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Earth Image from NASA

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The International Association of Bioethics Newsletter would like to hear from you.
If you have comments, suggestions, or if you would like to contribute to the next issue, or have events announced, please contact any of the IAB News editors.

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Message from the Editors

Informed Consent

The issue of informed consent has been at the heart of bioethics since its beginnings. Many of the central cases in early discussions about research ethics involved the issue of consent (e.g. Nuremberg, Willowbrook, Tuskegee[1]). Controversy continues today in relation to research in the developing world, with a particularly lively set of discussions about HIV prevention studies in Africa[2]. More generally, the issue of informed consent was taken up by many early bioethicists as a means of clearly moving away from what they saw as inappropriately paternalistic health care (See Cummiskey). The importance attached to gaining an informed consent in medicine has grown to the point that it has been adopted as a universal norm (See Manickavel), and much work has been done looking at the role of informed consent in different countries and cultural contexts across the world (See Siriwardhana et al.).

However, there has been a new strand to work on informed consent in recent years. This research tends to be more critical about the ability to provide sufficient information and achieve comprehension in real-life situations such as routine antenatal care (See Seavilleklein) or points out problems in relation to the pursuit of informed consent in a context of an expanding programme of neonatal screening (See Nijsingh). Such work often looks to empirical studies, and argues for research in bioethics to be grounded in social reality. Do patients and research participants always understand the information? If not, what (if anything) is the significance of this? How ought research ethics frameworks respond to such findings?[3] In addition, the meaning, role and appropriate limits for informed consent are being explored from a more philosophical perspective (See Manson). As a result of this more sceptical and critical approach, the apparent consensus in favour of a necessary requirement to always gain an informed consent is now increasingly questioned. We look forward to seeing how the literature develops in this area in the future.

This newsletter continues with our new format of having a core theme for each issue. The next issue will focus on the issue of **global justice**. We welcome submissions on this theme (and any reflections upon the work in bioethics published in this and the previous newsletter). We are also glad to accept any announcements of bioethics conferences and workshops or other pieces of news that you believe would interest colleagues across the world. Please send copy for the next newsletter before the deadline of **1st January, 2009**.

Jay Azariah
Inez de Beaufort
Angus Dawson
Editors

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The Genealogy of Informed Consent

By David Cummiskey

Principles of Medical Ethics: 1847 to 2001

The relationship between doctors and patients has undergone a revolutionary transformation from a traditional ethic of medical paternalism to the contemporary emphasis on patient autonomy and patient rights. The transformation in the West from the physician's role as a benevolent, paternalistic authority figure to a medical relationship emphasizing patient autonomy and patient rights is nowhere more evident than in the recent history of codes of medical ethics.

Article 1 section 1 of the 1847 Code of the American Medical Association (AMA)[1] nicely captures the moral stance of the classic paternalism of the "Hippocratic tradition:"

Art. I.-*Duties of Physicians to their Patients*.

§1. A Physician should not only be ever ready to obey the calls of the sick, but his mind ought also to be imbued with the greatness of his mission, and the responsibility he habitually incurs in its discharge. Those obligations are the more deep and enduring, because there is no tribunal other than his own conscience, to adjudge penalties for carelessness or neglect. Physicians should, therefore, minister to the sick with due impressions of the importance of their office; reflecting that the ease, the health, and the lives of those committed to their charge, depend on their skill, attention and fidelity. They should study, also, in their deportment, so to unite *tenderness* with *firmness*, and *condescension* with *authority*, as to inspire the minds of their patients with gratitude, respect and confidence. (italics in original)

By 1957 the AMA Code of Ethics had changed substantially.[2] Rather than focusing on uniting "tenderness and firmness, and condescension with authority," the focus was shifting to one emphasizing respect for human dignity.

Here is the 1957 version of the AMA First Principle**:**

Section 1**:** The principal objective of the medical profession is to render service to humanity with full respect for the dignity of man. Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion.

In the 1980 version of the *AMA Principles of Medical Ethics*,[3] we find a deceptively simple and concise statement of the first principle of medical ethics:

I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.

The language of the AMA Code has first shifted from the "duties of physicians" (1847) to "principles of medical ethics" (1957); second, the core principles are reduced to the two principles of compassion and respect (1980). Equally striking is the shift from the "greatness of his mission" and the "deep and enduring" obligations (1847) to the more minimal and basic commitment to provide "competent medical service" (1980). In addition, Article IV of the 1980 Code adds the language of "patient rights" to the 1957 Code:

IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.

The shift to a focus on principles of ethics, respect for dignity, and respect for rights, is a significant and fundamental ethical shift. In contrast to the one-page statement of abstract principles in the 1980 Code, the 1847 Code is a substantial document over 20 pages long, and sets out in significant detail the obligations and responsibilities of physicians and of patients. Indeed, the description of the obligations of patients in the 1847 Code is also revealing. Consider Section 1 of Article II:

ART. II. - *Obligations of Patients to their Physicians*.

§1. The members of the medical profession, upon whom are enjoined the performance of so many important and arduous duties towards the community, and who are required to make so many sacrifices of comfort, ease, and health, for the welfare of those who avail themselves of their services, certainly have a right to expect and require, that their patients should entertain a just sense of the duties which they owe to their medical attendants. (emphasis added)

Here we find the assertion of "a right" but it is a right of physicians that patients show due attention to the duties *they owe* to physicians. In the preamble to the 1847 Code this is emphasized as well: "As it is the duty of a physician to advise, *so has he a right to be attentively and respectfully listened to*" (emphasis added). Every single mention of rights in the 1847 code asserts the rights and prerogatives of physicians. Of course, rights of patients may be assumed but they are not mentioned. The rights of patients are protected by the benevolence of physicians. It is quite clear that it would be inappropriate for patients to assert and stand up for their rights. In section 6 of Article II of the 1847 Code, we find an explicit statement that patients owe unquestioning obedience to their physicians:

§6. The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them. A failure in one particular may render an otherwise judicious treatment dangerous, and even fatal. This remark is equally applicable to diet, drink, and exercise. As patients become convalescent they are very apt to suppose that the rules prescribed for them may be disregarded, and the consequence but too often, is a relapse. Patients should never allow themselves to be persuaded to take any medicine whatever, that may be recommended to them by the self-constituted doctors and doctresses, who are so frequently met with, and who pretend to possess infallible remedies for the cure of every disease. However simple some of their prescriptions may appear to be, it often happens that they are productive of much mischief, and in all cases they are injurious, by contravening the plan of treatment adopted by the physician.

Contemporary physicians may appreciate some of the sentiment expressed here. Non-compliance by patients with doctor's orders has surely always been a source of frustration for doctors everywhere. Again, however, the language used and the emphasis are in striking contrast to contemporary sensibilities: Patients have an obligation of "obedience" to physicians and patients should disregard their own "crude opinions" as to the adequacy of medical advice. Patients also have an obligation to avoid alternative remedies, and alternative medicine generally, when they are not authorized by a duly certified physician. Furthermore, the deference by patients to physicians does not end when health is restored (and monetary payment is made):

§10. A patient should, after his recovery, entertain a just and enduring sense of the value of the services rendered him by his physician; for these are of such a character, that no mere pecuniary acknowledgment can repay or cancel them.

The 1847 AMA code focuses on the mutual obligations and responsibilities of patients and physicians, with substantial and lengthy description of each. By 1980, the detailed AMA statement of mutual obligations is replaced by the simplest possible statement of principles and a complete reorientation towards patient rights. Since 1980, the focus on the priority of the patient and patient rights has been strengthened even further. In the current AMA 2001 Code of the first principle of medical ethics, for example, the link between respect for the dignity of patients and respect for rights is now made explicit:[4]

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

The differences in emphasis and orientation can really only be captured by the statements themselves. I have for this reason quoted from these codes at length. The 1847 Code is too long to be quoted in its entirety (it is over 20 pages long), but it is readily available on the website of the American Medical Association.[5]

Starting in the 1950s, and taking full shape by 2001, there was a shift in emphasis from a conception of medical authority based on *paternalistic but benevolent authority* to an emphasis on *respect for patient dignity and rights*. This shift in the focus of medical ethics is found in many countries and cultural contexts, but it is not universal, and the emphasis on rights in particular has been resisted, especially in some Asian countries, where an insistence on maintaining a focus on obligations and responsibilities has been emphasized and defended. For example, the current physician's ethical pledge from the Singapore Medical Association emphasizes the responsibility and the "conscience and dignity" of the profession and a dedication to "the service of humanity" and "the health of my patients," but does not mention patient rights at all.[6] Similarly, the Japanese statement of Principles of Medical Ethics emphasizes a concern for patients and a respect for their individuality, but it also forgoes any reference to patient rights. The emphasis is instead on compassionate care and earning the trust of patients.[7] The Indian Medical Association (IMA) Code of Medical Ethics, 2002,[8] also does not reference patient's rights; and in its tone it resembles the AMA 1847 Code in emphasizing, as its First Principle, the physician's duty to "uphold the dignity and honor of his profession." The IMA Code emphasizes throughout the physician's responsibility to the dignity and honor of the profession and the duty to earn and deserve the patient's trust. The IMA code is an explicitly more Hippocratic vision of medical practice, which emphasizes a sense of responsibility, of devotion and duty. The goal is to truly deserve the trust of one's patients and to dedicate oneself to the care of humanity. This is a noble vision indeed, but it is also noteworthy in its exclusion of talk of respecting the rights of patients.

