Some Ethical issues in medical developments and treatments in the 21\textsuperscript{ST} century (and their interface with Law)
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1. Introduction

An excellent segue into a reflection on the responsibilities and challenges of medical researchers and practitioners in the 21st Century is the Foreword, written by Dafna Feinholz, Chief, Bioethics Section, UNESCO, Paris, of the Casebook on Human Dignity and Human Rights. She quotes from the Framework for Action of the 1999 World Conference on Science which was held in Budapest and says, *inter alia*: “….ethics and the responsibility of science should be an integral part of the education and training of all scientists, and that they should be encouraged to respect and adhere to basic ethical principles and responsibilities of science”

Unfortunately ethics is still not part of the curriculum of many training hospitals and many medical doctors and researchers are graduating and practicing without having had an introduction to basic ethics and ethical principles. Slowly, however, with the ever-increasing medical issues which are emerging, the need for this is more apparent and more Schools are having this as part of the requirement before a doctor is allowed to practice.

Ethics is often confused with morality and this is quite understandable. When we speak of a person being ethical for instance, the usual perception is that s/he is doing the right thing, the moral thing, the socially acceptable thing. But the moral thing, depending on the particular society or the specific situation, need not always be the right or the most appropriate thing in another context or society. To complicate matters, with the advancement of technology and all the resources available to members of the medical fraternity, even the definitions of such things as life, death, consent have changed or been enlarged over time, especially so in this the twenty first century.
Decisions are fraught with ethical and legal repercussions and what is legal is not always considered ethical and so on.

If one were to ask for a quick and easy distinction between morality and ethics, one would be forced to say that one deals solely with the individual and the other with the individual and/in society. But even this is only half-true. A person’s sense of morality is based on that individual’s perception of right and wrong and the values that person has internalized. The way that person then deals with society is greatly affected by his/her personal morality. This personalized sense of morality can and does conflict with another’s equally strong and equally valid sense of morality. One brings one’s morality and values into discussions which are supposedly ethical. One has only to attend a session of the IGBC or the IBC to understand that the perceived and inherent values of an individual which are coloured often by culture and religion come to bear on any discussion involving ethical considerations.

Ethics, or moral philosophy also deals with concepts of right and wrong and there is further confusion when some say that ethics tries to find moral standards for “proper” behaviour. They are referring here to a category or type of ethics which is called “normative” and which has as its basic principle “do unto others as one would have them do unto you” – the equitable principle of justice: fairness. However, this normative principle assumes at its root that there is one and only one standard for moral/ethical conduct; that all are agreed on what this is and that this standard is that which should be the norm.

This then leads one into a discussion of whose norm? What ought to exist is normative. But ought to exist in what society? On the other hand, that which actually does exist is
called descriptive ethics. The latter tends to be culture-specific and much more varied in reality.

Then there is “consequentialism”. This is perhaps the major one when one is dealing with medical research and practice since it deals with the effects of actions – whether they be good or bad.

The final category of ethics (there are others) which I wish to briefly mention is that which will to a large extent form the base of this paper – and that is “applied ethics”.

Applied ethics is that which organizations such as the IBC are predominantly concerned with. Why? Applied ethics has two major components: it has to be concerned with something controversial (for example cloning and abortion where there are extremely diverse attitudes) and secondly, it is felt that it has to deal with an issue considered to impinge on the rights of individuals in society. This tends to be where the legal and the ethical abut or overlap or contradict.

This latter can be applied to considerations in health, business, environmental issues and so on. One must assert however, that in ethical discussions on almost any matter, the distinctions re varying types of ethics blur and meld as the division into various types of ethics is almost an artificial construct as all aspects are brought to bear.

Since ethics consists of those standards of conduct which society wishes all members to follow one sees the interface with the Law or Justice which in each society depends on what is termed “right” for the group as a whole. Justice is usually represented by a set of scales, a balance between the benefits and the burdens and ethics also has inherent in it, “beneficence”,...
that is one ought to do no harm; maximise benefits and minimize all possible harms.

