BIOETHICAL CONSIDERATIONS, THE COMMON GOOD APPROACH AND SOME SHORTFALLS OF THE BELMONT REPORT

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ABSTRACT
The Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research established ethical principles to shield human subjects in biomedical research from unjustifiable exploitation by researchers. This was a response to the “Tuskegee Study” in the United States, where the rights of participants were grossly violated. Today, researchers and physicians often make use of human beings as subjects in scientific investigations. One of the key issues is that of informed consent. The ethical principles stressed in the Belmont Report have significant implications for the matter of informed consent. Informed consent must be required for any legal research involving human subjects. Regulatory frameworks must ensure that human subjects in bioethical or other research are not exploited either physically or psychologically. The need for effective humanistic ethical guidelines for biomedical research is great, but how does this tie in with the Common Good Approach if at all?

KEYWORDS
Bioethics, ethics, clinical research, Belmont Report, informed consent

INTRODUCTION
In 1979, the National Commission for the Protection of Human Subjects in the United States issued “The Belmont Report.” This report delineated suggested guidelines for guiding ethical research involving human subjects. Bioethics was once again under the spotlight. Bioethics was first given its name in 1927[4] and this concerned the research procedures on animals and plants.

Bioethics is a certain type of practical normative ethics in which there are norms that are standards of right and wrong action and conduct. Normative ethics is essentially concerned with how people should act, what sort of person one ought to be or what sort of policies ought to be effected. Principles and theories of normative ethics are applied to motivate and justify actions that are taken and policies that are adhered to in biomedicine. It thus probes the reasoning behind one’s moral life within the context of the life sciences and how people decide what is morally right or wrong in the biosciences. The need for medical practitioners to conduct their duties in an ethical manner is not a new idea and has been emphasised from ancient times.

From as early as the 5th century B.C., the Hippocratic Oath had been devised and was used as rite of passage for practitioners of medicine in many nations although it has been revamped and somewhat reformulated over the years. Does it make practitioners ethical beings?

Ethics is, in a sense, different from morals in that the former attempts to probe the reasoning behind our moral life, by examining and analysing the thinking used to justify our moral choices and actions in particular situations. It is thus predicated on an assumption that some solutions to the ethical problems that arise in science and medicine are more moral than others and that these solutions can be arrived at by clear moral reasoning and careful reflections.

An ethical system, similar to a legal system, is required to regulate human behaviour such as research using living subjects. An ethical system is less formal than a legal one since ethical authority may be vested in a shared system of rules which are understood and enforced by everyone in general and by no one in particular. Ethical theory on research is a rational explanation, justification and evaluation of the rules of what makes ethical common sense. Applied ethics is the extension of elucidated common sense to fresh issues that may arise. Ethics is thus rule-based and applies inter alia to research with human subjects. Ethics is vital for conducting sound research and is primarily “concerned with moral principles, values and standards of conduct.”[46] A wide range of codes and principles of ethics have been created over the last two millennia and all have been aimed at providing basic guidelines for researchers through which they can conduct research without harming the research subjects.

In fact, the oldest known code after the Hippocratic Oath was created in the 5th century and was known as the Formula Comitis Archiatriorum. A Code of Ethics for Public Health was made available by the American Journal of Public Health in 2002, and it identified the “distinctive elements of public health and the ethical principles that follow from or respond to those elements.” Numerous new issues creep into research on a regular basis and so greater deliberation is required as research ethics is dynamic.