In comparing the codes of medical ethics in different cultures and countries one of the most thorough statements of ethical principles is found in the current South African Medical Association (SAMA) Code of Medical ethics.[9] It consists of nine pages of four columns outlining the reciprocal and corollary *rights* and *responsibilities* of *doctors* and *patients*. In spirit, the SAMA Code most fully captures the sentiment of the 1847 AMA Code that both patients and physicians have obligations in the medical settings, but it adds to this a robust contemporary focus on the rights of patients. The SAMA Code's egalitarian vision of reciprocal rights and responsibilities, as the ideal model of the physician-patient relationship, reflects a real balance of rights and responsibilities. Indeed, it may best capture a more deliberative and shared decision-making model of the patient-physician relationship, which is defended in the final section below.

In closing this discussion of different medical codes, we should note the commonality in all of these codes. They all emphasize

- the compassionate and caring nature of medicine;
- the importance of respecting the privacy and confidentiality of patients;
- the social duties and responsibilities of physicians;
- the duties of physicians to other medical professionals;
- the importance of medical training and of continuing education;
- the virtues of professionalism;
- the necessity of practicing medicine within the constraints of the law; and
- the priority of the patient over other considerations, including monetary considerations.

Despite vast cultural differences, the nature of the medical profession itself determines near universal ethical constraints on medical practice. The only core issue in dispute is over the legitimacy of an ethic of benevolent medical paternalism as opposed to a focus on respect for the autonomy and rights of patients. In exploring this issue, we look at the specific objections to medical paternalism and the origin and basis of

principles of informed consent and patient autonomy. These are substantive philosophical issues, and we need to see whether the *reasons and arguments* do indeed support a patient-centered and autonomy-based conception of medical ethics.

Clearly a major reason for the shift in Western medical ethics is the more egalitarian ethic that has struck down hierarchical relationships in general. Relationships of authority, of course, still exist but the exercise of authority increasingly must be softened by a due regard to the underlying dignity and equality of humanity. I leave aside this significant background cultural shift in the structure of social relations and focus instead on two shifts in the medical relationship in particular. The first is the decline of the principle of therapeutic privilege and the second is the role of medical research in undermining the classic model of authoritarian paternalism.

Physician Authority and Therapeutic Privilege

One of the more significant features of the paternalistic approach is the practice of non-disclosure of bad medical news. It was common to insist that full disclosure can actually harm the prognosis of patients, and thus it is medically contra-indicated. The 1847 AMA Code of Ethics makes this point with its usual eloquence.

> Art. 1 § 4: A physician should not be forward to make gloomy prognostications because they savor of empiricism, by magnifying the importance of his services in the treatment or cure of the disease. But he should not fail, on proper occasions, to give to the friends of the patient timely notice of danger, when it really occurs; and even to the patient himself, if absolutely necessary. This office, however, is so peculiarly alarming when executed by him, that it ought to be declined whenever it can be assigned to any other person of sufficient judgment and delicacy. For, the physician should be the minister of hope and comfort to the sick; that, by such cordials to the drooping spirit, he may smooth the bed of death, revive expiring life, and counteract the depressing influence of those maladies which often disturb the tranquility of the most resigned, in their last moments. The life of a sick person can be shortened not only by the acts, but also by the words or the manner of a physician. It is, therefore, a sacred duty to guard himself carefully in this respect, and to avoid all things which have a tendency to discourage the patient and to depress his spirits.

The principle guiding disclosure here is essentially therapeutic, and thus the practice of non-disclosure is based on therapeutic privilege. The goal is to keep the patients spirits high, to be "the minister of hope and comfort," and to avoid "gloomy prognostications," unless "absolutely necessary." The justification for non-disclosure is that a blunt empirical disclosure of the medical facts can actually harm the patient.

These harms come in two forms. First, the attitude of the patient itself has a therapeutic effect, and so "the life of a sick person can be shortened not only by the acts, but also by the words or the manner of a physician." Second, a straightforward account of a patient's probable fate and perhaps clearly terminal condition unnecessarily darkens the last days of life. The physician should "smooth the bed of death … and counteract the depressing influence of those maladies which often disturb the tranquility of the most resigned, in their last moments." For these two reasons, "it is, therefore, a sacred duty to guard himself carefully in this respect, and to avoid all things which have a tendency to discourage the patient and to depress his spirits." This duty to decide what the patient needs to know, and to protect the patient from depressing news, is thus clearly aimed at the patient's own health and peace of mind.

This principle of therapeutic privilege has been under sustained attack for at least the last 30 years. The first and most obvious problem is that it makes widely sweeping and overbroad psychological generalizations. Some patients may become so despondent and depressed when given an honest diagnosis that disclosure is a medical harm, but it is implausible to claim that this is true of all patients, or even most patients. First, most people have a remarkable ability to retain hope in light of even the most improbable odds of recovery. Second, the research on death and dying documents a range

of responses to a dire diagnosis, including denial, anger, depression, "bargaining" with fate, and even acceptance of death. Different people respond differently, and most people go through at least some of these different responsesas stages, so to speakas they come to terms with the reality of their own imminent death. There is little evidence of any significant proportion of patients losing all hope and sinking into suicidal depression or listless despondency. It is much more likely that patients will steel themselves to "beat the odds" and survive despite the doctor's "gloomy prognostications." So at the very most, therapeutic privilege would warrant doctors withholding (or candy-coating) information *sometimes* from *some* patients.

The second problem with the doctrine of non-disclosure based on therapeutic privilege is that it does not distinguish specific medical harm from harm overall. In the case of a terminal diagnosis it is simply not true that what you don't know won't hurt you. Keeping the dying patient ignorant but as cheery and happy as is possible, even if this does indeed delay death (which is doubtful), may not in fact serve the overall best interest of the patient. The patient's interest maybe better served by coming to terms with death and using the remaining time as he or she sees fit. Even if I die sooner, I may seize the time I have left and use it in ways that serve my particular needs and values.

Medical Research and Consent

The doctor's charge to help, and above all not to harm, patients may seem too obvious to be worth stating. One of my favorite medical cartoons has a friend telling a patient in the waiting room, "Don't worry, a doctor's first rule is to not harm their patients." The patient responds, "What worries me is that they need a Rule for that!" One clear source of this classic limit on physician authority is that, in addition to the immediate medical end of helping patients, the doctor also has a natural desire to try new medical procedures; but doing so actually involves experimenting on one's patients. On the other hand, if new approaches are not tried, there will be no medical progress, which is itself detrimental to patients. There is thus always a tension between using already established procedures and trying new approaches. But in fighting disease and illness, physicians must stay focused on the primacy of the particular patient that is in their immediate care. When is it ethical to try new approaches with unknown risks? When is it ethical to essentially mix medical care and medical research?

The doctrine of informed consent was first born in the context of medical research where the patient's interests and the physician-researcher's interests can so easily come into conflict. It was also born out of the legacy of the Nazis' doctors and their clearly unethical experimentation on human subjects. It is not just Nazis, however, who are tempted by the clearly unethical. The unethical, and racist Tuskegee syphilis experiments in the United States are another clear example of research interest overwhelming patient interest. Informed consent for medical research began as a necessary research protocol to protect human subjects, and it has since spread to a more general requirement for all medical procedures.

Indeed, in the research environment, the paternalistic model of benevolent authoritarianism is especially out of place. Experimental procedures are by their very nature more risky than established procedures, and indeed might not benefit the patient at all. The Hippocratic imperative that physicians use *their own best judgment* to help, but above all to not harm, their patients is simply out of place. The aim of the research is to establish which procedures are beneficial and which are harmful. Consequently, in a research setting, patients are also experimental subjects, and thus their consent is a necessary tool that helps to protect them from excessive experimental zeal, or that simply allows them the opportunity to weigh the risks and benefits for themselves.