One must also state that it would be difficult to find an area of modern human life which does not have an ethical component. News and concerns in ethics/bioethics are constantly being put in the forefront and the areas of concern are constantly being enlarged. Everything which has to do with the human in society has an ethical component. This ranges from issues at the birth of a human, to those at the end of life and during. Often, the issues pre-date the actual birth as there has yet to be consensus on when the human being is formed – at conception or when the foetus is viable. A few examples:

• In the on-line publication Bioedge (Saturday, April 14, 2012), the Editor, Michael Cook makes the point that the news in Ethics/Bioethics ebbs and flows and the emphasis might change from time to time. However, the issues remain the same whatever the area of research or medical concern.

• Michael Cook in the same edition of Bioedge says (From The Editor): “We discovered two important stories in two leading journals. The target article of the latest issue of the American Journal of Bioethics suggests that some parents are morally obliged to use pre-implantation genetic diagnosis. I detect a slow movement towards the feeling that parents are to blame if their child is born with a defect....But the second story undermines this to some extent. A biologist from Wellesley College, near Boston, writes in the Journal of Medical Ethics that IVF clinics hardly ever inform their clients of the risks of PGD for children and they are not negligible. Given the confidence of the authors of the
previous article, perhaps they don’t inform bioethicists either”.

In this quotation alone we see so many areas where discussion is required and where ethical/legal issues are raised. We have that of a parent or other adult determining the state of health of a foetus and thus whether or not that foetus should be born. This to some raises the issue of the rights of the individual and whether or not the individual does have rights before it is a functioning human being. The use of the word “moral” to some might also not be appropriate. Additionally one finds the question of relevant information being given to a patient – an ethical essential for most – and finally, the fact that information of relevance to the health of patients is not always shared among Health Professionals.

Further, if one reads the Universal Declaration on Bioethics and Human Rights, one finds that the aims include:

- “To ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law;

- To recognize the great benefit derived from scientific and technological developments, while ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms; and to prevent practices contrary to human dignity;

- To foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional
groups concerned, policy-makers and society as a whole"\textsuperscript{1}

These principles are universal and have no shelf life or “use by” date. They are timeless. Most of them are linked by the fact that whatever the individual details and the specificity of the medical/research issue the ethical considerations are always part of what has to be factored in.

The main issues to be touched on in this paper and which are almost always part of every ethical discussion are and form part of the Universal Declaration on Bioethics and Human Rights and which indicate how legal and ethical issues can and do overlap are:

- Assault
- Privacy & Confidentiality
- Respect for human dignity and human rights
- Integrity of the person
- Conflict of interest
- Informed consent
- Capacity and
- Vulnerability.

In a very real way every one of the things cited above is encapsulated in the Offenses Against The Person Act (2009) used here in Jamaica and in many such Acts and Statutes at Law worldwide.

The twenty-first century has brought with it a plethora of wonderful and amazing scientific discoveries and inventions emanating from medical research. Life as we knew it even fifty

\textsuperscript{1} ten Have, Henk A.M.J. and Michele S. Jean (editors), \textit{The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application}, UNESCO Publishing, Paris, 2009, p.84
(50) years ago has changed irrevocably. No one would have thought at the beginning of the previous century that there were the possibilities which we now take for granted. Cloning; bio banking, all types of organ transplants; re-definitions of life (when is a person dead; when, in fact, does life start; extending the life of a mother until a foetus is born and so on).

Most of us are happy to be alive in this century, but with each of these achievements and advances have come a myriad, a proliferation of ethical and legal considerations which had not bent our minds hitherto.

Further, at times what ought to be an ethical issue has had to be decided in a court of law. The minds of doctors – in fact most medical personnel – are being taxed by these problems as the meaning of “First do no Harm” and of responsibility to patients is morphing into clouds of uncertainty compounded by cultural and religious differences and resource problems. And since ethics deals with man in society, the society at large and the policies of the country involved also have to be taken into account when thoughts are brought to bear on ethical issues.

We are reminded of this when we read from the preamble of the General Conference (2005) before the formal adoption of the Universal Declaration of Bioethics and Human Rights, the following clauses:

- Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors…
- Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals,
families, groups or communities and humankind as a whole…

- Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments….