In August 1947, the “Nuremberg Code” was accepted as “permissible medical experiments ... in order to satisfy moral, ethical and legal concepts” for experiments relating to human subjects.[21] Various other declarations concerning ethical issues in research were distributed, including inter alia the Declaration of Geneva (1948), World Medical Association (WMA) International Code of Medical Ethics (1949), Wilson Memo (1953), WMA Principles for Those in Research and Experimentation (1954), and the Declaration of Helsinki (1964)[28], which is detailed further down in the article. Each of these declarations fur-
ther emphasised ethical issues, and consequently encouraged researchers to focus more on ethical aspects of their work. There were numerous experiments on prisoners in Guatemala, as well as prostitutes in 1946 in the United States, and particularly the Nazi scientific experiments on Prisoners of War (POWs) and concentration camp victims during the Second World War. All are examples of the horrific dehumanising aspects of medical practice and research which prompted the Nuremberg Code in 1947. Essentially, the Nuremberg Code came into being as a result of the atrocious human experimentation performed by Nazi doctors in concentration camps throughout the German Nazi Third Reich. Experimentation on humans without their consent was totally outlawed by the Nuremberg Code and so the notion of Informed Consent became enshrined in Medical Ethics Codes and there was now a patient-oriented approach for the first time. Medical ethics was no longer the sole domain of medical practitioners and it was now tested against the principles of society. The judgment by the war crimes tribunal resulted in ten principles or standards to guide physicians in all human experimentation. Before the Nazi war crimes tribunal, there was indeed no written international code for doctors to observe. The standards called for the conforming of medical practitioners to ethical actions when carrying out experiments on human subjects. The prosecutors at the Nuremberg Trials stated that the policy of mass extermination which was part of Hitler’s Final Solution, could not have been as effectively carried out without the active participation of German medical scientists. The Nazi medical experiments implemented in the concentration camps made it clear that medical experiments on human beings must conform to well-defined ethical standards and should supplant the justification that such experiments may produce results for the benefit of the whole of society. The main components of the code stated inter alia, that there should be a strong requirement for voluntary participation; the notion of informed consent; a satisfactory risk/benefit analysis and a person’s right to withdraw without penalty. It was heavily criticised for being too legalistic and was thus to a large extent ignored by medicine. There was no mention of independent review or fair selection of participants. The Universal Declaration of Human Rights was adopted by the General Assembly of the United Nations in 1948. The General Assembly adopted the International Covenant on Civil and Political Rights (ICCPR) in 1966 to support it. Article 7 of the ICCPR states that: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation”. Thus we see the value given to human beings and how all research involving human subjects should be regulated. In the 1960s there was far less obsequiousness to authority across the globe especially in the United States where the Vietnam anti-war movements waged protest after protest. Into this mix was added the Cold War fears and the Cuban Missile crisis. Hippies added their ‘fuel to the fires’ of unrest and there were public demonstrations for ‘rights’, civil rights and also feminism. People were consequently more emphatic on issues of individual human rights and their ability to self-determine what was right or wrong, just and fair or not. In the 1970s bioethics was described as a eugenic enterprise: “to help mankind toward a rational but cautious participation in the process of biological and cultural evolution”. What the Nuremberg Code made critically important was that in order for informed consent to be considered and to be ethically permissible, there must be full disclosure. Consequently, any potential partaker must be as to the purpose of the research and procedures which are going to be used. Participants must be assured of confidentiality or anonymity. Additionally, the benefits to the participant, if any, and all the potential risks of participating in the research, need to be divulged. Deception of any sort is unacceptable. Any participant’s consent to participate in the research must be voluntary and free of any coercion. Participants must comprehend what is explicated and provided with an opportunity to ask relevant questions. Participants must also be fully competent to provide their consent and do so in writing. When an individual is deemed incompetent, a legally approved entity may provide consent. People face a multitude of health challenges, and some are physical or mental or both. Via research many advances have been made in medicine and many diseases are being combated effectively. Medical researchers participate in therapeutic and non-therapeutic research. The former is conducted with the intention of treating the many diseases that plague humanity. The latter research is aimed at advancing the limits of knowledge concerning the health of humanity. Since 1971, bioethics is a new discipline that pools biological knowledge with knowledge of human value systems (Potter, 1971) and is now a study of the ethical dimensions of medicine and the biological sciences. The ethos came to include academic deliberation and a move from meta-ethics to applied ethics. Issues became societal ones and both philosophers and sociologists gave input on the manner in which medicine and science should be controlled, and how doctors and scientists should conduct themselves. Behaviour should be constantly ethical so that there can be moral progress in which we can apply the same moral yardstick to the past and the present. The passing of time must not affect the cogency of moral decision making.

DECLARATION OF HELSINKI (2013)

The World Medical Association (WMA) developed the Declaration of Helsinki (DoH) as a binding report of ethical principles for medical research which involves human subjects, and this includes all research on distinguishable human material and data. The Declaration of Helsinki delivered by the WMA, is the most renowned current policy statement. It was originally adopted in 1964 and has been amended no less than seven times since then. It is the central document in the field of ethics in biomedical research and has greatly impacted upon the content and thus formulation of international, regional and national legislation and codes of conduct. The Declaration is thus a wide-ranging international statement of the ethics of research involving all human subjects including those with capacity and those without, as well as communities. It sets out clear and carefully crafted ethical guidelines for physicians and researchers who are engaged in both clinical and nonclinical biomedical research. The most recent changes were made at the General Assembly of the UNO in October 2013. The declaration makes it clear that it is the duty of the physician to promote and safeguard the health, well-being and rights of all patients, including those who are involved in medical research. Like the Belmont Report, it asserts that all medical progress is based on research that in due
had contracted syphilis, and a further 201 in the control group. The men used in the research, were predominantly uneducated sharecroppers and they were left untreated with syphilis, and thus suffered enormously while under medical ‘care’. No informed consent was requested and the respondents were lied to and told they were to be treated for “bad blood”. [7]

No active treatment was in fact given at all. In exchange for their participation in the study, the men received free medical examinations and all meals, as well as burial insurance. The study was originally expected to last six months, but instead became a longitudinal study lasting forty years. Vonderlehr, Taliaferro, Heller & Wenger (1936) noted: “such individuals seemed to offer an unusual opportunity to study the untreated syphilitic patient from the beginning of the disease to death of the infected person”.[8,26]