One reason that the principle of medical paternalism gave way to the principle of informed consent was the need for consent to medical research. As new treatments for previously hopeless diseases were developed, physicians needed to get the consent of patients for clinical trials. If one considers that cancers were the main area where physicians typically argued for non-disclosure, and the avalanche of treatments

for cancers that have been developed in the past 50 years, it is not surprising that attitudes to non-disclosure of cancer also changed. In a modern, advanced medical system, the prognosis for all diseases has improved remarkably. Full disclosure is rarely a death sentence anymore, and so the need to protect patients from the news of their own certain death has slipped away. Whatever the diagnosis, there is now almost always some basis for hope, and this significantly mitigates the potential shock and trauma of disclosure.

Similarly, consent to surgery, with full disclosure of risks, is necessary to avoid liability and so the new treatments, often involving surgery, brought in their wake the need for informed consent. In addition, there are always new pharmacological treatments for virtually every condition. Here again disclosure is necessary. Patients need to know the possible side-effects, and weigh these against the potential benefits. As research and new treatments merged seamlessly together, informed consent becomes a part of medicine (at least for any invasive or new treatment).

This shift in the ethics of medicine is an especially clear example of the relationship between ethical principles and particular circumstances. The progress of medicine itself causes a contextual shift that has led to a substantial change in medical ethics. This shift is truly remarkable in its extent. In 1962, in the Oken Survey, only 12% of physicians disclosed a diagnosis of cancer. This is despite the fact that 87% of the general public and thus patients even then wanted to know if they had cancer. By 1979, in the Novak Study, we see a complete change in physician behavior with 98% of physicians reporting that their usual policy was full disclosure of cancer and all serious medical conditions. The reasons for this transformation of medical practice are now clear. First, we have seen that the doctrine of therapeutic privilege lacks a sound basis, and second that the development and success of medicine brought with it a need for routine consent. The practice of non-disclosure was in fact an unnecessary fetter on medical research. Notice, however that this shows only that *non-disclosure is not justified by principles of medical paternalism*. These arguments don't directly challenge the doctrine of medical paternalism itself as an ethical approach to day-to-day practice.

The Physician-Patient Relationship Reconsidered

Classic medical paternalism has two core elements: First, the main duty of a physician is to help (*the principle of beneficence*), but above all do no harm (*the principle of non-maleficence*); and second, the physician is the judge of what is a benefit or harm to the patient (*the principle of physician authority*). In the new patient-centered approach to medicine, respect for patient autonomy replaces the physician's authority. In this new paradigm the first duty is to respect patient autonomy and self-determination. In judging beneficence and non-maleficence, the physician must base these judgments on *the particular patient's own values*; and second, the patient is the final judge of his or her own best interests, and thus of what is a benefit and what is a harm (*the principle of autonomy and informed consent*).

Of course, respect for the patient self-determination assumes that the patient is first of all *competent* and second of all *informed*. When patients are under duress or inadequately informed, their choices may not reflect what their best interest at all. Indeed when patients are incompetent, then they lack the preconditions for autonomous choice and thus we do not respect them as a self-determining person by honoring their request. Medical paternalism is most clearly questionable in cases where the patient is clearly competent and fully informed. There will be countless cases, however, where the patient's level of competence is not so clear or the extent of understanding is less than perfect. In the morass of these normal cases the physician must decide whether some degree of paternalism is called for. This is no easy or simple matter. The broad distinction between paternalism and autonomy seems overly simplistic.

Ezekiel and Linda Emanuel have argued that we actually need to distinguish four models of the physician-patient relationship: The Paternalistic Model, The Informational Model, The Interpretive Model, and the Deliberative Model. We have

discussed the paternalistic model at length; it is the distinction between the other three models that is now of interest.

According to *The Informational Model,* the physician presents the medical information and the patient supplies the values that govern deliberation and makes the decision. This model assumes that the patient's values are clear and well-defined and that the medical information provided by the physician is essentially value-neutral. Both of these assumptions are problematic. Indeed, merely presenting the medical facts does not even include a physician's recommendation, which is necessarily value-laden. If a physician were to simply report the medical facts, the patient would surely respond, "What do you think I should do?"

The Interpretive Model is more plausible in that it recognizes that in the medical context the physician must play a more active role in helping patients form and articulate their values. When faced with a difficult medical decision, the real consequences, the costs and benefits, of the different options typically will be unclear. Patients thus need help figuring out what they in fact want. Physicians here play the role of a medical advisor and counselor helping patients formulate their own values.

The last model is *The Deliberative Model* and it most fully blends the principles of beneficence and autonomy. On the deliberative model, the physician even more actively helps the patient shape their medically related values, and the goal is explicitly to have the patient affirm the *most justified and appropriate* set of medical values. This model recognizes that a patient's preferences are not clearly fixed and that they are instead always developing and, one hopes, improving. In a medical context, one's preferences will naturally develop and adjust to the new situation. As a result, even if the physician does not have the paternalistic role of a parent, ideally they should take on the role of a trusted advisor. The physician's goal is to work through difficult medical situations with patients and help them figure out what is really the *best* course of action. This last model attempts to blend respect for autonomy and a realistic medical paternalism; it provides a high ideal for physicians to meet.

The deliberative model always runs the risk of being too paternalistic, but it also rightly treats autonomy as more than simple preference satisfaction; autonomy is an achievement based on critical thought and reflection. On the other hand, it is an advantage of the interpretive model that it more starkly emphasizes that distinction between the physician's values and the patient's own values; the interpretive physician helps patients articulate their values but does not second-guess their patients. Which of these two models is "the best model" surely depends on the particular individuals involved, the prior relationship between physician and patient, and the particular medical issue under consideration. What seems clear, however, is that although the old ethic of medical paternalism is clearly dated, the physician's role is not captured by the unrealistic informative model, which artificially distinguishes facts and values. As the medical relationship evolves to more fully respect patient autonomy and patient rights, physicians must still exercise judgment that is rooted in their special expertise and experience. As the medical patriarch recedes into history, the contemporary physician must assume the more difficult role of a trusted and benevolent advisor. ❑

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Issues in Informed Consent and Globalization

By V. Manickavel

Informed consent in medical practice has emerged as a dominant bioethical consideration in recent times. As globalization demands to have uniform standard in all products and activities it is not surprising to hear arguments that we also ought to have a uniform code for informed consent. Informed consent is definitely one of the important principles to consider in the field of medicine. It recognizes autonomy and respect to the 'other' in the important human relationship between doctor and patient, but also the fact that society has the responsibility to protect the vulnerable partner of this relationship who is the patient.

In modern medicine, there are many aspects that have to be dealt with. Primarily, modern medicine is concerned with the treatment and cure of patients; that is, persons with discomfort or disease. Because of this, patients can become fearful of their health and worried about their future. In some cases, such anxiety may mean that they are not in a position to make a justified and rational decision. The process of obtaining an informed consent is primarily aimed at ensuring that the right information about the treatment and the course of the disease is received. This information ought to help them in deciding which is the most suitable option. In the circumstances where the patient is not able to comprehend the nature of treatment family members may be allowed to give consent for the treatment. However, every effort has to be made to find out the intention of the patient regarding the treatment. The health care giver should not ignore the wishes of the patient even if it may result in their death. For example, knowingly giving a blood transfusion to an adult Jehovah's Witness even if the patient is not able to express their opinion can be considered as intrusion upon the autonomy of that patient. In such a case unless consent is given by the patient for the transfusion, it should be withheld.

Further, the patient is free to choose the treatment options given by the health care giver. To ensure this is the case, patients should be provided with all information regarding the treatment and side effects. The patient should be able to comprehend all the information, make a decision, and accept responsibility for the decision. Here, the health care payment providers should not restrict the options.

Research is part of modern medicine and progress depends on this aspect of modern medicine. There are two types of research we have to consider. One is clinical research and the other is medical research.

On this view, 'clinical research' is an activity usually conducted within the place of treatment. The goal of this research is, generally, to find a better treatment option or to find an efficient way

of doing surgery (in the case of surgical research). All other types of research, including research on healthy subjects counts as 'medical research'. This will include epidemiological studies and all phases of drug testing. Global or transnational research is not uncommon in this type of medical research. There are many aspects that have to be considered in the process of obtaining an informed consent in this type of medical research.

