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Ethical Aspects of Treatment of Women Who Have Been Raped

This article discusses the care that should be given to women who have been raped. It focuses on the complex ethical issue of preventing conception in these cases.

More frequently than in the past the media report cases of sexual assault in which men subjugate women to their will. Insult is added to injury when women are blamed for provoking these attacks. From time immemorial rape has been used to terrorise and humiliate populations as a strategy of war. Women who have been raped are often

women who have been raped need professional counselling

immobilised by shock and need professional counselling to help them cope with the inevitable trauma caused by the assault. They need to be able to turn to a trusted person who is significant to them for understanding and support. They need immediate medical care from a doctor and a metropolitan rape crisis centre. In rural areas it is preferable to see a doctor with some forensic training who would have the required skills. Professional care minimises the effect that the assault has on victims' lives. Follow-up counselling would also be needed for the women, their families and supportive friends.

These women need encouragement to report the crime to police and to freely consent to provide samples for DNA testing as forensic evidence of the attack so that rapists can be brought to justice. They need to be assessed for their degree of psychological trauma, which is often severe, and given appropriate psychiatric or psychological therapy. They may also need medical and ethical advice on the contraceptive therapy available after rape if they were not previously informed.

The Ethical Dilemma

Sexual offences are crimes and should be denounced as such. The presence of semen in a raped woman's body represents an extension of the injustice of the original sexual assault if conception is a real possibility. Since we are dealing with an act of violence it is ethically permissible to prevent con-

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ception after rape. The same applies if rape occurs within a marriage relationship because sexual intercourse without consent is not a marital act. However, from the perspective of the sanctity of human life from conception, it would be unethical to deliberately prevent the implantation of an embryo which results from rape. This would be the moral equivalent of *direct* abortion since, as Pope John Paul II has taught, the fruit 'of human procreation, from the first moment of its existence, must be guaranteed the unconditional respect which is morally due to the human being in his or her totality and unity as body and spirit.'[1] It needs to be admitted, however, that some rape victims in their confusion and distress, may, in good faith, believe they are morally justified to prevent an embryo from implanting or to have an early abortion.

The challenge is to find an ethical way to respect the rights of the violated woman without at the same time neglecting to protect the life of the human embryo. It may be possible to prevent conception after rape without undue risks to the life of an embryo. To do this requires knowledge of the human reproductive process and of the mode of action of the commonly available post-coital drugs to prevent pregnancy, i.e. emergency contraceptive pills (ECPs).

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Post-coital Prevention of Conception

Mifepristone, formerly known as RU 486, is a post-coital drug given to prevent pregnancy. It is 100% effective because it inhibits implantation of embryos. It is marketed for abortion in France, Sweden, United Kingdom and China. Mifepristone can also inhibit ovulation.[2] When used in combination with a prostaglandin, it can abort fetuses for up to 20 weeks of pregnancy.[3]

Some ECPs, often known as 'morning after pills', can prevent pregnancy by inhibiting or delaying ovulation or by preventing the implantation of an embryo. An example of this is the Yuzpe regimen of oestrogen-progestogen pills. This hormonal treatment is prescribed by a doctor to be taken within 72 hours of unprotected intercourse and repeated 12 hours later. It can prevent ovulation and render the lining of the womb inhospitable for implantation.[4] It is most effective in preventing pregnancy when commenced within 12-24 hours of unprotected intercourse.[5] A recent survey of ten clinical trials of the Yuzpe regimen as pregnancy prevention after unprotected sexual intercourse found it 75% effective in reducing the number of actual pregnancies compared to the expected number.[6] Another more recent example of ECPs is the high dose progestogen, levonorgestrel. It is more effective than the Yuzpe regimen — 89% compared to 75%.[7]

Recent research which involved 221 women who planned to become pregnant showed that in 625 menstrual cycles for which dates for ovulation could be estimated, 192 (31%) conceptions occurred during the six-day period ending on the estimated day of ovulation. Evidence of conception was based on an elevated level of the hormone human chorion gonadotrophin (hCG) produced by a blastocyst, which is formed about 6 days after conception. If intercourse occurred every other day during these 6 days, the conception rate was estimated to be 33%, but it was 15% if intercourse randomly occurred only once.[7]

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Within five minutes of sexual intercourse the first batch of sperm reach the fallopian tubes where conception normally occurs.[9] Although the median life of sperm in a woman's genital tract is one to three days after intercourse, sperm are able to live in a woman's cervical crypts for up to five or six days and still be able to fertilise an egg. But an egg is only capable of being fertilised for about 12 hours, and at most 24 hours, after ovulation. Most eggs are fertilised by sperm derived from intercourse one or more days before ovulation. It is not surprising, then, to find that an important review article concluded it is likely the Yuzpe regimen mainly works by inhibiting ovulation.[10]

In fact**,** research shows the Yuzpe regimen prevents ovulation in 21-27% of cases when taken one or more days before ovulation was expected, whereas progestogen only ECPs inhibit ovulation in 33% of cases when given 3-4 days before expected ovulation, and possibly even longer.[11] In the light of today's knowledge of the mode of action of these ECPs, some authorities have suggested their failure 'may be more likely if ovulation and fertilization have already taken place at the time of treatment and, thus, prevention of implantation may not be one of the primary modes of action.'[12]

In a case of rape, it would seldom be known with certainty whether ovulation had already occurred or was due to occur on the day of rape, because the assault might happen on any day of the woman's cycle. Conception after rape, however, could only occur on one of seven fertile days of a woman's cycle, including the day after ovulation. This means for most of the cycle ECPs would have no effect at all: they would not inhibit ovulation or implantation. Assuming rape was the only instance of unprotected intercourse during a woman's fertile period and the right doses of ECPs were taken, ovulation would be inhibited in up to 30% of

conception after rape could only occur on one of seven fertile days of a woman's cycle

cases, whereas the probability of conception would be 15%.

