific dishonesty are shown in Table 3. In cases, with no proven scientific dishonesty, the Danish committee still found some deviations from good scientific practice. These cases are presented in Table 4.

It can been seen that the number of cases is relatively small, considering that they cover a whole nation with 5.2 million inhabitants, and that the independence of the National Committee probably secured an open access to the system, in other words that the figures presented are representative. Owing to the intensive preventive actions taken throughout Nordic countries, and to be dealt with below, the small—and cautiously judged: decreasing—Nordic figures might also reflect the influence of these initiatives.

Actions for prevention

Throughout the Nordic countries preventive initiatives have been taken. In the following they will accordingly be dealt with as a whole, not distributed on national policies.

Information of the scientific society has been essential Sweden's 'Note of Guidance on Good Scientific Research' has been mentioned earlier. Finland and Norway have taken similar initiatives and Denmark published in 1998 four detailed sets of guidelines in Danish and English: writing a project protocol in laboratory, clinical or epidemiological research; writing a contract of cooperation for collaborating groups of scientists; guidance concerning rights and duties in storing and using scientific data; and guidelines concerning authorship (10).

The education of scientists in good scientific practice focusing on research ethics and researchers' ethics has been an obligatory part of PhD training courses and of post-graduate courses for senior scientists. Special attention has been given to the definition of the true biomedical authorship, probably the greatest conduct/misconduct problem in the grey zone between scientific misconduct and good scientific behaviour (11, 12).

The mere existence of an independent national system, with its inquiries and investigations, seems also to have contributed to prevention. Furthermore, the global impact of international experiences within this area has clearly shown that scientific dishonesty is *not* an esoteric fantasy

of groups of 'national missionaries', but is a reality that the research society has to take seriously.

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ADVANCED course on Ethics in Oncology

PROGRAM AND COURSE MATERIAL

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