I will just touch on three areas which the doctors in this country find ethically challenging to illustrate some of the problems which have emerged from the research and developments in medicine in the twenty first century and demonstrate some of the ethical considerations which have to be taken into account in all of them. One will see what ought to be; what is and the consequences of actions which are not based on ethical principles. These are:

- HIV
- Medical Trials

End – of - life Issues, including euthanasia. But the importance of ethical thinking and constructs is the same with nearly every aspect of modern medical practice.

2. The Human Immunodeficiency Virus (HIV)

Since the onset of this disease doctors have been taxed by the many issues which they have to consider and the fact that benefits and harm often contradict. The stigma which still attaches to HIV is partly moral and the discrimination which is sometimes meted out to a HIV patient stems from this perception that there must have been something untoward, something which goes against the norm, something for which dire punishment is required, which caused it.
Article 11 of the Universal Declaration on Bioethics and Human Rights addresses this issue. It clearly states that no individual or group should be discriminated against and also speaks to human dignity and human rights.

Part of human dignity is to be treated with respect and to have one’s autonomy respected. Many health workers when doing research on persons with this virus or treating them, are themselves biased towards the patients even before treatment and care have begun. Received and preconceived ideas about the morals and values of the patients often colour the method of care and treatment.

“Harm” is not only physical; harm is psychological and emotional and even without being conscious of it, much harm is done to a HIV patient by the very persons who ought to be dispensing care. The stigma which attaches to persons with HIV is only now very slowly being erased in the minds of society and medical workers are also part of the society.

There have been cases of doctors and nurses who have declined to treat patients with HIV and some go beyond normal, expected caution in treating them. While their natural fear for themselves is understood, one is advised to have due respect for the vulnerability of these patients.

One of the major ethical issues is entrenched in Article 3 of the Universal Declaration…..where there is an obvious tension between the duty owed to the individual and that owed to society. Much has been written about a priest’s ethical duty and obligation to speak when he has been told in confidence, for instance, that someone is not only a murderer but likely to commit murder again. The ethical issue here is that of the dual responsibilities and this is also true when a doctor is confronted
with a person with HIV or AIDS. The duty of privacy and confidentiality refers.

What is a doctor to do when his first duty as a health practitioner is to his patient – or thus he was taught – and then there is a law which says that all cases of HIV must be reported and with the names of the individual attached? It is now accepted internationally that these cases must be reported to a responsible body and in the case of Jamaica, the Public Health Act makes it a requirement that each occurrence be reported to the Ministry of Health. Article 9 refers to this by saying that a “breach” is permissible if consistent with international law.

The ethical duty remains, however, in this balancing act, to make access to this private information as restricted as possible. The names when given to the Ministry of Health are in compliance with another ethical duty - what is termed “contact training”, to minimise the spread of the disease and only the Ministry and the laboratory where the blood was tested ought to have names attached. Other institutions or organisations such as those which need the information for census reasons, have only the incidences, not the names and the doctors owe an ethical duty to the patient not to have the information on file where it is easily seen but coded and handled by one designated person.

At the moment one of the problems, however, is that there is no Data Protection Act as exists in some other countries. This is left to the discretion of the persons involved.

In the treatment of HIV and in research involving HIV one sees, therefore, ethical concerns about how to reconcile one’s values with those of the patient’s; how one is challenged to respect confidentiality when one also has to do that which is
required by law and the demands and rights of others who might be negatively affected.

End of Life Issues are always fraught with ethical considerations. In the “Letter of the Day” was entitled: “Make euthanasia legal in Jamaica”. This very heading already tells us that euthanasia is not legal, that is, not the norm for the society. (The letter is filled with topics which are in and of themselves subject to an entire paper on ethics).