Suppose again rape was the only act of unprotected intercourse a woman had during her fertile days, and we were to be over cautious and accept a 25% probability that both the above mentioned ECPs would inhibit ovulation. Then, of 100 women who were raped in the days before ovulation and who took ECPs, about 75 would ovulate and an estimated 15% (11) of these would be likely to conceive. Hence the odds of preventing ovulation after rape would be 25% whereas the odds of preventing the implantation of an embryo would be 11%.[12]

Ethical Response

An ethical response to rape cannot ignore the trauma experienced by these women. This trauma is prolonged if pregnancy results. It is hard for people who have not been subjected to sexual assault and pregnancy resulting from it to grasp the indignity suffered and the degree of personal hurt and brokenness endured. All of us need to reflect carefully if we are to comprehend the suffering a woman made pregnant by rape has to endure all her life.
If the information given above is correct, then in accord with the legitimate application of the principle of double effect, it would be ethi-

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cally permissible to administer ECPs within 72 hours after rape unless there were reasonable grounds to believe that the woman had conceived prior to the rape or that ovulation had already occurred, or would occur on the day of treatment. The risk of loss of life of an embryo would be a permissible side-effect justified by the need to prevent the injustice of conception and a traumatic pregnancy caused by rape. The Catholic Bishops of England and Wales recognised this and in 1985 approved the use of '*hormonal* postcoital contraception after insemination by sexual assault, provided, (i) that there are no grounds for judging that ovulation preceded

post-coital ECPs can, but need not, act as direct abortifacients

or will coincide with the administration of postcoital contraception, and (ii) that the postcoital contraceptive is administered urgently, within about a day, after the assault'.[14] This advice was based on the scientific information available at the time. By the same token, an injured or sick pregnant woman could ethically undergo necessary, but not life saving, medical treatment, even if it were to pose a comparable risk to the life of her fetus.
Clearly, ECPs can, but need not, act as *direct* abortifacients. It is not true to imply that one who uses ECPs to prevent ovulation as explained above 'voluntarily and deliberately

on ethical as well as medical grounds ECPs should not be used for family planning

risks provoking an abortion. In other words, if there were a pregnancy the woman or doctor would have decided for an abortion.'[15] Right knowledge of their mode of action and of the principle of double effect are needed for making correct ethical and clinical judgements in caring for rape victims. On ethical as well as medical grounds ECPs should not be used for family planning. But fear of their abuse does not negate their right use after rape.

END NOTES

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[11] Fabienne Grou and Isabel Rodrigues, 'The morning-after pill—How long after?', *American Journal of Obstetrics and Gynecology* 171 (1994) 1529-34.
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[13] Even if the probability of ECPs inhibiting ovulation were 20%, the odds of their use preventing implantation of an embryo would still be only 12%.
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Norman Ford SDB

What Affects Health?

This article will discuss concepts of health and how narrow definitions are totally inadequate.

"Wellness of the individual is influenced by genetic endowment, social and family relations, emotional robustness, economic security, recognition and worldly success, and at a societal level, absence of gross social inequalities, as well as freedom from environmental toxins, pathogens and accidental injury."[1]

Health policy should not be separated from social and economic policy, as there are no clear-cut boundaries of responsibility. It is difficult to specifically identify the causes and effects of ill health, as there are many contributing factors. Much of current health policy targets individual risk factors, genetic predisposition, access to the health care system and the outcomes following interaction with the health care system. Government policies have to recognise that to ensure optimal 'health' for society they have to acknowledge the social and economic factors that also affect health, and focus policies accordingly.

What is Health?

Health is a means towards fulfilling potential and improving quality of life. Health is a state of physical and mental wellbeing that facilitates the achievement of individual and societal goals. A society regards as healthy those people who are able to follow and achieve those things considered necessary for a 'good life' in that community.

The definition of health that is accepted in most westernised health care systems is a predominantly negative concept that focuses on the absence of disease or injury. It is implied that if you do not have an acute or chronic illness then you should be healthy. The classical medical model defines disease as the disturbance of man's adaptation to the environment, and offers an implicit apology for the specific environment. 'The word "disease" indicates that which has to be changed. If the relationship between the body and the environment is inadequate, and the body is considered to be ill, this means that the environment is acceptable and the body has to be changed.'[2] Changing the body is the focus of western scientific medicine. The biomedical model of health and

changing the body is the focus of western medicine

illness assumes a clear distinction between the person and the body. Treatment is focussed on the body rather than the embodied person. It reduces illness to disordered bodily functions that become diseases of the individual. It presumes that a specific, potentially identifiable, agent causes each disease. This may work well with infectious conditions but it doesn't explain the causes and progression of complex chronic diseases. The biomedical model tends to treat the body as a machine that malfunctions. There is increasing specialisation in medicine, honing in of expertise on smaller and smaller parts of the body, along the lines of machine parts, to the exclusion of an image of the totality of the person's body. The body is conceptualised as an object over which control must be exercised in order to maintain or restore health.[3]

Ill health ***is*** a social process. The physical signs and symptoms are the outcome of that process. It cannot be concluded that ill health is purely the result of a biological event when so many interacting factors such as class (or socioeconomic status), gender, ethnicity, division of labour, medical dominance, the relations of medical technology, the technology itself and political influences, affect the development and indeed the outcome of the ill health process. An individual's position in society greatly affects whether they get sick, how often, what illness they may contract, the likelihood of a cure, their experience of the health care system and, their treatment.