At the turn of this century many agencies such as the Nuffield Council of Bioethics in the UK and the National Bioethics Advisory Commission in the US outlined frameworks for thinking about research in the developing world. Most developing countries were satisfied with the conclusions of such documents, despite the fact they were produced by the 'developed' countries and shaped by their cultural practices. For example, such documents emphasized human dignity and respect for autonomy, and although they draw attention to the importance of families and communities, they generally stress the role of individual decision making. Another example, of a potential imbalance is that, although they agree in recognizing and protecting some compromised populations where individual consent can not be obtained, others are missing. One notable absence is that of the economically compromised. In a globalized world the danger is that such people make decisions based on economics rather than considering their own health: selling their kidney or renting their wombs. Very often this practice is welcomed and is accepted by health care givers as a means of narrowing the gap between the rich and poor. However, any such financial benefit tends to be short term, and in extreme cases the poor are even willing to sell their other kidney, despite the results for their own life. Poverty alleviation is a social problem and such simple solutions do not work. Such rings are operating illegally across national borders, and in some cases, the kidneys were stolen from people who were undergoing surgery for a different procedure.

Wherever, culture is an issue in obtaining the individual informed consent the current practice is to concentrate upon obtaining legal documentation of informed consent by other means. In this way we do not deliver the right information to enable the individuals to give an informed consent. Many times the person providing the information, does not explain to the individuals concerned the appropriate information and the risks and benefits of participation. This is very much in practice in transnational medical research as it is advantageous to the sponsor. This type of double standard practiced by the host countries in applying bioethical regulations or not applying them had been discussed at length elsewhere.[1]

Culture should be recognized as of prime importance as a factor in respecting personhood. Sometimes the cultural practices in the host countries may not be in agreement with the sponsor countries' practices and international bioethical guidelines. In such situations instead of manipulating or interfering with the local moral values the research may be conducted elsewhere where is acceptable. In some economically compromised countries collaborators may be willing to overlook or manipulate the international bioethical regulations. This should not be allowed at any cost. This may be interpreted as bioethical imperialism. However, this is the only way to promote autonomy across the whole of humanity.

For this to work we should recognize two sets of values, in applying bioethical regulations. One set of values are purely moral based and can be applied only to the local population. Here, the local cultural practices should be given importance. These set of values should guide us in implementing bioethical regulations in the local research activities. However, when transnational research is involved, we should uniformly apply the bioethical regulations proposed by WHO, CIOMS, UNESCO or any other international agencies governing the modern medical practices. In transnational research, only research activities that do not compromise these universal bioethical regulations should be undertaken. In following this approach, we could avoid the horror stories we hear in the press. The local cultural practices should be given consideration in the national research and in transnational research they should neither take advantage of the sponsor nor host and both should always work with

international rather than national bioethical regulations. Moral values should be understood to be based heavily on the local cultural values and are influenced by time and place. However, ethical values transcend space and time and are universally applicable to all humanity.

In summary, we should recognize that the practice of modern medicine has changed and the market does play a dominant role.[2] As a result the prime bioethical values of medical practice of non-maleficence and beneficence have given way to those of autonomy and distributive justice. Informed consent thus has become very important as it gives respect to individuals. Further in transnational research international bioethical guidelines should be used, and if there is a clash with local values, the research should be conducted in some other place. A utilitarian approach should not be allowed to govern in the application of bioethical guidelines in transnational research.❑

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Informed Consent in Sri Lanka: *A comprehensive analysis*

By Chesmal Siriwardhana, Athula Sumathipala & Sisira Siribaddana

The pace and complexity of recent developments in biomedical research have created a wide range of concerns about the extent to which research participants are aware of just what it means to participate in a research project. In the developing world these problems are particularly acute given the fact that subjects may not be familiar with the methods, objectives or outcomes of scientific research.

The potential for abuse, intentional or unintentional is considerable and strong given that international collaborations are taking place more frequently. It may be possible to assume that international collaborations improve the consent process, but it could also lead to exploitation of participants, especially from vulnerable populations.

Sri Lanka has a long and well-established tradition of scientific research. However, this tends to be individualistic and fragmented. As noted in the Annual Health Bulletin published by the Ministry of Health, an over-arching research culture is lacking and there is a near absence of multidisciplinary and intersectional approaches to research.[1] As a consequence, debates over how best to facilitate, manage and regulate scientific research are still in their infancy, and attempts are underway to incorporate local and international bioethical perspectives into current practice.[2]

The Institute for Research & Development (IRD), a non-profit private academic institution mainly involved in health research, initiated a research project in 2004 to fill the void in information regarding informed consent and related issues in Sri Lanka.

This project was led by Dr Athula Sumathipala and was conducted in collaboration with academics from Kings College, London. IRD received a grant from the Wellcome Trust to fund the research work. A team of researchers from IRD and King's College was involved in the designing, implementation and conduct of the project. Two research papers containing the findings from the project have been published in BMC Medical Ethics, a well-known peer-reviewed publication on bioethics.[3,4]

The study aimed to provide a comprehensive review of consent practices as they were portrayed in research projects originating from, and subsequently carried out in Sri Lanka over the last five years. The study also aimed to capture the perspectives of researchers, research participants and those involved with ethical review process as members of ethics

review committees in Sri Lanka. Another important aim of the project was to enhance capacity building by conducting empirical research in ethics.

Three main components were featured in the study. These components were designed to cover the whole range of issues from informed consent and ethics review of research to understanding about health research by general public;

1. An analysis of biomedical publications originating from Sri Lanka on Ethics Review Committee approval and informed consent
2. A survey among ethics committee members about the current practices on granting ethical approval for research proposals and their views on informed consent.
3. An analysis of the public understanding about health research.

As mentioned above, two research papers, containing the findings from the first and second components of this study has been published. A paper containing findings from the third component is in the process of preparation.

In this article, a summary of key points from the two published papers as well as an overall description about the whole project is presented.

Ethics Review Committee approval and informed consent: an analysis of biomedical publications originating from Sri Lanka

This section of the study aimed to determine the extent of ERC approval and informed consent procedure documentation in locally and internationally published human subject research carried out in Sri Lanka.

Theses from 1985 to 2005 available at the Postgraduate Institute of Medicine (PGIM) library affiliated to the University of Colombo were scrutinized using checklists agreed in consultation with senior research collaborators. A Medline search was carried out with MeSH major and minor heading 'Sri Lanka' as the search term for international publications originating in Sri Lanka during 1999 to 2004. All research publications from Ceylon Medical Journal (CMJ) during 1999 to 2005 were also scrutinized.

From a total of 291 theses found at the PGIM, Colombo, matching the research criteria, 34% documented ERC approvals and 61% documented obtaining consent. Findings from the international journal survey indicated that 250 publications originated from Sri Lanka of which only 79 full text original research publications could be accessed electronically. From these, 38% documented ERC approval and 39% documented obtaining consent. In the Ceylon Medical Journal 36% documented ERC approval and 37% documented obtaining consent.

Through these findings, it was observed that only one third of the publications scrutinized recorded ERC approval and procurement of informed consent. However, it was also found out that there is a positive trend in documenting these ethical requirements in local postgraduate research and in the local medical journal.

Informed consent in Sri Lanka: A survey among ethics committee members

Approval of the research proposal by an ethical review committee from both sponsoring and host countries is a generally agreed requirement in externally sponsored research.

However, capacity for ethics review is not universal. This part of the study tried to identify opinions and views of the members serving in ethical review and ethics committees in Sri Lanka on informed consent, essential components in the information leaflet and the consent form in order to provide insight to this issue.

A series of consensus generation meetings on the initial protocol were conducted and a task oriented interview guide was developed. The interview was based on open-ended questionnaire. Also, the participants were given a WHO checklist on informed consent and

requested to rate the items on a three point scale ranging from extremely important to not important.

Twenty-nine members from several functioning ethics committees from various universities throughout Sri Lanka participated in this stage of the study. The majority of participants (23), believed a copy of the information leaflet and consent form, should accompany research proposal. Opinions about the items that should be included in the information leaflets varied. Participants identified various criteria as requirements in the information leaflet and in the consent form. The majority, 20 (69%), believed that all research need ethical approval but identified limited human resource, time and inadequate capacity as constraints. Fifteen (52%) believed that written consent is not required for all research. Verbal consent emerged as an alternative to written consent. The majority of participants rated all components of the WHO checklist as important.