The researchers wanted to compare the progression of uninfected syphilis by modern treatments with the results which were obtained when treatment had been administered. Many participants suffered huge side effects, including paralysis of limbs which was the result of spinal tapping procedures that were used to extract spinal cord fluid and many suffered intense neuronal damage. [26] A number died due to advanced syphilitic lesions and many wives were infected. A number of children were born with congenital syphilis and many men became blind or insane from the infection that ravaged their bodies. Throughout this time, the United States government, the so-called bastion of liberty and human rights, made certain that the men in the study received no treatment. This was despite the availability of penicillin. The best that was offered was cheap burial cover.[9] Clearly human dignity and ethical principles were severely violated in the Tuskegee Study, with the idea that the study would make life safer for many after the results became available and treatments could be fine-tuned. The researchers denied the participants their rights and took away all their dignity. They considered the participants to be incapable of making autonomous moral determinations of what happened to their bodies. The patient’s autonomy was negated as a highly paternalistic approach turned the clinical research into a burden and terror rather than something to be viewed as voluntary participation in research. No informed consent was undertaken whatsoever. Interestingly, in 1997, President Bill Clinton apologised for what he described as “deeply, profoundly, and morally wrong” behaviour by medical scientists conducting research.[10] Many issues manifested from the study, such as the lack of informed consent, extreme racism given that all the men were African Americans, lying, paternalism, unwarranted subject selection, maleficence, human dignity and justice.

**TWO OF THE MANY OTHER CASES OF UNETHICAL PRACTICE**

Another disturbing case is that of Henrietta Lacks who was was born on August 1, 1920, in Roanoke, Virginia. She died of cervical cancer on 4 October 1951 aged 31. Cells were extracted from her body without her knowledge were used to form the HeLa cell line, which has been used at length in medical research since then. Her case created a major stir and a series of legal and ethical debates over the rights of a person to their genetic material and tissue. On January 29, 1951, Lacks went to Johns Hopkins Hospital to establish the cause of abnormal pain she was experiencing and bleeding in her abdomen. A physi-
cian diagnosed her with cervical cancer. During the course of her subsequent radiation treatments, doctors removed two cervical samples from Lacks without her awareness and thus no approval was granted. She died at the hospital and the cells from Lacks’s tumour made their way to the laboratory of a researcher who noticed an unusual quality in the cells in that they were very durable. The researcher isolated and multiplied a specific cell, creating a cell line which he named HeLa, derived from the name Henrietta Lacks. The HeLa strain revolutionised medical research and the famous Jonas Salk used the HeLa strain to develop the polio vaccine. Scientists eventually cloned the cells in 1955, as demand for them multiplied. This became so rife that over ten thousand patents involving HeLa cells were registered. Researchers used the cells to investigate disease and test human sensitivity to new products and substances. The Lacks family only learned about the HeLa cells in the 1970s. Henrietta Lacks’s contribution to research was thus enormous and her family was honoured at the Smithsonian Institution and the National Foundation for Cancer Research. The HeLa case raised important ethical questions about the legitimacy of using genetic materials without permission. We must note that neither Lacks nor her family granted any permission to scientists to harvest her cells, which were then cloned and sold. In 2013, German researchers published the genome of a strain of HeLa cells without authorisation from the Lacks family, but later that year an agreement between the family and the National Institutes of Health granted the Lacks family acknowledgement in scientific papers and some oversight of the Lacks genome. The Lacks family has however been very restricted in their attempts in gaining control of the HeLa strain.[11]

In another case, in the 1960s, Thalidomide was presented for the treatment of hyperemesis gravidarum in Europe, while still under review in the United States. A group of practitioners started using it before it became obvious that it was causing many birth defects. Consequently, there was a huge public outcry, which led to legislation that required researchers to obtain informed consent before administering investigational medication of any sort. There have been numerous cases of unethical conduct, especially in the United States. The doctors involved probably felt that they were doing wonderful work for the rest of humanity.

It is precisely such cases that John Stuart Mill would abhor, since he stressed the huge importance of allowing people the freedom to choose what to do with their lives, with the provision that no one else suffers as a result. This is thus a strong liberty case for utilitarian researchers of all types, in that they should think very carefully about the consequences of their actions, and how they treat their profession and its reputation.

THE HIPPOCRATIC OATH

This raises the important issue of breaking of oaths. In the Hippocratic Oath it is clear that medical practitioners of all sorts must only prescribe regimens for the good of patients according to their ability and judgment and never do harm to anyone. The code established the principles of beneficence and non-maleficence. It also taught that exploitation must be avoided and that the best interests’ of patients should be sought continuously. Equally important was the maintenance of confidentiality.