There has to be an acceptance of the social, political and economic determinants of health as genetic and biological factors do not adequately explain the marked differences in health status that occur not only among human populations, but among subgroups within populations. The health status of populations is gauged by looking at such indicators as rates of death (mortality), rates and types of illness (morbidity), life expectancy and the use of health services. These inequities in health may be the unequal distribution of certain biological disease states or the unequal access to health care by certain groups in the community.
The health status of Indigenous people in Australia provides a very visi-

infant mortality and hospitalisation rates are also higher for Indigenous Australians

ble example of inequities in health. Their life expectancy is less than that of the general Australian population. Unpublished data from the Australian Bureau of Statistics (ABS) puts the life expectancy at birth, 1991 – 1996 of an Indigenous Australian male at 56.9 years whereas for other Australian males across Australia it is 75.2 years. For Indigenous Australian females the life expectancy is 61.7 years while for other Australian women it is 81.1 years.[4] Infant mortality and hospitalisation rates are also higher for Indigenous Australians than for other Australians and it is reported that they have one of the highest prevalence rates of type 2 diabetes in the

world. Such inequities in health cannot be explained purely by genetic or biological differences.

The contextual experience of illness is also evident in the fact that persons diagnosed with the 'same disease' (from the point of view of the health system), with similar biological parameters, prognoses, and treatment options and implications, can experience very different levels of symptoms and distress that affect their ability to function in their various social roles.

Social Determinants of Health

There are many social factors that have been acknowledged as having an effect on health status. These include the following: social gradient – the lower the socioeconomic status, the higher the morbidity rates and a decrease in life expectancy; stress, that is, continuing anxiety and insecurity adversely affects health; the effects of early life in

the amount of control people feel that they have over their work

childhood; social exclusion such as homelessness and poverty; work, especially the type of work, the amount of control people feel that they have over their work or indeed whether they are even employed; social support; addiction; food, specifically peoples' opportunities to buy what is considered to be 'good' food or even to know what to buy and finally, transport.[5] Social conditions expose people to risk factors, which, in turn cause disease. Social patterns of disease persist however, despite effective interventions on risk factors.

Initially it was factors like substandard housing and poverty which were specifically linked with such conditions as infectious diseases and lung disorders. More recently it has been the link between socioeconomic status and life expectancy or infant mortality that has been acknowledged and described. Richard Wilkinson is even more specific about the relationship. He claims that the health of a population depends upon the equality of the income distribution, rather than the average income and that rising average incomes can be associated with declining health, if the resulting wealth ends up being concentrated in fewer pockets.[6]

Quantifying and Qualifying the Social Determinants of Health

When determining the social factors that contribute to ill health there are methodological problems. Measuring and comparing blood cholesterol or glucose levels is a relatively easy, objective thing to do. Measuring or comparing family support or social cohesion however is not so easy. The randomised control trial (RCT) is one method that can, and has been used for evaluating many interventions and is regarded as scientifically reliable even though it has many inherent problems. It would be very difficult however, but not totally inconceivable, to use RCTs to evaluate socially oriented interventions whose worth is more likely to be determined on their implied potential from observational studies.
Measuring and evaluating the social determinants of health can only

worth is more likely to be determined on their implied potential

really be done effectively through longitudinal studies. One such study known as the Whitehall study of London Civil Servants has been conducted over 25 years and looks at the effects of many social, demographic and economic factors on health status. There are however, problems in evaluating the effects as understanding the correlation between two variables is difficult because the direction of causality is not always easily determined. For example, does lower socioeconomic status and the poor living conditions that accompany it lead to bad health, or does bad health lead to downward social mobility and lower income, or, do both situations interact?
There have been other attempts to evaluate the social determinants of

social indicators and the conditions they represent do not occur in isolation

health. One institute in America has developed an index of social health that brings together a diverse set of indicators and assesses their performance over time. Each indicator represents a stage of life from childhood to old age and draws from an important area of life that shapes the quality of life at that particular stage, such as, health, employment, income, education, and security. The performance of each indicator reflects the strength of social establishments such as family, school, community and employment. The index demonstrates the fact that social indicators and the conditions they represent do not occur in isolation and that their impact is not totally confined to individuals themselves.[7]