The number of themes generated for the consent form was numerically similar with the information leaflet and had several overlaps. This suggests that the consent form should be itemized to reflect the contents covered in the information leaflet. The participants' opinion on components of the information leaflets and consent forms proved to be similar to the WHO checklist on informed consent, suggesting that ERC members share a functional knowledge of the basics of informed consent and an ethical approval of research.

Public understanding of health research

The international research community has discussed, debated and promoted the issue of informed consent in human subject research for a considerable time. Even if this is true, a considerable gap still exists between research participants and investigators, particularly so in the developing world where an authoritative position is held by the academia.

Lack of proper understanding about what and how the public understand about science, research and consent processes will only widen this existing gap and create more opportunities for various malpractices in conducting research and exploitation of vulnerable subjects, especially in the developing world setting.

Assessing the public understanding of the research may vary depending on many factors. Education, existence of a research culture, literacy rate are few of the main factors while the value placed on individual informed consent practices may have certain cultural variations.

At this stage the study was designed to measure the public understanding about health research by capturing views and assessing perspectives of healthcare professionals, research participants, and non-research participating lay public in the developing country setting of Sri Lanka.

A series of focus group meetings were conducted where ethical dilemmas in recruiting participants for the study were discussed in depth. An interview based on an open-ended questionnaire was conducted with participants selected from a pool of persons with/without previous research experience.

A total of 66 persons participated. These included 30 previous research project participants and 36 persons without prior research participation including selected clinic attendees in the government and GP settings, researchers (medical and non-medical), research assistants and teachers.

The findings from this stage of the project are to be published soon.

Findings from this study so far has revealed valuable information about consent practices in contemporary Sri Lanka and the degree of adherence to the international standards in the informed consent process in the healthcare research sector of the country.

This project has provided evidence on the use and the quality of the information leaflets and consent forms. It has also provided insight in to the degree of understanding of research participants and thus will help healthcare

researchers to understand and judge whether they are actually doing what they think they are doing, among their sincere efforts to safeguard research participants. The understanding gained from this study will have implications for the change in practices of informed consent procedures and will allow researchers to plan the best strategies to inform the participants in a research project and obtain their consent without any collusion and conflicts of interest.❑

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Falling Short of the Mark: *Informed consent as a measure for choice in prenatal screening*

By Victoria Seavilleklein

Introduction

Informed consent is commonly used as a placeholder for individual autonomy in health care, and this is particularly obvious in the case of prenatal screening. Prenatal screening consists of maternal serum screening (a blood test done on the pregnant woman) and nuchal translucency screening (an ultrasound done on the fetus). Traditionally, it has been offered to 'high-risk' women to detect the likelihood of certain conditions in the fetus, namely Down syndrome, open neural tube defects (primarily spina bifida), and Trisomy 18. However, screening is expanding in Canada, both in terms of the number of conditions that are screened for and the number of women to whom it is offered. The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommended in February 2007 that screening be expanded to include all pregnant women regardless of age, disease history or risk status.[1] Similar expansions are occurring in other countries.[2]

One of the principle justifications for this screening and its expansion is that it enhances reproductive choice for pregnant women. Since the conditions screened for usually result in some form of disability, this screening allows women to decide the kind of children that they want to raise. Given the importance of autonomy in our society generally, and in genetics in particular due to past transgressions of the eugenics movements, the value of reproductive choice is particularly emphasized. As in other health care interventions, however, autonomy is held to be protected by the theory of informed consent. In this article, I explore informed consent as a measure for women's choice in prenatal screening and argue that it fails to protect and promote women's reproductive choice.

Informed Consent

Tom Beauchamp and James Childress' widely popularized account of informed consent breaks it down into five elements: 1) competence; 2) disclosure; 3) understanding; 4) voluntariness; and 5) consent (i.e. Authorization).[3] Most pregnant women are competent to make decisions, so research studying the success of informed consent in prenatal screening tends to focus on the remaining four elements. According to a multitude of research studies and a health technology assessment of 78 studies conducted in North America, the UK, and other European countries, informed consent is not being met in the vast majority of cases in prenatal screening.[4-7]

There is no one element of informed consent that consistently fails to achieve an adequate threshold level in prenatal screening. Rather, the adequacy of each of disclosure, understanding, voluntariness and consent can be challenged in light of the empirical evidence of current practice. For example, pregnant women must be told about the screening, the conditions being screened for, the meaning of the potential results and the follow-up options.[8] However, these

discussions take place during a regular and short doctor's visit where only a few minutes are spent discussing the screening.[9,10] In many cases, relevant details are not disclosed correctly or not disclosed at all.[5,9,11]

Women must also understand enough about the procedure and its consequences in order to make a decision. Studies also show significant failures in meeting this standard in prenatal screening. For example, a large study conducted in Canada of almost a thousand well-educated pregnant women found 'information gaps overall and in all domains.'[5] This lack of understanding may be due partly to the fact that it is very hard to apply population statistics at the individual level; after all, a chance of 1 in 250 of having a child with a certain condition is a much more meaningful statistic at a group level than for any individual woman within that group.

A decision must then be made voluntarily, or without substantially controlling influence. Decisions are always influenced by many factors, but they must still be made primarily on the basis of one's own will to satisfy informed consent. Sometimes concerns about future lawsuits if women have a child with a disability may cause health care providers to try to direct women's choices in favour of having the testing.[10] Pregnant women also cannot make decisions voluntarily if they are not even asked whether they want the testing; if they are not asked, then the last of the five elements, consent or authorization, is also not met. In the early days of prenatal screening in Canada, 40% of clinicians performed the screening without asking pregnant women for their authorization and only 38% asked for express consent the form of consent currently recommended by the SOGC.[8] A more recent study in Ontario found that 360 out of 941 participants believed they did not have a choice about undergoing screening.[5]

Therefore, even though informed consent is being relied upon to safeguard autonomy in the practice of prenatal screening, it is doing a very poor job. This is not to say that informed consent is never achieved in prenatal screening. Some clinicians may be very skilled at disclosing a lot of information in a short period of time, and some pregnant women may be very capable of understanding this information and providing voluntary consent (or refusal) for the test. However, empirical evidence shows that in most cases, adequate standards of informed consent are not being met.

Beyond Informed Consent

Informed consent provides a basic protection for women's choice in the clinic; as a result, it is essential that this process be improved. However, the theory of informed consent itself may be inadequate to reflect what advocates of screening mean when they talk about screening enhancing women's choices about their reproductive lives. Informed consent simply measures whether patients can agree to or decline a procedure once they have weighed its benefits and risks; the theory of informed consent takes for granted both the options and the practice itself. Whether women really want these choices or whether other screens or options would better promote women's reproductive choice is an open question.

A broader interpretation of choice that allows an analysis of prenatal screening both within and outside the clinic would reveal additional insights regarding the implications of prenatal screening for women's choice. A relational approach to choice, for example, enables an analysis of prenatal screening in the larger social, cultural, and political context and reveals additional challenges facing prenatal screening as a means of protecting and promoting women's autonomy.

For a closer look at these issues and an exploration of a relational approach to measure choice in prenatal screening, please see this author's upcoming article in the Bioethics special issue, volume 22, number 28, October 2008.❑

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Informed Consent and the Possibilities of Newborn Screening

By Niels Nijsingh

To some, it is self-evident that in the case of medical interventions in relation to children, the perspective of parents trumps that of the state. It is deemed patently obvious that when different, mutually exclusive and reasonable perspectives on the best course of action are possible, parents should be in the position to consent or dissent. The practice of newborn screening offers reasons to refute this common view, or at least to refine it.

Newborn screening usually involves taking a drop of blood from the heel of a newborn infant, which is why the procedure is also referred to as the 'heel prick'. The blood is analyzed and screened for a variety of inborn diseases. The heel prick has been a common practice in many countries for over thirty years now. It started out as a screening program solely for the purpose of detecting children affected with PKU (phenylketonuria), but over the years different diseases have been added to the screening programs. Due to proceeding technological developments, more and more possibilities for screening have become available. As a result, there has been an expansion in the different screening programs that now routinely include dozens of (relatively rare) diseases. Not all of the possibilities for expansion, however, appeal to everyone.

One category of diseases that is particularly contested is that of conditions where early detection has no medical benefit. Some people hold that it is wrong to "force feed" people information that they have no use for. Others claim that withholding such information would on the contrary be unjustifiably paternalistic. In any case, it is unclear whether diseases of this category are suitable candidates for screening programs. Both positions seem reasonable and there is no a priori reason to prefer one over the other.