Research Ethics Committees eventually became institutionalised and in 1975 the DoH was revised.[12] This was important as it first introduced the concept of oversight by an ‘independent committee’ (Article 1.2). A system of Institutional Review Boards (IRB) was also developed and governed by Codes of Federal Regulations (CFR) in the United States. In other countries, research ethics committees or ethical review boards were also developed. A groundbreaking aspect was the US Congressional mandate of 1974. This required the secretary of the then Department of Health, Education and Welfare (now Health and Human Services) to select a national commission to “identify the basic ethical principles” for the federal government to use when making determinations on ethical dilemmas in medical research.[12]

THE BELMONT REPORT

In 1979 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978) fashioned the Belmont Report which became the guiding light for Research Ethics Committees in the United States. The Belmont Report demonstrates the possibilities and limitations of the standardisation of ethical principles. It is renowned for its three guiding principles namely: respect for persons, beneficence, and justice. It requires bioethicists, and indeed all medical researchers and practitioners, to demonstrate utter respect for all persons and appreciate their autonomy and to get informed consent before conducting any research.

The Belmont Report states categorically that its “objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects”, but such a framework needs to be clear and uncontroversial if it is to resolve ethical dilemmas. The Report has by and large become the ethical standard for the handling of human subjects in research despite the fact that its ethical principles and interpretations are based on the universal approach that, “one-size-fits-all”. IRBs, frequently make use of the generally accepted standards pronounced in the Belmont Report. It has great practical significance for the supervision of research on human subjects, but its ethical analysis does not consider any adequate measured factors such as culture, ethnicity, gender and geographical locations of those under analysis. Such aspects require deeper consideration.

Consequently, frameworks such as the “Emanuel, Wendler, and Grady framework for Biomedical Ethics” were designed as a universal tool for use in a range of settings including developing nations. In this regard, there is still uncertainty as to the merits of the framework for African health research ethics committees (RECs). It is evident from research on the “Emanuel Wendler, and Grady framework” that the most frequent issues that emerge in a South African context are informed consent, scientific validity, fair participant selection, and ongoing respect for the participants.[17]

Those of reduced autonomy must be safeguarded and beneficence should be the rule. Any researcher needs to consider both the risk and benefit of their research and to never do any harm while operating in a spirit of justice. The selection of any subjects must be fair and those who are vulnerable need additional protection. No person must be exploited by any research. Respect for all persons should always involve adhering to every person’s individual autonomy and protecting persons.
with diminished autonomy should be a given. There must be a guarantee that any subject participating in an experiment does so voluntarily and with the full knowledge of the potential risks and benefits associated with the research. This aspect is termed “informed consent”.

Beneficence incorporates two common rules, namely: “(1) do not harm and (2) maximise possible benefits and minimise possible harms”.[13] Researchers are accountable for the participant’s well-being and this crucial value of medical ethics has also been extended to research ethics as a whole. Beneficence involves foreseeing, scrutinising, and balancing both the risks and benefits to all research subjects. The principle of justice stresses that the subjects selected for research do not unfairly bear the encumbrances that is anticipated to benefit different segments of the population. It is also important that no person be denied a benefit to which they are entitled or be burdened with an unjustifiable yoke.

Beauchamp, a founding father of Bioethics, told the President’s Council on Bioethics in 2006:

“The National Commission was very concerned throughout its work that it had become too easy in the biomedical world to use utilitarian justifications of research. The Nazi experiments, Tuskegee, Willowbrook, and Jewish Chronic Disease Hospital case ... had left a legacy of being driven by a very utilitarian view of social beneficence, that justified using human subjects on grounds of benefit to the broader public.”[14]

The Belmont Report makes it very clear that an ethical course of action that is respectful, beneficent, or considered to be just is not always obvious, and may in fact fluctuate between diverse experiments. While there are IRBs and laws in place to guide researchers to hold fast to the principles of the Belmont Report, it remains the researchers’ responsibility, to protect the interests of all subjects, even if the protection may be against the desired results of the work they are conducting. Such principles cannot be ignored in either the humanities or social science research as the well-being of human subjects should always come first. These guidelines of The Belmont Report have hopefully assisted in resolving the ethical dilemmas that envelop the conduct of research with human subjects and still there are problems.

The Belmont Report has by and large become the ethical standard for the handling of human subjects in research. IRBs, frequently make use of the generally accepted standards pronounced in the Belmont Report. The Report has great practical significance for the supervision of research on human subjects. However, the Report states that it is not entirely accurate in parts in not so many words: “Broader ethical principles will provide a basis on which specific rules may be formulated, criticised and interpreted”.14

The Belmont Report may be too philosophical and has to be tailored to suit the needs of some researchers’ who were not philosophically inclined. One problem for example, is that people involved in the practice of research battle to comprehend the ethical conceptual framework of Belmont, including the responsibilities of those involved in using the ideas and the laws of the land. In the Belmont Report, the primary principles do not override one another in the sense that justice and autonomy should be of equal status. In practice, justice is downplayed and there is hardly any discussion of it. Respect for persons should be the most important principle. This implies that there must be acceptable informed consent, of either a first or third party. Beneficence is also downplayed.