Problems with Current Strategies

Most current strategies designed to improve health status are individualistic in that they focus either on alleviating signs and symptoms of illness or on controlling the risk factors by modifying individual behaviour to prevent or minimise the effects of illness. This emphasis on controlling risk factors presumes the autonomy of individuals. Autonomy, interpreted as individual free choice or personal liberty, is an ethical principle that is much respected in today's world. However, if it is argued that everybody should be able to choose freely with respect to their own health, then ultimately they should have to take responsibility for any behaviour that may lead to illness. Inherent in such reasoning is an assumption however, that

there is actually a choice to make about whether to indulge in risky behaviour or to endure certain socioeconomic conditions that may lead to ill health. Unhealthy habits are more common among lower social classes. One of the many ways that people respond to stress, unhappiness and unmet emotional needs is to increase their consumption of various comforting foods which have high sugar and fat content and of various drugs such as alcohol and tobacco.[8] Health promotion messages attempt to inform the community so that any action taken is based on knowledge and understanding rather than ignorance. Feasibly, such choices about behaviour can be made. However, as more knowledge is generated about individually avoidable risks of disease a *certain* segment of the population will be affected by this information and change their behaviour. Other segments however, will not avoid these health risks and health inequalities will actually increase. Being able to make autonomous choices about factors such as one's socioeconomic or employment status however, is not so achievable.

It has been argued that the 'principle

'principle of autonomy ..... is a moral standpoint usually adopted from an advantaged social position'

of autonomy ….. is a moral standpoint usually adopted from an advantaged social position.'[9] The value of individual liberty and a preference for individual solutions is a view of the world held by individuals at the top of the social hierarchy.[10] These people are able to experience a much greater degree of free choice than those who are lower down in the social hierarchy. As it is the people who are highly educated and who have more buying power that usually orchestrate public discussion, it is no wonder that autonomy has become an important principle on which policy is based.

Should We Look at the 'Whole' Society?

If we acknowledge that the social environment has a great impact on the health status of individuals and groups and that the effects can be cumulative then it is logical that we should have a life course approach to government policy making. We would need to look at the ways in which all policies affect a person's whole life. We would need to look at how the 'socially critical periods' of life such as early childhood, schooling, entry into employment or further education, leaving home, establishing one's own home, parenthood, job insecurity (and the levels of government income support and the availability of publicly funded services), chronic illness and retirement are addressed. The size of the gap between the mortality and morbidity rates of the most advantaged and that of the least advantaged groups gives some indication of the potential for improvement in a country's health.

If social factors are recognised as contributing to illness and disease then interventions should be those that modify whole communities rather than those that are aimed at individuals' behaviour. Such a suggestion, however, may imply a kind of 'social engineering', which in today's world of individual rights would not be popular. It would ask questions about the structure of society and the distribution of wealth and power. It would raise issues of justice and these may take precedence over respect for autonomy.

'In terms of the quality of life, which

it would ask questions about the structure of society

is ultimately a matter of people's subjective sense of well-being, the psychosocial processes round inequality, social cohesion and its effect on health, are overwhelmingly important. They are important not only from the point of view of those down the social scale who suffer them most, but also because the deterioration of public life, the loss of a sense of community, and particularly the increase in crime and violence, are fundamentally important to the quality of life for everyone.'[11]

ENDNOTES

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[10] Lindbladh, 1019.
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Deirdre Fetherstonhaugh

Subscription Renewal

Please note that your subscription renewal is now due for Volume 5, and an invoice is enclosed in this issue.

Clinical Trials in Developing Countries: The Ethical Difficulties

This article briefly investigates whether or not it is possible to conduct clinical trials, which are both ethically acceptable and scientifically rigorous, in the developing world.

Ethics of Clinical Trials

The aim of late phase clinical trials is to establish the effectiveness and efficiency of a particular treatment, procedure or practice. It is widely accepted that such trials should be conducted in accordance with well-established ethical principles. I will not go into detail about these principles here as they have been discussed in earlier editions of the Bulletin in articles on Randomised Clinical Trials (RCTs) and human experimentation. The purpose of this article is to explore the added ethical difficulties that arise when RCTs are conducted in foreign countries. In particular, I will consider the kinds of ethical issues that arise when clinical trials, especially those involved with HIV and AIDS, are conducted in the developing world.

Why Are Clinical Trials Conducted in the Developing World?

Developed countries in particular, America, conduct HIV and AIDS vaccination and prevention trials in the developing world for a variety of reasons some of which are ethically problematic. Perhaps the primary and least complicated reason for conducting this type of research in the developing world is because there is a vast number of potential trial participants because of the vast population and the high rates of infection. At the end of 1997, it was estimated that about twenty-one million people were living with HIV/AIDS in sub-Saharan Africa and that this figure would increase rapidly because of other endemic sexually transmitted diseases which significantly increase the chances of HIV transmission.[1]

Another reason for conducting trials in the developing world is because currently, due to extremely limited health funding in these countries, there is almost no treatment available for HIV/AIDS. This allowed an argument to be mounted that placebo controlled trials conducted in the developing world would be ethically acceptable. The issues are perhaps best demonstrated by exploring the actual events surrounding the now infamous HIV vertical transmission trial, which aimed to investigate HIV transmission from in-

something had to be done to reduce vertical transmission rates as soon as possible

fected mothers to their offspring. The use of placebos in HIV vertical transmission trials was no longer ethically acceptable in developed countries because protocol ACTG 076, a zidovudine regimen, had been proven to be effective in reducing vertical transmission rates by up to two thirds.[2] However, the exorbitant cost of the ACTG 076 regimen, which involves administering zidovudine to the HIV infected pregnant woman orally during pregnancy, intravenously during labour and subsequently to the infant, was and remains prohibitive to developing nations. A cheaper, yet equally effective way of reducing vertical HIV transmission was needed urgently because projections indicated that by the year 2000 six million pregnant women in Asia and Africa would be infected with HIV. Although something had to be done to reduce vertical transmission rates as soon as possible, the Declaration of Helsinki clearly states that every patient participating in clinical trials should be assured that they will be given the best proven diagnostic and therapeutic method.[3] It seems clear that while there may have been good economic reasons, especially for drug manufacturers, for allowing the HIV vertical transmission trial to proceed, the trials were ethically unacceptable.