A tempting response to the stand-off between proponents and opponents of screening for these diseases is to appeal to the right to autonomous choice: expanded screening requires a proper informed consent procedure, thus ensuring the individual's right to choose what one deems right. This argument appeals to the widely shared idea that in a liberal society, individuals should be in a position to choose among divergent (reasonable) conceptions of the good life.

Things are not that simple however. For one, it is not clear how the right to autonomous choice of parents relates to the interests of the child. It is not even clear why in the case of parental

discretion over their children one should speak of 'autonomy' at all. Furthermore, even if we grant that parents exercise the right to autonomy when making choices concerning their children, it has been doubted whether the relation between autonomy and informed consent is as straightforward as the argument supposes.[1] At the very least, this would require fleshing out the notion of the 'right to autonomy', which is not likely to be an uncontroversial undertaking.

Distinct from these problems is the complication that the informed consent procedure may *itself* be morally problematic. Elsewhere, I have argued that informed consent procedures can be burdensome, especially when we consider large scale operations, such as screening.[2] Two types of burdens may occur here, burdens of information and burdens of choice. If we want parents to make an informed decision, vast amounts of highly complex information need to be processed. This may be time-consuming and may require - given the rarity of the diseases - excessive efforts of all parties involved. The burdens of choice connect to the implicit responsibility that is attributed to parents for making the *right* choice. Parents tend to want what is best for their child. Therefore, explicitly laying down the choice (whether or not to screen) before the parents may lead to unnecessary anxiety and doubt.

The implication of this is that an appeal to informed consent - as a tool to do justice to the worries we have towards the expansion of newborn screening - may be morally problematic. Particularly for an expanded program, proper informed consent may not be desirable, even assuming that it would be feasible. However, this in itself should not deter us from such an expansion. To refrain from expanding the heel prick, thus limiting people's possibilities for choosing between different options, would pre-empt their decisions in a way that is equally problematic. Hence, even if we think that parental autonomy trumps all other considerations here, it does not follow that a more limited program is preferable.

What does follow is that whatever policy one chooses, one has to accept that informed consent does not guarantee the moral permissibility, but on the contrary might threaten the acceptability of that policy. Therefore, when we discuss the desirability of expanding newborn screening, we should be aware that this issue cannot be separated from questions concerning the value and desirability of informed consent. It will not do to simply expand, hoping that the resulting difficulties will be solved by way of an informed consent procedure.❑

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Rethinking Informed Consent

By Neil C. Manson & Onora O'Neill

Informed consent is not only one of the cornerstones of bioethics and medical ethics, but has assumed central place in a very broad range of legal and regulatory instruments around the world. Informed consent is typically justified by appeals to respect for individual autonomy and lurking in the background of any discussion of informed consent is a concern with the limits of paternalism. The shift of informed consent to centre stage, in a variety of arenas, brings with it a wide variety of problems. How much information should a person have in order to be properly informed? Does more information mean more informed? What if people do not want more information? Should people be coerced or forced into accepting it? Isn't there a risk of being paternalistic, insisting that they be informed in their own best interests (where 'best' means something other than 'the agent's own view of what's best for her')?

Issues about the conveyance of informationhow much, by whom, at what time, and so onare central to discussions of informed consent. But information features in bioethics in a second broader way. Medical information about individuals is a key part of clinical care and medical research. The acquisition, storage and

use of medical information are regulated by various forms of data protection legislation. Such legislation and regulation protects 'informational privacy' rights. Data protection legislation identifies legally and ethically significant types of information—e.g., personal information—and then specifies a range of obligations, rights, penalties and so on to govern acts and actors using such types of information in certain contexts.

But here too there are problems. In some epidemiological research, for example, informed consent must be sought for the secondary use of nonanonymised personal data (where total anonymisation would undermine the research), even though the concern is to discover features about populations, not about identifiable individuals. Seeking and gaining consent is costly, time consuming and may, in many cases, prove to be impossible. Gaining informed consent proves to be costly and time consuming in many other areas of biomedicine. Given finite resources, the question arises as to what constitutes ethically sound practice in biomedicine.

Rethinking Informed Consent in Bioethics aims to engage with puzzles and problems with consent, and with the regulation of information, in a new way.[1] Rather than viewing informed consent as a device to ensure respect for individual autonomy, informed consent is identified as—obviously, perhaps—a species of consent; but then—less obviously—consent is construed as a kind of communicative act which is not fundamental, but acts as waiver of other more fundamental first-order rights. Consent is a communicative act which adjusts, and allows others to keep track of adjustments to, various rights and obligations. For example, in consenting to a medical examination I waive—temporarily and locally—my rights against invasive acts, and against battery (by touching). Viewed this way, informed consent can never be fundamental. Consent is a procedural, communicative, device used to adjust and shape duties and obligations. It is not denied that individual liberty has a role to play here. Consent involves a second-order liberty right (i.e., the right to decide whether or not to waive one's first order rights, in the context specified), but consent should never be viewed in isolation from broader sets of more fundamental first-order rights and correlative obligations.

Consent is a communicative act, and in order for consent to be valid, various parties need to know certain things. Those whose acts would otherwise be impermissible—e.g., a clinician who is about to do an intimate examination—need to know that first-order rights have been waived. Those who give consent need to know about proposed, or intended, courses of action that would otherwise infringe their first-order rights. But here two points are stressed. First, how this knowledge is obtained is likely to be heterogeneous, and will vary from context to context. Second, how we think about knowledge and communication influences how we think about consent.

Our everyday talk and thought about knowledge and communication is shaped by a set of metaphors—conduit and container metaphors—where information is acquired, stored, conveyed, transferred, passed on, concealed, broadcast, distributed, taken up, and so on. The use of such metaphors is not wrong, but they do highlight some aspects of communication and information whilst downplaying others. In particular, many rational and normative elements of communication (which have to be in place for communication to take place at all) are downplayed or ignored: norms of truthfulness and relevance, for example. This is particularly relevant for bioethics: first, because a central ethical notion—informed consent—typically framed in terms of information being conveyed from one party to another; second because the regulation of information has implications for clinical practice and biomedical research.

Rethinking Informed Consent applies the model of consent, and the discussion of information, to a range of issues to do with consent, data protection, confidentiality and accountability. For example, drawing upon this alternative way of thinking about consent and information it is argued that many secondary uses of medical data are ethically permissible and that they breach no important first-order rights. Consent is

not required, but seems to be required because the conduit and container metaphors make it easy to conceive of information as falling into significant classes—and this is central to data protection legislation—as if all uses or acts involving certain types of information were impermissible.

More generally, by identifying consent as a communicative act within a rich framework of communicative norms questions are raised about why and whether narrow formalized forms of communication (e.g., standard "consent" forms) are ethically required at all. The adjustment of rights and obligations by communication does not presuppose it, and communication is typically an open-ended and unformalised affair. We acknowledge that there are other demands which shape communication—legal, institutional, financial and administrative demands, for example—but it is important to keep apart putative ethical justifications for informed consent from pragmatic considerations.

In short, by focusing on first order rights and obligations, upon consent as a communicative act, and upon a proper conception of what communicative action involves, we believe we can secure a more robust and defensible basis for core bioethical notions like informed consent and informational privacy.❑

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An Asian Initiative to Tackle Organ Trafficking: Asian Task Force Recommendations

By Alireza Bagheri

The increasing gap between organ demand and supply for transplantation has been documented worldwide. While this gap is widening, patients in need have been traveling beyond geographical borders to receive transplants, either because of organ shortage at home or because transplant service has not been well established in their home countries. As a result, agents and middlemen have exploited the situation as organ trafficking expands worldwide. However, despite of the fact that organ trafficking and exploitation of individuals as organ providers are reported worldwide, limited practical measures for tackling the issues have been put into practice. In fact, the experiences from the past show, that the mere condemnation could not stop exploitation of poor as organ providers.

Many Asian countries have notoriously become the sources of black market organs and the hub for transplant tourism which serves the patients from wealthier countries.

The Asian Task Force on Organ Trafficking was established to formulate a set of recommendations on how to tackle organ trafficking particularly in Asia and now calls on regional efforts to tackle organ trafficking. The Task Force consists of fourteen independent scholars from Asia and other parts of the world. The invited scholars were experts from multidisciplinary fields of medicine, ethics, law, philosophy and social science which brought their experiences and innovative ideas to the Task Force for developing strategies and recommendations on dealing with organ trafficking in Asia. With the support of the Center for Ethics, Law, and Society in Biomedicine & Technology, joint with the Asian Center of WTO and International Health Law and Policy, National Taiwan University the Task Force members met twice in 2007 and 2008 in Taipei, Taiwan.