The Belmont Report was aimed at providing adequate and increased protection to vulnerable populations. The critical issue being the inability to effectively navigate and balance risks and benefits. The Report is adequate in the regulations it has in place, but in terms of incompetent persons and those that are vulnerable, it is not adequate. It is in a sense emphasising the uncertainty between what it means to respect persons and what it is to provide them with benefits and protect them against any harm. What respect for persons’ remains unclear in the report? The word ‘person’ applies to all people and the ideas of incompetence and competence are equally encapsulated under that principle. Another issue is that the principles of beneficence and non-maleficence are not clearly delineated when it comes to the Report.

**BIOETHICS TODAY**

If we interrogate Immanuel Kant’s (1724-1804) principles and the categorical imperative, we need to accept that ordinary people are correct to believe that morality is essentially about adherence to sets of compulsory rules. The notion of ‘autonomy’ was presented to ethical theory by Kant.[25] His ideas diverge from those in the Belmont Report. The Belmont Report defines autonomy as self-determination and refers to one’s psychological capacity for personal consideration and action. However, for Kant, autonomy is the ability one has to freely exercise his or her applied reasoning in agreement with the good. We are thus guided by logic and this has clear consequences for how we act, irrespective of our individual needs and wants. We should not be coerced or deceived to act in any fashion that benefits us and harms others. It is also argued that moral actions are performed from a sense of duty rather than by following preferences or doing what one wants. Ethics is about uncovering what the duties of people are, how they are discovered and why they require obedience. People have theoretical motives which allow them to do complex tasks such as logic. They also have practical reason to service their good will, which is the motive that makes them determined to be good citizens and practical reason supports their journey. People cannot then be obliged to accept treatment or be subjected to any type of medical experimentation for the common good. Kant asserts that people should always be treated as “ends” and never as only the “means”. Society cannot use any part of the population as “slaves”, because then they are mainly viewed as “means”. It is conceivable that one can perform acts that link duty and inclination, but those acts which are performed from duty are superior. Concerning beneficence and respect for persons, it is very difficult to align consequentialist considerations with deontology. Immanuel Kant, would choose deontological ethics and discard any effort at compromising with consequences.[31] When a group of people or an individual are exploited for the ultimate gain of the rest, this is reflective of utilitarian principles. In a utilitarian system, a little happiness felt by the majority will outweigh far greater degrees of misery that only some may experience. For utilitarians happiness is for the ‘public good’. The overriding group in bioethics today is motivated by utilitarian values.

Bioethicists tend to apply a moral determination grounded in business ethics. They regularly apply a cost-benefit computation to public health guidelines. Bioethicists consider a risk /
benefit relationship from the standpoint of society. They generally believe that individual rights must be second to the notion of the “greater good”. The eugenic denunciation of the equality of human beings as a principle which should guide government policy, namely, individual human rights, are no longer revered. Sadly, utilitarianism has been used to rationalise, coerce and bigot genocidal state policy in some countries, with the excuse that whatsoever is done, is done to improve human characteristics and remake society.

Bioethicists consider themselves to be moral experts and believe that their main task is to advise other biomedical professionals on how best to conduct their work ethically. Bioethicists are expected to possess high ethical standards, however, the majority of bioethicists do not generally critique what is done in the name of science and fail to stop ethically unacceptable biomedical activities. Nonetheless, many health associations realise that there is indeed a great need to craft ethical codes of conduct by which to assess research projects involving human participants. The practice of obtaining informed consent is increasingly being viewed by medical practitioners, researchers and ethicists as an imperative but is this enough when it comes to the practice of ethical clinical research? It seems that today, the philosophers of ethics who used to criticise any abuse of power, and who molded public policy have “aligned themselves with money and power”. Patient’s rights are not recognised as they should be. This is probably due to the fact that bioethics is generally devoid of a meaningful code of professional ethical conduct.

Medical researchers have an ethical obligation to adhere to government regulations and to expose unethical research that is conducted. The ethical legitimacy of research principles must not be left to the judgment of the medical community which often demonstrates an inclination to reconcile the wrongdoing of its fraternity. Medical researchers require a comprehensive code of ethics. Fukuyama has asserted that “many bioethicists have become nothing more than sophisticated and sophistic justifiers of whatever it is the scientific community wants to do”. IRBs, are in the main responsible for the review and approval of all research involving human subjects and are guided by the ethical principles as expressed in the “Belmont Report”. The important question to consider is how effective is the Belmont Report in driving ethical practice? It certainly seems that bioethicists are in many ways complicit with government officials who are extending the ethical boundaries as defined in the Belmont Report. Why is medical research becoming confused with everyday medical practice? Perhaps it is because the latter does not need informed consent but research requires full disclosure of any foreseeable risks and written, voluntary informed consent by participants or by a parent or guardian in the case of a minor.