The major challenge still confronting RCTs conducted in the developing world is to be both ethically sound and at the same time to remain scientifically rigorous. While the scientific demands are the same for all clinical trials, the ethics involved in research become more complicated when a trial is being conducted by one group of people and the research subjects are an entirely different group of people. This is the situation that arises when RCTs are conducted in parts of Asia and Africa on a variety of diseases including malaria, small pox and numerous sexually transmitted diseases. I will now focus on HIV/AIDS trials as they continue to be the most widely publicised.

Different Standards of Informed Consent

One of the key issues in conducting research in the developing world is the trade off which has to occur between the ethical requirements of research in western countries, who are providing most of the research teams, and the cultural sensitivities of the countries in which the research is being conducted.[4] For ex-

all potential research subjects should be fully informed about the research

ample, it is widely accepted in Western societies that all potential research subjects should be fully informed about the research and that they must consent to participate. This is in contrast to other countries in which individual consent is not

given nearly as much significance, such as parts of West Africa, where elders and community leaders are charged with making decisions of behalf of individuals and the community. This difference in decision-making models raises difficulties for the research protocol. While, in the West it seems ethically appropriate that consent should be gained from each individual research subject so that respect for autonomy is maintained, enforcing this standard of consent upon another culture risks being both inappropriate and unnecessarily invasive upon the ethical and social norms of that culture. An ethically appropriate solution to this problem must be investigated and a compromise met. Perhaps a solution may be reached by seeking elders' or community leaders' consent and then informing the specific individuals that the elders have consented and ensuring that this is sufficient for the individual to participate.

Treatment as Coercion

The standard of health care in the developing world is often poor and for some diseases virtually non-existent. By enrolling in clinical trials subjects often receive thorough physical examinations and simple, cheap treatments for conditions which are unrelated to the trial. Subjects should not be coerced into participating in clinical trials because otherwise they cannot give truly free and informed consent. Even if a community's elders have accepted and agreed to an RCT being conducted the provision of even basic health care, which is otherwise not available, to potential subjects should be considered coercive. One way of overcoming this ethical difficulty is to provide a basic health check and simple treatments to the entire community. This ensures that inclusion in the trial is not based on gaining access to basic health care. This alternative also avoids the further difficulty of stigmatization because often RCTs are conducted on sexually transmitted diseases which have a stigma associated with them and especially how they may have been contracted. If some basic health care was provided to the entire community it would make it difficult for community members to identify the particular individuals who have the disease under investigation.

Defining Placebos in the Developing World

Institutional Review Boards (IRBs) or Human Research Ethics Committees (HRECs) usually review research protocols with reference to several key criteria including informed consent and the potential risks and benefits that the research poses for subjects. They also endeavour to ensure that the proposed research conforms to their own national as well as international ethical guidelines on research. As mentioned above, the Declaration of Helsinki makes specific mention of how research subjects participating in trials should be treated. The standard of health care in many developing countries is so poor that any provision of treatment, even if only half the trial participants receive it, is considered under utilitarian criteria to be an ethically acceptable outcome. The further advantage of allowing placebo controlled trials is the reduced number of trial participants needed in order to determine if the treatment is effective. However, Peter Lurie argues that while this may be true of placebo controlled trials, ethically acceptable equivalency studies, which compare two treatment options without a placebo arm, could produce the same results equally as fast and, that the hurdle of requiring more research subjects could be overcome by aggressive recruiting in multi-centre trials.[5]

After Trial Completion

Once a trial has been completed in a developing country many issues still remain. For example, if someone in Australia participates in an HIV prevention trial but who still unfortunately contracts HIV, they will be cared for with combination therapy and provided with the best medical care we can offer. If someone in Uganda participates in a similar trial firstly, they may not have completely understood what the trial was for and had the misconception that they would be protected from contracting HIV if they participated in the trial. Secondly, they may also not have freely consented even if they were aware of how the trial was to be conducted and how this might effect their health. Finally, once the trial is completed and the medical team returns home, the Ugandan who has contracted HIV will be left without treatment. In particular they would not receive the expensive combination therapy available in developed countries and possibly they would not even receive basic care because they can no longer work and no pension or sickness benefits are available in their country. This means that RCTs conducted in the developing world must address the situation they create upon departure as well as the ethics of their protocols.