The Asian initiative aimed to develop a set of recommendations to guide institutions and health professionals and Asian governments in particular on how to deal with the issue of organ trafficking collectively. The working group received thoughtful and constructive comments from individual scholars, organizations and government officials to our consultation document as well as from the referees of the draft Recommendations.

The Task Force hopes that these recommendations will be fully considered and endorsed by Asian governments, health professionals and organizations who are equally committed to the prevention and elimination of organ trafficking.

Recommendations on the Prohibition, Prevention and Elimination of Organ Trafficking In Asia

1. Urge relevant organizations and governments to promote greater awareness of the ethical, legal and social issues relating to organ trafficking in Asia through education;

2. Urge the passage of legislation or an international treaty which would be necessary for the effective implementation of international norms that relate to the organ trafficking;

3. Call on all countries to pass legislation clearly defining prohibitions as well as allowable practices pertaining to organ transplantation, including those related to the recovery and donation of organs;

4. Support Asian countries in their commitments to prohibit and prevent organ trafficking and undertake full implementation of the United Nations Convention Against Trans-national Organised Crime and its protocols;

5. Urge Asian countries to rely more on deceased donation (including the use of organ recovery from brain dead and non-heart beating donors) in order to increase supply and to identify alternative solutions in order to decrease organ demand, such as prevention and treatment of organ failure;

6. Urge Asian countries to address the needs of the population who suffer from economic disadvantages in order to prevent organ trafficking;

7. Encourage Asian countries to conduct an inventory of Non-Governmental Organizations and other groups in the region that could be called upon for help;

8. Propose the establishment of reliable infrastructure in the countries of the region to monitor activities pertaining to organ trafficking;

9. Urge Asian countries to achieve national self-sufficiency in order to provide a sufficient number of organs for their residents who need transplantation;

10. Propose to establish registries of transplant recipients and waiting lists, as well as registries of living donors to facilitate the implementation of activities that could serve to prevent and eliminate organ trafficking;

11. Encourage to conduct further studies and exchange of information regarding practices pertaining to organ trafficking and the related socio-cultural, economic and political issues;

12. Urge Asian countries to exchange information and technical expertise relating to prevention and elimination of organ trafficking;

13. Urge all parties involved in organ transplantation to observe transparency and accountability in their related regulations and practices;

14. Call on all countries to adopt a policy which discourages their citizens to travel abroad in order to obtain organs for transplantation;

15. Urge insurance companies to abstain from policies that have the effect of supporting illegal practices in organ transplantation;

16. Urge Asian countries to restrict organ transplantation to recipients with the same nationality as the donors;

17. Encourage all countries to consider a reasonable and socially accepted cost reimbursement as compensation for altruistic living organ donors;

18. Enjoin all parties involved to ensure the physical and psychological health of live organ donors by providing counseling and supports, such as insurance coverage for the long-term follow-up and potential donation related disability, death and job loss;

19. Urge countries to engage in consultations internally and externally with all interested parties regarding these Recommendations. The Asian Task Force is also ready to provide consultation to the interested Asian governments; and

20. Urge all countries, organizations and individuals to bring these Recommendations to the attention of the concerned Ministries of Health, medical associations, and all national and international institutions with functions relevant to organ transplantation.

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Bioethics in Singapore

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Bioethics was formally recognised as a matter of public interest in Singapore with the establishment of the Bioethics Advisory Committee (BAC; www.bioethics-singapore.org) by the Cabinet in December 2000, to provide the government with advice on ethical, legal and social issues arising from biomedical research. Since then, the BAC has provided recommendations to the Steering Committee on Life Sciences, which is responsible for fostering the development of biomedical science through various policy measures including the coordination of activities of government ministries such as the Ministry of Trade and Industry, the Ministry of Education and the Ministry of Health (MOH). These developments follow from the government's desire to develop Singapore into a premier centre for life sciences research and development activities, ranging from clinical trials to full scale manufacturing and healthcare delivery. As such, the establishment of the BAC is a proactive initiative to ensure that biomedical research in Singapore is conducted under standards of ethical governance that are acceptable both locally and internationally.

The BAC works through sub-committees and working groups. The Human Stem Cell Research Sub-Committee (HSCRS) and the Human Genetics Sub-Committee (HGS) were formed in 2001 and by 2007 had concluded their work. The work of the Publicity and Education Sub-Committee (PES), also set up in 2001, is still ongoing. In 2007, a Sub-committee on Research involving Human Participants and a Working Group on Human Embryo and Chimera Research (HECR) were formed, and their work is also ongoing. Between 2002 to 2008, five reports with recommendations have been published, relating to human embryonic stem cell research and cloning, human tissue research, research involving human subjects and genetic research. All the recommendations have been accepted by the government.

The first set of recommendations was prepared by the HSCRS and published in a report entitled "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning" in June 2002. These recommendations include proposals for stringent regulation of human embryonic stem cell research in Singapore and the legal prohibition of reproductive cloning, which was taken up by the legislature with the enactment of the *Human Cloning and other Prohibited Practices Act* in 2004. Following the publication of these recommendations, scientific and technological developments in relation to stem cell research necessitated continuing review of the ethical policies. In 2007, a review of the 2002 recommendations was formally undertaken by the HECR Working Group, with focus on ethical, legal and social issues arising from the procurement and use of human eggs for research, and on research involving human-animal combinations. Apart from scientific developments, review of these areas was considered to be necessary following the scandal involving unethical procurement of human eggs for research in South Korea and, more importantly, from revisions to ethical policies and guidelines in the United States, Australia, Canada and a number of European countries such as the Britain and Denmark. The BAC's recommendations relating to the donation of human eggs for biomedical research will be published at the end of 2008, following a public consultation in late 2007. A consultation paper on research involving human-animal combinations was also distributed for public discussion and comment in early 2008. Recommendations on this subject are still being considered by the HECR Working Group and the BAC.

The HGS was responsible for a series of recommendations which served to systematise ethical governance of research using human tissue, research involving human subjects and genetic research. These recommendations were published in four reports. The report on "Human Tissue Research" was published in November 2002 to provide a set of national ethical guidelines applicable to all persons conducting human tissue banking and research using human tissue in Singapore. The ethical principles embodied in the guidelines include the primacy of the welfare of tissue donors, the need for informed consent and confidentiality, respect

for the human body and sensitivity towards the religious and cultural perspectives and traditions of tissue donors.

In November 2004, publication of the report on "Research Involving Human Subjects: Guidelines for IRBs" essentially formalised the requirement for all human biomedical research in Singapore, including research involving human tissue or medical information, to be subject to ethics review by institutional review boards. These guidelines built on the existing system of regulations for pharmaceutical trials and biomedical research conducted by hospitals, private clinics and other healthcare establishments under the supervision of the MOH. They also set out the constitution, accreditation and operation of institutional review boards, as well as their roles and responsibilities, in addition to the responsibilities of research institutions and individual researchers. In the main, the BAC regards high standards of ethical governance for the protection of life, health, privacy and dignity of human subjects in biomedical research as vital to the progress of biomedical sciences in Singapore and sees a suitable system of ethics review as an essential regulatory mechanism to this end.

Ethical governance of genetic research was formulated at two different junctures: at the point where genetic information is derived through various means of testing, and in the management and use of the information itself. The report on "Genetic Testing and Genetic Research" published in November 2005 served to operationalise a number of internationally recognised ethical principles in the local context. These ethical principles include the voluntary and informed basis of genetic testing, special care and responsibility when vulnerable persons are tested, and privacy safeguards for genetic information. The BAC also recommended that non-consensual or deceitful taking of human tissue for the purpose of genetic testing be prohibited by law. A further report relating to genetic information was published in May 2007 entitled "Personal Information in Biomedical Research". The issues considered in the report include legal protection of personal information in biomedical research, privacy and confidentiality concerns, and access to personal information by third parties such as employers and insurers. The BAC's recommendation to provide a firm legal footing to disease registries that employ personal information in public health research was taken up in legislation with the enactment of the *National Registries of Disease Act* later that year.

The recommendations of the BAC have the benefit of professional feedback and, except for the Report on Research Involving Human Subjects, also extensive public feedback. As part of the process of public consultation, healthcare and research institutions, governmental entities, professional and religious organisations are specifically invited to provide their views on proposed recommendations as set out and explained in a consultation paper. In order to encourage public deliberation and participation, all the public consultations are widely publicised by the local media, and at least one public forum is organised to explain the ethical issues and provide the public with an opportunity to clarify any doubts. In a number of cases, special meetings with religious leaders and with researchers were convened. Each report and the recommendations presented are prepared and finalised with advice from an International Panel of Experts. The current experts on this Panel are Professor Martin Bobrow (University of Cambridge), Professor Bartha Knoppers (University of Montreal), Professor Bernard Lo (University of California at San Francisco) and Dr. Thomas Murray (President of the Hastings Center).