The Council for International Organizations of Medical Sciences (CIOMS) in 2002 stated that all research involving human subjects should be conducted in agreement with three basic ethical principles namely, respect for persons, beneficence and justice. In any Belmont Report, beneficence refers to the ethical obligation to maximise benefits and to minimise harm to participants while Justice refers to the ethical duty to treat each person in accordance with what is morally right and proper. Thus distributive justice, is important requiring the equitable distribution of both the burdens and the benefits of participation in research.

The Council of Europe is currently developing a Protocol on Biomedical Research, which will serve as a supplementary protocol to its 1997 Convention on Human Rights and Biomedicine. The Universal Declaration of Human Rights has undoubtedly played a significant role in the formulation of such protocols. From the period of the Nuremberg trials, human rights law has now grown to encapsulate aspects such as the protection of women (Convention on the Elimination of All Forms of Discrimination against Women) and children (Convention on the Rights of the Child). It also provides guidelines for adolescent research, stem cell research and research which involves communities at large. Most of these protocols support the general ethical principles that have motivated the CIOMS International Ethical Guidelines.

A PATIENT-CENTRED APPROACH

Patients are increasingly more involved in their own medical decisions and are gaining a more active role in health care systems. For example Western nations such as the United States, United Kingdom and Germany, insurance payments are progressively linked to the provision of patient-centered care. Patients need to be recognised as persons in the milieu of their own social worlds, listened to, informed, respected, and involved in their own care. Patient-centred care stresses a quality of personal, professional, and organisational relationships which accepts patient-centeredness and also their families, clinicians, as well as the overall health system's. Patients should be encouraged to become more active participants and doctors need to be more visibly empathetic, mindful and informative as they work with their patient/s. The doctor should invite the patient to contribute and information should be personalised to individual patient needs to allow for meaningful discussion/s, consideration/s and shared mind/s. Patients’ preferences, must be justified on ethical grounds alone, and this should be independent of their relationship to the health consequences. Patient-centred care behaviours are gradually contributing to improved outcomes. When patients feel that they are respected as a person of worth and are engaged, they are less likely to be distressed concerning their illness. Doctors and all care-givers and researchers need to be candid with those whom they serve. Patient-centred care is undoubtedly on the rise and requires greater consideration. Carefully considered measures must be in place to drive it forward.

THE COMMON GOOD APPROACH

The Belmont Report states that the divisions between research and treatment are nebulous. Consequently any subjects must be clearly informed as to what the research will entail and what the risks and benefits could be. The Common Good Approach asserts that such a distinction is redundant if best interest of the subject is safeguarded by curtailing risks. In any event this approach suggests that subjects must be involved in research whether or not they stand to benefit personally. Any participant/s in research should willingly respond to opportunities to cooperate to establish and maintain the common good. The bioethical principle of “Distributive Justice” was developed by Beauchamp and Childress and also relates to the common good. It is important in that it speaks to the notion of just and fair health care. It also states that bioethicists and other medical practitioners should always consider the whole of society and not simply individual needs.
The Common Good Approach uses the rationale that a moral obligation exists for human research to be conducted to benefit society as a whole. It also essentially rejects the idea of differentiating between research and treatment. If certain individuals or groups are made to carry unequal burdens for the common good, this will be unfair and unjust. Even if people are incapacitated, cognitively impaired, minors or the elderly, they should be treated with dignity and their autonomy should be respected conditional on rationality diminishes their value.

For example, non-maleficence should include an analysis of both the real or potential harm that can be done to individuals. Beneficence ought to encompass all medical endeavours, requiring careful community reflection and buy-in. Justice demands a fair judgment on all health related matters and how subjects are treated and related research and experimentation initiatives. A social stance therefore prevails over individualism in the Common Good Approach.

HOW THE BELMONT REPORT FAILS

Unfortunately, the report fails to complement beneficence with respect for person/s. This is important given that there is a delicate but yet important difference is the way informed consent is understood depending on whether the basic approach followed is deontological or consequentialist in orientation. A consequentialist may maintain that informed consent is needed mainly because it is the actual individual who feels the effects of the treatment, for example the headache which results or other effects. Who is best placed to explain how good or bad it feels?

The principle of voluntary informed consent is a crucial ethical requirement in biomedical research comprising human beings. People are moral free agents and have the ability to determine for themselves what they should participate in or not. Social scientists argue that to rebuff people of their basic human rights is unacceptable and is analogous to divesting them of their lives. The Belmont Report seeks to offer a suitable ethical theoretical backdrop by which to adequately evaluate actual and anticipated codes of conduct for medical and all other researchers. It offers broad ethical principles that provide specific rules by which ethically suitable conduct may be devised, censured and construed. The three main ethical principles upon which the report hinges are respect for persons, beneficence and justice.

The Belmont Report calls on bioethicists to use ethical common sense and maintains that its primary concern is to provide an analytical framework that will direct the resolution of ethical problems occurring from research involving human subjects. Consequently, it is imperative that any general principles for the assessment of precise rules must be unambiguous and uncontroversial so that ethical issues can be tackled effectively. Unfortunately, the Belmont Report is somewhat unclear around the rules and the links between different rules. Novices conducting research on human subjects and seek assistance from the Report on how to think morally about issues obtain meager quality guidance based on the vagueness of principles and how they link with each other.