One further ethical difficulty associated with research in the developing

RCTs conducted in the developing world must address the situation they create upon departure

world is demonstrating that the research offers some benefits to the communities and countries in which it is conducted. This did not occur with the vertical transmission trial mentioned earlier in this article. One reason for conducting the research was to establish whether or not a short course of treatment which was far cheaper than the long course, was effective in reducing transmission rates. However, although the trial did show that the short course of zidovudine was effective in reducing transmission rates, it is still too expensive for even relatively well off African countries such as South Africa. This leaves countries such as Uganda and Ivory Coast who participated in the trail with very little chance of affording the treatment, especially when they struggle to pro-

vide even basic health care. It would seem appropriate then that if a treatment is to be trialed in developing countries and is shown to be effective, then the treatment should be made available to the developing nation at a reduced and affordable rate. The drug manufacturer could absorb the price reduction alone or in a partnership agreement with the country who conducts the trial in the host nation.

Declaration of Helsinki

While questions surrounding the ethics of research conducted in the developing world are not new to medical and bioethical literature, the recent move to make changes to the Declaration of Helsinki does come as some surprise. The Declaration has provided the back bone of research ethics since its inception in 1975. It is true that it is not unusual to alter ethical guidelines, as either what is considered ethically appropriate within a given society changes or when new procedures become possible. However, the proposed changes to the Declaration alter the important protection it currently provides to all potential research subjects and especially those in the developing world. The proposed changes would alter the condition that all patients participating in research must receive the best proven diagnosis and therapy and would instead only guarantee that they receive the best diagnosis and therapy **that would otherwise be available to him or her** in their situation. This change may appear small but it would make way for the further exploitation of the poor by medical experimentation. It not only risks increasing the potential harm to people in the developing world but it also endangers the poor in communities where health care is unequally distributed or is only available at great personal expense. Documents such as the Declaration of Helsinki should not be altered if the changes risk endangering reducing the protection provided to the world's most vulnerable, the poor and the already disadvantaged.

proposed changes to the Declaration alter the important protection it currently provides

ENDNOTES

[1] G.A. Balint, 'Situation analysis of HIV/AIDS epidemic in sub-Saharan Africa', *East African Medical Journal* 75/12 (1998) 684-6.

[2] Peter Lurie and Sidney M. Wolfe, 'Unethical Trials of Interventions to Reduce Perinatal Transmissions of the Human Immunodefiency Virus in Developing Countries', *The New England Journal of Medicine* 337/12 (1997) 853-856.

[3] Declaration of Helsinki (1964) Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, and the 35th World Medical Assembly, Venice, Italy, October 1983.

[4] Mary Terrell White, 'Guidelines for IRB Review of International Collaborative Medical Research: A Proposal', *The Journal of Law, Medicine and Ethics* 27(1999) 87-94.

[5] Lurie, 835. ✣

Tracey Phelan

From the Director

Readers will notice that we have no article in this issue written by Anna Stokes. Due to the financial restraints affecting all hospitals in Victoria, our Centre, which is funded by Victorian Catholic healthcare institutions, had to reduce staff levels. As a result of this, the Centre was unfortunately unable to renew Anna's contact when it expired earlier this year. We greatly appreciated her valuable contribution to the work of the Centre over the last three years. We wish her well in her future career.

This year the Centre has made submissions to the *Australian Health Ethics Committee* on the following: National Data Collection on Artificial Reproductive Technology; draft Guidelines for Genetic Registers and Associated Genetic Material and draft Guidelines for Human Somatic Cell Gene Therapy and Related Technologies. The Centre also made a submission on the Review of the Health Act 1958 to the State Government. Finally the Centre contributed to the submission jointly made by Catholic health care providers in Victoria on the Health Services Policy Review Discussion Paper (March 1999).

The Centre was privileged to organise and host a Round Table Discussion on a variety of topics on Health Ethics with visiting U.S. moral theologian Dr Jim Keenan SJ as our expert guest.

The Proceedings of the Centre's 1998 Conference 'Aboriginal Health: The Ethical Challenges' have been published and are available for purchase from the Centre.

Norman Ford SDB

Withdrawing Tube Feeding – Medico-Moral Considerations

This article discusses situations in which it may be permissible to withdraw artificial nutrition and hydration.

When discussing tube feeding for patients in the permanent vegetative state, there is no need to go beyond the requirements of traditional Catholic morality, Australian law and contemporary standards of good medical care. It appears to me that those who claim that there can be no ethical place for it do just that. This view is probably best articulated by Dr Anthony Fisher OP and Professor John Finnis. [1,2,3]

even though feeding tubes may be properly removed in certain circumstances, the topic does hold inherent dangers

Even though I think feeding tubes may be properly removed in certain circumstances, the topic does hold inherent dangers which need to be kept in mind. One danger is the claim by observers to be making an objective assessment of the patient's quality of life as a criterion for removing treatment while this remains an impossible task. Other dangers include the consideration of medical costs without defining their applicability, confusion about the relationship between a doctor's intention and possible foreseen but unintended outcomes and, resulting from this confusion, the risk of the practice being interpreted by observers as intentional life-taking or euthanasia, when no such intention exists.

In his address to doctors on 24 November 1957, when discussing the ethical treatment of seriously ill persons, Pope Pius XII said: 'Normally one is held to use only ordinary means...that is to say means that do not involve any grave burden for oneself or another. A more strict obligation would be too burdensome for most people and would render the attainment of the higher good too difficult. Life, health, all temporal activities are in fact subordinated to spiritual ends'. Pope John Paul II also refers to the 'excessive burden on the patient and his family.'[4] Note the view that the forgoing of treatment can be compatible with the achievement of a higher good and that primacy is accorded to the person's spiritual ends.