In the very first paragraph the writer says: “Euthanasia is a health-care option...” but is this a health-care option and in whose opinion? What about the Biblical injunction “Thou shalt not kill” in a society with more churches per square mile than any other in the world? What about the legal repercussions for those who do? What about the Hippocratic Oath taken by all doctors: “First do no harm”? This is a definitive statement but as we have seen, it is not socially, culturally or legally yet acceptable in this society. Particularly so when he ends his letter by noting that this “will undoubtedly face opposition from the Church and some legal experts see it as a ‘recipe for the abuse of the elderly and a threat to individual patient rights’”

Immediately one sees the moral, legal, normative, descriptive, consequential ramifications called into question. The statement with which the letter begins makes the assumption that this is the norm but throughout the body of the letter he begins to retreat from this definitive statement and begins to consider who should make the decision for the critically ill patient. Also under consideration is the fact that this practice is not “legally permitted in Jamaica”.

2 In: Gleaner of Saturday, April 28, 2012, page A7, for instance
Let us now reflect more fully on some of the ethical considerations involved in euthanasia of the terminally ill patient. One needs to return to the Hippocratic Oath. Wikipedia defines it as “…historically taken by physicians and other health care professionals swearing to practice medicine ethically…” The Oath might be encapsulated in the words “Do no Harm” but it is a long and detailed promise. Parts of it actually say: “Abstain from whatever is deleterious….whatever in connection with my professional practice or not... I see or hear...I will not divulge”.

Right here we have the concepts of confidentiality and respect for the human being as part of the larger oath. These are ethical concepts. One might well be faced with the philosophical conundrum of what is a human being in the following scenario.

Where the patient is comatose and unlikely to recover one now has to understand that from an ethical point of view this does not remove his intrinsic right to respect and to the preservation of his dignity. These are his human rights and until he is pronounced dead, these rights attach. (Yet another ethical and legal and medical question is when is a person dead). There are those who feel that life includes death, that there is a seamless transition from one state to the other and that death should thereby be with dignity. Further, if one who is physically capable of choosing to end his life can do so, this right should extend to someone who is physically unable to do it for himself. The question arises then, who ought to do this?

The law does not allow for an active intervention in the natural process of dying. By this is meant that withholding food and water and other types of nutrition is considered “active” and

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3 In: Harvard Classics, Volume 38, 1910
is illegal and unethical in most countries. At law it is a form of assault and battery since the person – even though it might be felt s/he would feel nothing – is having the organs and systems go through what might be a prolonged, if not excruciating period of withdrawal which impinges on their very dignity.

If however, the person would not be able to survive for a short period without artificial aids and life support, there is one view that there is nothing unethical in “pulling the plug”. The distinction is that this is called “passive”. And yet, it is obvious that one is still not sure there is a difference since several years ago, it was felt necessary to ask Kenneth Goodman, an ethicist from the University of Miami, his view in a case involving a young woman who had been in a coma for years. She was “dead” to all intents and purposes -no brain activity- and it seemed to be a medical issue; it had gone through the courts and then an ethicist was called. The inter-linking of all these ways of “seeing” is obvious -illustrating the fact that ethical factors are intrinsic in so many medical/scientific decisions- and at times so often overlap with legal ones.

There is still the question concerning who actually does the termination. No doctor or other medical staff ought to be forced to perform acts which are against his conscience or beliefs. Some say that if the doctor/staff in a particular medical institution believe that this is unethical and illegal and knows of another where this could be done under supervision, then there is the duty of respect for the person’s wishes. If the person cannot articulate the wish then the one who is in loco parentis should have the final say. But here again one has to balance what is the right of the patient with what is allowed under the law; what is a matter of the health provider’s conscience; what
is ethical (normative and consequential) and what is culturally accepted.

Again there is the tension between what is right, moral, legal. If it goes against the ethics of one set of persons should it be tolerated with another set?

There are many other ethical considerations when the patient is a minor. One now enters fully into the realm of “capacity”. The minor falls into the category of the vulnerable population for whom and on whose behalf decisions are often made. This category is one for which there has to be very careful weighing of the ethical issues such as the integrity, autonomy and right to respect of the patient all of which have to be considered.

Article 7 of the Universal Declaration speaks to this very issue and says that special consideration should be given to those who do not have the capacity to consent.