The Report is not clear on a researcher’s obligation to persons with diminished capacity for cogent deliberation and choices that exist. The Report also fails to differentiate between the need to respect the autonomy of agents with diminished capacity from the need to protect them from any harm which is the result of research initiatives. There are times when an agent’s past or future independent decision would be restricted by actions the researcher may take in the present. It is very difficult, ethically speaking, to make decisions for those with diminished capacities.

It is also vague about its rules concerning those involved in research. This is exacerbated by the fact that many that use the Belmont Report have little to no training in ethics. They are obliged to find out how to conduct research on human subjects and hope to obtain guidance and help from the Report on how to deliberate about the issues arising from the research they are conducting. Sadly, the guidance from the Report is not clearly articulated. It provides a researcher with very little guidance to conclude which limits are justifiable and which are not. For example, the Report expresses that the treatment of the notion of respect for persons. This can be broken down into what is needed of one to demonstrate proper respect for the autonomy of fully competent agents and what is needed concerning the protection of human beings who are of a diminished autonomy. When it comes to the norm or those who are fully autonomous, the report states: “To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show a lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.”

The core idea of research with human subjects is the wish to acquire knowledge that will be of benefit to all people in general. This invariably is an area of huge potential conflict concerning the rights of other individual subjects of research. The Report offers very little to the researcher on how to tackle such issues and conflicts. The Report does not make it clear if we should seek not to harm society or individual research subjects, or indeed both. It appears to be saying that the individual research subject should not be harmed and that all research should promise benefits to society now as well as in the future, but this is not clear. Researchers need to balance the costs and benefits of their research while giving special attention to all the known risks imposed on the subjects of the research. There may well be cases in which the effects on the research subjects do not carry any weight at all. The Report fails to provide any indication of how to rectify this.

The Report states that there are differences of opinion about the just distribution of burdens and benefits of research but does not clarify those that apply to medical or behavioural research. It fails to clarify what is meant by ‘equal share’ and the Report’s notion of justice is also clouded and researchers have to rely on their intuition which is often highly subjective. The Belmont Report leaves open to interpretation the question of whether the risk involved in conducting medical research on cognitively impaired individuals outweighs the possible positive outcomes. The Belmont Report also indicates that third-party proxies should be established but does not outline the corrective procedure for when these proxies have not been designated ahead of time. The subjects of any research must be protected by guaranteeing that they are aware of all risks and benefits, possible alternatives, and what will in fact transpire or be likely in the research outcomes.
Effective guidelines for informed consent have been prescribed by the United States Office for Human Research Protections. They explain *inter alia* that research subjects must be provided with a clear statement, explaining the reason for the research and the procedures to be followed and the fact that they are volunteers and can leave a study at any time. In addition any experimental procedures, the expected time limits of participation and any potential risks and/or benefits need to be spelt out. If there are any alternative options these should also be disclosed and explained.

The confidentiality of the findings and the subject's details must be maintained. In the event of research involving more than negligible risk, research subjects must be informed of procedures for injuries and for procuring treatment. The subjects also have a right to the findings of the study. The Belmont Report does recognise that a grasp of the information provided may be inadequate for certain groups of individuals, such as the elderly, children and the cognitively impaired but is not entirely clear in defining such groups. Nonetheless, it states that third parties may be selected to support compromised individuals and to thus shield them from any harm.

Persons with the capability for self-determination including those who are capable of reflection about their personal goals and of acting under the direction of such reflection should be treated as autonomous agents and their independence must be appreciated. We need to respect the autonomy of people by giving weight to their considered opinions and choices while desisting from hindering their actions except they are harmful to others. When we demonstrate a lack of respect for an autonomous agent we renounce their considered judgments to deny an individual the freedom to act on their considered judgments. We are also guilty when we withhold information essential to make a considered judgment, when in fact there are no compelling reasons to do so. Persons who can determine things for themselves should be at liberty to act on their well-thought-out judgments as long as they do no harm to others.

The Report does not differentiate between the need to respect the autonomy of agents with reduced capacity from the need to protect them from anything that may be of detriment to them.

Respect for persons is a fundamental ethical principle and the Belmont Report offers clear ethical guidance and suggests that no benefits to society at large can ever justify any harm done to human subjects of research. The Report is contradictory in that, on the one hand, it states that subjects should not be harmed in any way, and on the other, researchers are told to carefully weigh up any harm done to subjects against potential benefits to society. Informed consent should not be the main tool for preventing research subjects from being harmed and guaranteeing fairness. Ethics practices should certify that subjects are not exposed to unreasonable risks or treated unfairly. If we place the encumbrance of assessing the risks and benefits of participation on individual subjects via informed consent we are being prejudicial towards them.