Regarding the making of a correct judgment about treatment necessary in particular circumstances, the Declaration on Euthanasia says this will be possible:

> 'by studying the type of treatment to be used, its degree of complexity or risk, its cost and the possibilities of using it, and comparing these elements with the result that can be expected, taking into account the state of the sick person and his or her physical and moral resources'.[5]

Herein is described a balance, with patient factors on one side and anticipated benefits on the other. The reference to moral resources cannot refer to moral status as a human being, since that is the same for everyone and is unalterable. I suggest it refers to the person's ability to cope and to experience and express the spiritual dimensions of life. Elsewhere, the Declaration says:

> 'In the final analysis, it pertains to the conscience either of the sick person, or of those qualified to speak in the sick person's name, or of the doctors, to decide, in the light of moral obligations and of the various aspects of the case'.

The 'various aspects of the case' will be the factors listed in the previous quote. Note that the responsibility to decide is placed on the family and/or the doctors, in the absence of the patient's ability to do so.

Further, Pope John Paul II insisted that, for a definition of euthanasia to be strictly accurate, there must be the intention for the act to cause death.[6]

I agree with Childress and Lynn when they say: 'medical nutrition and hydration do not appear to be distinguishable in any morally relevant way from other life-sustaining treatments that may on occasion be withheld or withdrawn'.[7] This would include ventilators. In each, a function necessary for the maintenance of spontaneous life has been irretrievably lost. Despite what may appear at the bedside, all patients in both groups continue to have, at every moment, an untreatable life-threatening illness, and without intervention they would all have already died. If the moral content of the groups is thought to be different, this needs to be carefully explained. When the diagnosis and prognosis of irreversibility are known with certainty, there is at present no hesi-

treatment is futile when it has no recognised capacity to cure the illness, to restore function or to relieve distress adequately, and when this will not change with time

tation by clinicians and the community in accepting the legitimacy of withdrawing ventilator support from those who cannot breathe, but less certainty about removing a feeding tube from those who cannot swallow. In one group, the supply of air is ceased, and in the other, the supply of food, air being at least as fundamentally necessary to life as food and drink. Though dehydration is much discussed and deprecated as the mode of death in one group, little concern is expressed about death from asphyxia in the other, though,

if the patient were sentient, asphyxia would cause much more suffering.[8]

The outcomes of withdrawal in the two groups naturally have quite different time courses, and there is much emphasis on the relationship between food and life, whether symbolic or actual. But if we may not starve our patients, surely neither may we asphyxiate them.

I do not think that providing nutrition and hydration is any form of medical treatment per se, but the use

I do not think that providing nutrition and hydration is any form of medical treatment per se, but the use of a naso-gastric tube can be so regarded

of a naso-gastric tube can be so regarded. Finnis argues that 'no distinctive medical skills are needed to insert a naso-gastric tube or maintain the supply of nutriments through it'.[9] In fact, its insertion in a person who is unconscious and cannot swallow can be difficult and require the skills of an anaesthetist or an intensivist. In addition, such tubes often block and need replacement, while their use may have complications which, though rarely, can threaten life. Finally, permanently unconscious patients need expert nursing care to prevent or deal with bedsores, and will usually need regular digital removal of faeces. It is therefore insufficient to focus only on the tube and to suppose that care of such patients is simple, and able to be performed at home by anyone. For some families, even when it may be possible it will never be easy. We must not underestimate the human costs of such care.

Both Pope Pius XII and the Declaration allow that burdensomeness might be evaluated by those who carry the burden, most often the family, and this is surely reasonable and just. Finnis argues that there is 'no significant burden' to the patient,[10] and Fisher that such a procedure 'was not generally a burden to the patient'.[11] Both are correct, but are limited.

In a medical sense, and that judgment is the responsibility of doctors, treatment is futile when it has no

if a ventilator can be removed without intending the patient's death, why not a feeding tube?

recognised capacity to cure the illness, to restore function or to relieve distress adequately, and when this will not change with time. Thus, both tube feeding and artificial ventilation are futile for permanently and severely brain damaged persons, in medical terms. Doctors are not obliged, ethically or legally, to commence or continue to provide futile treatment. In the balance implied in the previous quote from the Declaration, there are no benefits to the patient to be put on one side. Note particularly that neither Pope Pius XII nor the Declaration say that there is merit alone in life being preserved, for its own sake.

Taking these points together, Fisher thinks that it is 'hard to see how (tube feeding) could be regarded as "extraordinary", since it is neither futile, nor is its provision generally a burden to the patient, given its benefits'.[12] But it is, in fact, futile in medical terms, and therefore conforms to the traditional Catholic definition of treatment that one is not morally obliged to provide or accept, whether or not one wishes to call it 'extraordinary'.

Since benefits from the continuation of life are claimed by Finnis and Fisher for patients being tube-fed, but not for those on a ventilator, the listed benefits must be considered. Finnis says that tube feeding should be continued because it is not unduly expensive and because to withdraw it would 'deny the personhood of these invalids by breaking off human solidarity with them at its root'.[13] Fisher believes it ought to be continued to 'affirm our respect for their humanity, express our love for them, maintain our human solidarity or communion with them, and conform with our basic duty of respect for every human life however diminished'.[14] None of these benefits, however, would accrue to the patient, or to a family that already felt intolerably burdened.