There are several groups which would fall under both “capacity” and “vulnerable”. Let us take two or so and start with the minor. In most countries there is a legal age to define what is considered a minor. However, there are exceptions and major ones. Under English law, there are several cases where it is recognized that someone who is legally a minor has the capacity to make decisions. It depends on maturity and the ability to comprehend issues.

In the case of a minor who is terminally ill, the subjectivity of the patient and the depression which might accompany any serious illness ought properly to be taken into account before allowing him to decide if life should be terminated. One does not deny that persons have a right to refuse medical treatment because one has a right to choice and
to determination over one’s life. In other words, one has autonomy. However, before any decision is made, the best interest of the minor should be assessed.

When ought one to allow the minor to decide if his life should be ended? The ethical questions abound. If the minor knows that there is no medical hope, does he have the right to refuse further treatment which might prolong life for a while? In other words, one has to assess the motives behind the wish for termination. Perhaps one ought to ask if pain, however intolerable is a justification to end a natural process. If the parents or guardians are making the decision, is one sure that these decisions are not expedient rather than in the best interests of the patient?

But let us return to the minor. This is a person who is usually deemed by law to have no capacity to make serious decisions. If s/he is to do so, then there is need for, as well, the ethical imperative of informed consent. The information not only has to be given in detail so that all the issues can be weighed, but one has to ensure that the real consequences of each bit of information are understood. Can the average minor – or even the guardian – fully understand the consequences of each action required? Here again one sees some of the burdens placed upon health care workers by modern technology and the fact that patients can be kept “alive” almost indefinitely. Is the termination going to fall into the category of active or passive? Is the desire for termination due to fear of prolonged pain and a sense of hopelessness? Are pain and hopelessness sufficient reasons to end a life? What would be the nature of the ending of the life – ceasing care, which is the duty of the worker, or simply not administering artificial means and allowing the body to cease functioning?
Before all the medical and technological advances which this century has brought, these questions were not asked since health care workers did what they could with the knowledge they had and there was not much reliance on machines which could extend the life of persons previously considered beyond recovery. Ironically, the advances in science and technology have brought with them as many burdens, as there are now so many more areas of concern with which the worker has to be involved.

In both the case of the comatose patient and that of the minor, we might have what is called at law a guardian “ad litem”. This is the person who should ensure that all options are investigated and whatever is done is in the best interest of the patient. But here again we have yet other ethical issues for the medical practitioners. Are the decisions being taken on behalf of the patient or because it is easier for the caregiver/guardian to put an end to it? There are even those questions posed as to the “usefulness” of the patient as if, ethically, this removed his right to respect and dignity and his basic human rights. Additionally, some bring the matter of allocation of scarce resources into play and argue that funds spent keeping “useless” people alive could be better spent.

What of the patient who is fully lucid and aware of all the issues? Agreeing to his or her request might well be in keeping with their autonomy and their human rights, but is it ethical? At what point do the laws and cultural norms take precedence over the wishes of the patient?

Some would argue that one should prolong life at any cost and others that the right to dignity takes precedence.

These are but some of the ethically-driven questions which care givers need to ponder. There are ethical issues
where the religious beliefs of a patient are at variance with that of the practitioner as well as cultural practices in some African countries where in rural areas it is still felt that dying with dignity allows for the old and infirm to go off by themselves until death has claimed them. The surface has just been scratched to give an idea of what health workers are faced with in the 21st century.

3. Medical Trials

Involve most of the areas already discussed, such as capacity, respect, human rights and so on. The ethical considerations which are more prevalent here would be confidentiality and integrity and respect, vulnerability and informed consent. And one must not forget that which is considered to be the most problematic – conflict of interest.

Researchers are expected to maintain the highest standards of honesty and integrity. Any form of dishonesty is a serious offence.

There is an established principle of “openness” in research and this includes the freedom of access by all interested persons to the underlying data, to the processes and to the final results of the research. Except under exceptional circumstances, no programme of research that requires secrecy should be undertaken. By secrecy, one here means that the aims, objectives and expected results perhaps of the research ought to be documented. No one wants a repeat of the Tuskegee incident.