As a policy body, the BAC's deliberations have been mainly anticipatory or forward-looking rather than routine reviews or urgent responses to an immediate or imminent crisis. The general approach of the BAC in formulating recommendations has a number of features similar to those in a consensus-recommendation model of practicing ethics that has been proposed for understanding the functions of ethics committees in institutional settings. The model presents an ethics committee as a forum for non-adversarial discussions aimed at hearing and mediating various relevant and often

conflicting perspectives. When a consensus develops from such discussion, the committee may articulate the consensus as a recommendation. This focus on consensus-building to find practicable responses to ethical challenges, through enabling ongoing dialogue about ethical issues in a pluralistic and non-confrontational manner, is typical of the BAC's approach.

In addition, the recommendations of the BAC have been grounded in the historical, as well as socio-cultural, situation of Singapore. Certain values, such as justice in a pluralistic and democratic sense, have acquired significance in public deliberations over time. Public policy should be just, in that no particular racial group or religious doctrine should be given preferential treatment in public discourse, even though both religious and secular views are solicited and carefully considered. Racial and religious harmony has always been particularly important for Singapore, and this is reflected in public policies, as well as in BAC's approach to formulating bioethics policies. Broader notions of common good (which includes the well-entrenched notion of "family before self"), consensus and harmony are some of the other features in BAC's approach. But aside from these, the BAC's approach also reflects elements of what Sheila Jasanoff considers to be a civic epistemology of the life sciences. In her study of the development of life sciences policies by bodies similar to the BAC in the United States, Britain and Germany, she identified six constitutive and interrelated dimensions of civic epistemology: (1) the dominant participatory styles of public knowledge-making; (2) the methods of ensuring accountability; (3) the practices relied on to secure public confidence; (4) the practices relied on to provide assurance on objectivity; (5) the accepted bases of expertise; and (6) the visibility of expert bodies.

Within this framework, she considered the approach in the United States to be more contentious than that in Britain, which was more communitarian, whereas the German approach emphasised consensus. In addition, the extent of public engagement and the level of transparency differed significantly even though public accountability has been emphasised in all three jurisdictions. The BAC's approach has a distinct character of its own, and we propose (by way of broad generalisation) the following characteristics in comparison with approaches in the United States, Britain and Germany (See Table, p. 26).

It is important to recognise that the BAC is not the sole contributor to ethical developments in Singapore. Besides the Singapore Medical Council's ethical code and ethical guidelines for the medical profession, ethical guidelines are also issued by the National Medical Ethics Committee (NMEC), which was established in January 1994 to assist the Ministry of Health in addressing ethical issues arising from clinical practice and to ensure a high standard of ethical practice in Singapore. The BAC works closely with the NMEC, particularly in areas that are relevant to both biomedical researchers and medical practitioners. For instance, BAC's recommendations relating to clinical genetic testing are built on the NMEC's 2001 *Ethical Guidelines for Gene Technology*. Separately, hospitals, research and academic institutions have their own ethics committees or institutional review boards. In addition, hospitals and professional bodies such as the Singapore Medical Association have conducted public forums on medical and research ethics. There is an effort underway to coordinate ethics education activities in the various set-ups.

Bioethics is also gaining recognition as an academic discipline in its own right. Bioethics or bioethics-related courses are offered in all four universities in Singapore. Thus, it is not surprising that Singapore's bid to host the 2010 World Congress of Bioethics received strong support from these institutions. In 2005, Singapore's first Chair in Medical Ethics was established at the Yong Loo Lin School of Medicine of the NUS, in honour of the late Dr. Chen Su Lan, one of Singapore's best known philanthropists. Professor Alastair Campbell, who is also a member of the BAC, was appointed to the inaugural Chair, and he now heads the Centre for Biomedical Ethics at the NUS. The BAC collaborates with the Centre in a variety of educational activities for members of ethics review committees, researchers and the public. In December 2008, the inaugural issue of the

Comparison of Approaches

	United States Contentious	Britain Communitarian	Singapore Communal-Consensual	Germany Consensus-seeking
Styles of Public knowledge-making	Pluralist, based on diverse interests	Institutional, service-based	Mixed pluralist and corporatist	Corporatist, institution-based
Public accountability (basis for trust)	Assumptions of distrust; Legal	Assumptions of trust; Relational (as opposed to legal)	Assumptions of trust; Role-based	Assumptions of trust; Role-based
Practices to Secure public confidence	Social scientific approach	Empirical science	Expert rationality	Expert rationality
Practices to assure objectivity	Formal, numerical, reasoned	Consultative, negotiated	Consultative, reasoned	Negotiated, reasoned
Expertise (foundations)	Professional skills	Experience	Professional skills, experience	Training, skills, experience
Visibility of expert bodies	Transparent	Variable	Variable	Non-transparent

journal "Asian Bioethics Review" will be jointly published by the NUS Centre for Biomedical Ethics and the Hastings Center. The inaugural issue will consider issues relating to the distinctiveness of Asian bioethics, if there is indeed such a phenomenon. The journal will be published on a quarterly basis and will be accessible online.

In its very first report, the BAC recognised that bioethics is not a matter of domestic concern only. International communication and cooperation are critically important for the formulation and implementation of sensible bioethical policies and guidelines. This importance is evident in the increasingly cross-border character of biomedical research, as well as the global need for public health (such as in the SARS epidemic) and environmental concerns. The interest of the BAC in hosting to 10th World Congress of Bioethics arises in part from this recognition that bioethical issues cannot be addressed in isolation from developments outside of Singapore. Through hosting the Congress, the BAC also seeks to communicate a clear message that scientific progress must be achieved within a framework of good research governance based on internationally accepted ethical best practices. In this connection, the theme "Bioethics in a Globalised World" reflects Singapore's strong interest in the responsible pursuit of scientific knowledge.

The opportunity to host the 2010 World Congress will be especially meaningful for the BAC as the organisation celebrates its tenth anniversary. It would be an appropriate time to reflect on the development of bioethics in the past decade with the benefit of the experiences and views of bioethicists from around the world. Singapore is committed to the promotion of bioethics as it is intrinsic to excellence in biomedical research and development.

*Please note that the views stated herein are personal to the authors and may not necessarily represent the views of the Bioethics Advisory Committee.❑

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10th World Congress of Bioethics to be held in Singapore in 2010

The 10th World Congress of Bioethics will be held in Singapore from 28 to 31 July 2010. It will be hosted by the Bioethics Advisory Committee and is supported by the Agency for Science, Technology and Research, the National University of Singapore, the Ministry of Health and the Singapore Medical Association.

The theme "Bioethics in a Globalised World" reflects Singapore's strong interest in the responsible pursuit of scientific knowledge. As in previous congresses, a wide range of contemporary issues in bioethics will be discussed. The various sub-themes will also be explored in satellite meetings that will precede the 10th World Congress. For instance, the 8th International Congress on Feminist Approaches to Bioethics will be held from 26th to 28th July and is organised by the International Network on Feminist Approaches to Bioethics, which is an IAB network organisation. Satellite meetings may also be organised by independent entities. The 8th Global Summit of National Bioethics Advisory Bodies will be held from 26 to 27 July 2010, hosted by the Bioethics Advisory Committee and the Ministry of Health.

Call for Paper & Poster Abstracts now open till 1 Dec 2009.

More details available at:
www.bioethics-singapore.org/wcb2010

Theme: Bioethics in a Globalised World

Subthemes:

- Global and regional perspectives on bioethics
- Justice, access to health care, and health care reform in a globalised world
- Ethics of global health governance
- Ethical issues in international health research
- Clinical ethics: local concerns, international perspectives
- Public health ethics in a global context
- Ethical issues relating to international development, aid and reconstruction
- Bioethics, health and the environment
- Ethics, enhancement and the future of the human species
- Ethical issues arising from research using human stem cells, embryos and new medical technologies
- Infectious disease control and the threat of global epidemics
- Biotechnology and bioengineering: local, regional and global debates on policy and ethics
- Globalisation and commercialisation in biomedicine
- Ethical issues relating to vulnerable and minority populations
- Inequalities and discrimination in health
- Food and security