Informed consent protects the subject’s well-being, since judgments of what is onerous or advantageous are often relative to an individual’s conception of what is good, and the practice of one being forced, betrayed, or influenced, attacks that person’s very being. While informed consent is ethically necessary due to its acceptance of the notion of human self-determination, the simple fact that something is valuable, even inherently valuable, does not involve an ethical requirement to do whatsoever is required to endorse it.

When viewed deontologically or consequentially, informed consent is seen differently. A consequentialist may want informed consent because, as the person who feels the effects of experimental treatment, they are in the best position to tell how beneficial or non-beneficial the treatment is. To a deontologist, the term ‘consent’ is the most crucial consideration. The Belmont Report alludes to both understandings but fails to state which of the two principles is primary when there is conflicting advice. Clearly, the act of using human beings as research participants without considering their rights is in opposition to the objective of medical research, which is uphold human well-being.

**CONCLUSION**

The Tuskegee case and others has left us with a very poor impression of how doctors and bioethicists have neglected the oath they have taken to save lives. This necessitated the formulation of the Belmont report, which clearly recognise the respect for persons, beneficence and justice as credible and significant ethical considerations when it comes to the regulation of research conducted on human participants. However, the Report has problems concerning its key principles and their relation to one other.

On the issues of informed consent, risk-benefit analysis and the selection of research subjects and fair outcomes, it is sadly lacking. While basic ethical principles are deliberated upon none in fact interpret, defend or appraise specific guidelines. The most rudimentary ethical principles are applied in order to arrive at judgments about the appropriateness of specific types of research on human subjects. In addition, the ethical principles of the Belmont Report vague and questionably interpreted as supplanting precise rules and guidelines. The relationship between the rules to one another is not explained at all. The result is that the report is vague in its envisioned range and it does not distinguish behavioral sciences from social sciences.

The Belmont Report has framed its scope in *inter alia* Nazi biomedical experimentation, the Nuremberg Code, the Helsinki Declaration, the Hippocratic Oath, the Tuskegee syphilis study, the removal of health services, and vaccination as areas of primary concern and it cites ethical code of the American Psychological Association. There is no discussion on research in the social sciences per se. The primary focus is on ethics in psychology and medicine. Surprisingly, the definition of research in the Belmont Report does not equate to the definition in the commission’s report on IRBs, and it fails to mention the testing of hypotheses. The main principle is beneficence which applies to neither the intent nor the purpose of the majority of people conducting research. We need to carefully consider ethics when formulating codes of conduct and need to ask ourselves what rules and regulations would in fact protect the autonomy of research participants and prevent gross injustice and the violation of basic human rights. The Belmont Report argues correctly that the informed consent policy is justified by the respect for individuals and the concern of their autonomy. The rationalization for research should be based on Kantian independence principles and humanism, and not on self-determination. All research must be commensurable with collective values of local
cultures, and when using both young and elderly persons who are vulnerable it must be ethically conducted. Moral self-rule is imperative. In Kantian terms, the respect for persons as autonomous ends-in-themselves with a capacity to reason and to be able to apply the moral law to themselves is non-negotiable. Bioethics is a growing trans, multi and interdisciplinary field, which undoubtedly merges a wide range of perspectives to come to grips with in the ethical challenges in what is a highly complex and dynamic world of human medical research.[30] The principle of respect for persons that relates to research with all human subjects requires that autonomous adults should in no way be subjected to any risk of harm without their informed consent. Their dignity needs to be upheld as human beings and should never be violated.[50]

For research with human subjects to be ethical it should always be value aligned and for the enhancement of medical knowledge, which may be used to fight certain diseases and illnesses. The research should also be scientifically rigorous and valid.[28] When considering subjects, it is paramount that risk be limited while the benefit should be increased and thus valid scientific aims should to be sought. In trials involving terminally ill patients; is there: ever true clinical equipoise; should women be enrolled as participants in clinical trials if they are of childbearing age; should prisoners or people living in refugee camps be enrolled in non-therapeutic clinical research and should incompetent mentally ill patients be participants in research clinical trials?[27]

The Belmont Report deals with the issue of justice poorly. It is not possible to distribute either the benefits or the burdens of research on human subjects according to random characteristics such as race, ethnicity, gender, religion or even one’s socioeconomic status. Firstly, not all people can benefit from medical research.[28] Secondly, some groups do not generally have medical conditions which proliferate in others. While human medical research seeks the betterment of society it is not always ethically needed.[50] This is why research policies should not be based or rated on how far they go in offering people opportunities for personal deliberation. They should be rated by the extent to which they protect subjects against deception and coercion. The Belmont Report suggests that benefits to others in society may well outweigh any harm to an individual subject. Where one is harmed, there can be no justification of any likely benefits even if autonomous research subjects of their own volition knowingly subject themselves to harm. Regarding bioethics much has to be done in order to safeguard individuals partaking in any form of medical research.

REFERENCES