Such views, if interpreted literally, would never allow any treatment to be withdrawn from any patient, out of respect for every human life however diminished, and this would, in many instances, entail heroic efforts for compliance. It is a recognised Catholic moral position that it is not necessary, and is possibly a great injustice, to impose on people heavy burdens in the name of God, unless it is fully clear that this really is ethically required and is God's will.

Finnis and Fisher go well beyond what Pope Pius XII and the Declaration would allow, and exceed the traditional stance of the Church,

the proper removal of unwarranted treatment has nothing to do with intending death

quoted by Kelly and worth repeating: 'While preserving life is good – and even a great good— biological life is neither the highest value nor a value that holds ultimate claim on us'.[15]

Finnis declares that 'those who have a duty to care for someone may never exercise it in a manner intended to bring about that person's death.'[16] If we may not allow withdrawal of a feeding tube because it is impossible to suppose we might do so without intending the patient's death, then how are we to allow, as we do, withdrawal of a ventilator from those whom it is known will certainly die as a result, almost immediately? Alternatively, if a ventilator can be removed without intending the patient's death, why not a feeding tube? If a ventilator may never be validly removed, the medico-social consequences would be horrendous.

Withdrawals can be justified in

terms of foreseeing but not intending any subsequent death and in terms of medical futility, which cancels a

withdrawals can be justified in terms of foreseeing but not intending any subsequent death

doctor's obligation under the law of homicide to provide such treatment. The proper removal of unwarranted treatment has nothing to do with intending death. Lawyers, families and doctors can understand that. In any case, it could only be rarely, if at all, that a feeding tube should be withdrawn against a family's wishes.

Neither Pope Pius XII nor the Declaration thought that human dignity would be necessarily preserved by maintaining unconscious life indefinitely. If all capacity for spiritual experience has been lost forever, and if all human activity is subordinate to that end, how is the dignity of that life, as distinct from human dignity, to be measured?

Withdrawal of tube feeding under the ethical conditions alluded to in the Declaration, without any intention to take life, is not euthanasia. At this critical stage of the euthanasia debate, it is vital that we do not sideline ourselves by insisting on criteria which go beyond those which traditional morality and good law permit to patients, families and doctors. Rather, the imperative is to distinguish actions which are permissible, under certain circumstances, from those which intentionally attack life. Lawful actions should be able to be decided by reliance on principles which can be assented to by all people of good will so as not to 'render the attainment of the higher good too difficult'.

ENDNOTES

[1] Anthony Fisher, 'The road to euthanasia', *The Tablet*, 20 February 1993, 235-237.
[2] Anthony Fisher, 'On not starving the unconscious', *New Blackfriars*, March 1993, 130-145.
[3] John Finnis, 'Bland: Crossing the Rubicon?' *The Law Quarterly Review*, July 1993, 329-337.
[4] Pope Pius XII, 'The Prolongation of Life', *The Pope Speaks*, 4 (1958) 393-398; John Paul II, *Evangelium Vitae - Gospel of Life.* (Homebush: St Pauls, 1995) N.65.
[5] Declaration on Euthanasia, Sacred Congregation for the Doctrine of the Faith. (Sydney: St Paul Publications, 1980).
[6] *Evangelium Vitae*, N.65.
[7] Childress J.S. and Lynn J., 'Must Patients Always Be Given Food and Water?' *Hastings Center Report*, October 1983, 17-21.
[8] For a good discussion of the role of dehydration in dying persons, about which there is much understandable confusion, see Richard Wade, 'Artificial Hydration in Terminally Ill Patients: Is There a Moral Obligation?' *Caroline Chisholm Centre for Health Ethics Bulletin*, Winter 1998, 10-12.
[9] Ref 3, p335.
[10] Ref 3, p335.
[11] Ref 1, p236.
[12] Ref 1, p236.
[13] Ref 3, p335.
[14] Ref 2, p144.
[15] Kevin Kelly, 'Rest for Tony Bland', *The Tablet*, 13 March 1993, 334.
[16] Ref 3, p333. ✣

Brian Pollard MB BS (Syd), DA (Syd), FANZCA, GradCertBioeth

Correction

In the Article *Ethics and the Practice of Psychiatry. A Brief Review.*, by Professor Richard Ball in the Autumn 1999 issue, p.10, the following paragraph was omitted after the second paragraph in column one:

> Five years of formal academic training and experience in clinical psychiatry with a stipulated range of different types of clinical work and supervision leading to, in Victoria, a Masters degree of Psychological Medicine (or Psychiatry) and Fellowship of the Royal Australian and New Zealand College of Psychiatry.
> Those wishing to qualify in a major sub specialty of, for example, Child Psychiatry do a two year additional training with possibly one year overlap with the final year of general training.

Caroline Chisholm Centre for Health Ethics
7th fl., 166 Gipps Street East Melbourne Vic 3002
Tel (03) 9270 2681 Fax (03) 9270 2682 email: ccche@mercy.com.au

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Director/Editor: *Rev. Norman Ford SDB STL PhD, Adjunct Professor, Australian Catholic University*

Research Officers: *Deirdre Fetherstonhaugh* DipAppSc PGCert BA MA; *Tracey Phelan* BSc BA(Hons) MBioeth

Administrative Assistant/Layout/Sub-editor: *Margaret Casey* BTheol