This is all well and good but research often involves human beings and the rights of those persons ought to be considered. Whereas research should be transparent, the details of the subjects are not for the general public. In the absence of a
Data Protection Act, this is even more challenging but necessary. There therefore needs to be a balance between the openness (transparency) of the research and the ethical duty of confidentiality. In a programme where the subjects have some social disease, lack of privacy and confidentiality could do wrong even if it is not considered that the subjects are being harmed.

For instance, if the private papers, diaries and other analogous materials have been provided to the investigator, provision must be made not only to preserve the confidentiality of those materials for the purpose of protecting the individual privacy of the author/patient but of his immediate family.

Ethics also demands that there be no intentional misleading of subjects or withholding of information about the nature itself of the research. This can be viewed as deception and ethical concerns are increased when there is deception since, *de facto*, there cannot thereby be informed consent.

Deception is arguably necessary for certain types of behavioural research when full knowledge by the subject might bias the results, but in these cases it is imperative that subjects be fully de-briefed. Subjects must also have the opportunity to withdraw at whatever point in the research they might wish to and to have their data removed.

Informed consent is one of the most important ethical concepts and obligations for any research involving persons. This is part of the concept of respect for persons.

This means *inter alia* that one should guarantee that each participant understands his role in the experiment. The person must be told the nature, that is, control arm; randomized controlled clinical trial; single or double blind. Care must be
taken to have these terms very clearly explained and understood and where possible, the subject must be told if s/he is being given a cure or a placebo.

To further complicate matters for practising health care professionals, there is now thinking that placebos are contrary to the concept of doing no harm and rather, if there is an existing medication that has efficacy, it must be used.

One of the issues which concern doctors and medical researchers is that where the subject being used is a bona fide patient of the person doing the research. In most doctor/patient relationships, there is a trust which is built up and the patient comes to rely on what the doctor/caregiver says is in his best interest. As ethical as the doctor/researcher might be, he has to bear in mind that his statements to the subject will be loaded with “sub-texts” which would not have been there had this been a research being done by someone unknown. If the patient has a serious illness, he would not expect “his/her” doctor to be administering placebos when there is the possibility of an effective drug with positive effects being used.

One can thus question whether the consent given in these circumstances is, in fact voluntary. Voluntary consent has several meanings not the least of which is that there should be no duress or coercion and that the trust of the participant in a medical trial should be based on sufficient knowledge of the risks and benefits and the possible effects on his health.

For some, ethically there is coercion because the patient would feel that his caregiver is doing only that which is good for him and an element of fear of reprisals might enter into the equation. The fear might even extend to one where the patient feels the quality of his care might be less if he did not agree.
There are many other elements to consider when determining whether or not a subject should be recruited into research such as whether or not the person can indeed understand the complexity of the information or retain enough of this information to think the issues through adequately. Capacity again rears its head as we must determine if the person is legally able to consent and as suggested above, if he feels there are pressures on him to consent. This would not make it voluntary.

One needs to be cognisant of the fact that a signature on a form is not consent – even if at law one cannot thereby say: “This is not my deed”. True consent in medical research comes with the gaining of understanding by the potential subject.

Researchers are required to ensure that there is not tampering with data to reflect an outcome which they had wanted or wished for. This happens and will continue to happen in cases where much is to be gained from having a particular outcome. The temptations are legion.

Time and space do not allow for discussions on the plethora of issues such as persons in developing countries where there might be monetary enticements, however small, to partake and where the scientific validity of the research might be questionable or, further where the researcher has a vested interest in the research – a conflict of interest.

Most of the discussion in this paper has been based on consequential and applied ethics. We have attempted to show, however, that all forms of and concepts in ethics must be considered since, although one continues to speak of “the eternal verities”, there are normative and cultural differences from society to society and within individual societies, norms also change over time.
The difficulty in acting ethically can be increased by a combination of what is accepted in a particular environment, what the law allows and what is due to the individual according to various ethical Codes, and what is based on the conscience of individuals.

What is true, across the board, however, is that science, being fluid and not static will continue to throw up more *scenarios* and more ethical *conundrums* and difficult decisions will continue to plague the minds of those in the health care professions.