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Ethics in Perinatal Medicine

Abstract: Background: The current trend in perinatal medicine addresses the challenge posed to newborn survival by newborn prematurity and other morbidities requiring neonatal newborn intensive care. These ethical concerns span through the spectrum of education, clinical practice and research, domicile in obstetrics and neonatology. Effective application of ethics to perinatal medicine requires basic knowledge bioethics in health care and medical research. 

Objectives: The objective of the article is to highlight the basic aspects of ethics, review research ethics and practical ethical issues in perinatal medicine and provide an analytical application of the principles involved in bioethics. 

Methodology: A search for the relevant literature available on the internet, journal publications, textbooks and monographs was conducted 

Result: The basics of ethics span through the definition of medical ethics, ethical codes and bioethics. It also includes the various bioethical orientations (historical, duty-based, utilitarian, feminist, casuistry, communitarian and virtue orientation), together with the guiding principles of modern bioethics and their levels of application (micro-ethical, macro-ethical, meso-ethical and mega-ethical level). 

Research ethics developed tremendously during the 20th century and it was boosted by a number of regulations such as Nuremberg code, CIOMS, Helsinki declaration, Belmont Report and the Nigerian National Code of Health Research Ethics. Ethics in perinatal medicine focus on medical decision making and foeto-maternal conflict as well as the concept of a foetus as a patient and medical futility. It includes prenatal diagnosis and interventions for severe congenital malformations of the foetus, safe motherhood and cord blood collection and newborn care. 

Conclusion: Bioethics is an important component of perinatal medicine. The consideration and application of bioethics in all aspect of perinatal medicine will undoubtedly improve the quality of care for obstetric patients and their newborn infants.

Introduction 

Over the past five decades, perinatal medicine and neonatology have developed tremendously to respond to the challenges of newborn survival and well-being as related to prematurity and morbidities requiring newborn intensive care. Ethical concerns generated in response to this development have continued to pose tremendous challenges spanning the spectrum of education, clinical practice and research. Perinatal care is domicile in the specialty of obstetrics and the sub-specialty of neonatology. The International Federation of Gynaecology and Obstetrics (FIGO) has played a leading role in the development of ethical guidelines in both obstetric and perinatal practice through its committee on ethical aspects of human reproduction and women’s health, which published periodically revise ethical guidelines for health professionals practicing obstetrics and gynecology as well as perinatal care.1,2 

Ethical considerations have been recognized to arise over a wide area of obstetric issues ranging from preconception genetics and embryo research through assisted reproduction, pregnancy care and in particular, issues related to abortion, multiple gestation, HIV infection in pregnancy, caesarean section, surrogacy and others.3,4 Ethics built into professionalism, initiated and nurtured during training has been recognized to be a sine qua non towards professional specialty best-practices. In the recent quarter of a century, McNealy and Singer have highlighted the need to include ethics in the training of resident doctors.5 In the same vein, from the latter part of the nineties, the Royal College of Physicians and Surgeons of Canada, together with the Council on Resident Education in Obstetrics and Gynaecology, recommended that the teaching of bioethics be made a require-
ment for the accreditation of residency training programmes. In addition, “residents were expected to demonstrate an understanding of the basic principles of ethics together with the knowledge of the applications as related to obstetric and gynaecological practice."

Over the past 40 years and more, giant strides have been taken in the United States of America, in the development of perinatal medicine through the improvement of technical capabilities of the healthcare providers to promptly make accurate diagnoses and provide effective monitoring and specific treatments. Special Care Newborn Units, equipped with the necessary technologies to manage premature and sick infants have been established in all nooks and crannies of the United States. The results of these efforts have been varied. The mortality rate among preterm infants has reduced tremendously, although, the incidence rates of preterm and low birth weight babies have not shown any reduction. In addition, the overall infant mortality rate has declined but the incidence rate of birth defects has remained constant. Perinatal ethics is encumbered with peculiarities. Balancing the ethical issues between a foetus and the mother could be as challenging to the health professional as it is with regards to the clinical management of the newborn in the neonatal intensive care unit (NICU). In addressing some of the ethical issues in the NICU, the goals of specific monitoring, diagnostic tests, treatment, and patient-centered research protocols and the situation of the family who will live with the long term consequences of the day to day decisions made in the care of the infant should be put into consideration.

Effective application of ethics to perinatal medicine requires that the clinicians be vast in the fine details of bioethics as related to clinical practice. This review highlights the basic aspects of ethics – the definition of medical ethics, bioethical orientation and the guiding principles of modern bioethics together with analytical level of its applications. It also addresses research ethics and practical issues in perinatal medicine which requires ethical considerations.

**Basics of Ethics**

The three Greek philosophers – Socrates, Aristotle and Plato are regarded as the founding fathers of ethics. Ethics is a term derived from the Greek word “Ethos,” which means custom or habit. Medical ethics has been defined as the principles or norms that regulate the conduct of the relationships between medical practitioners and other groups with whom they come in contact in the course of their practice - professional colleagues, allied health professionals, patients, governments/non-governmental organizations and other actors in healthcare delivery. Ethical codes are sets of principles or rough guides to practice, usually developed following serious breach of ethical standards. An example of ethical code is the Nuremberg code of 1947, which was developed following the revelations of inhuman experiments carried out during the second world war by the German Nazi. Another example is the Helsinki Dec-
ing and behaviour into the value system of healthcare and clinical practice. It is a consequence of, hitherto exclusion of women from the historical sources of moral authority such as clergy, high ranking military commands and legislature.

Communitarianism refers to bioethical orientation that advances the good of the community while casuistry subscribes to the resolution of issues on the basis of their merit rather than on a resort to universal rules. Virtue represents the ethical orientation patterned after Hippocratic ideals – the tenets of which required health practitioners to pay stringent attention to kindness, trustworthiness, discernment and integrity in their practice.

Guiding principles and the levels of application of modern bioethics

The guiding principles of modern bioethics have been developed as a consensus resolution of the various bioethical orientations together with the recommendations made from the Belmont Report. This report was highlighted basically through the work of two notable American Ethicists, Tom Beauchamp and James Childress, together with British Raanan Gillon. The Belmont Report, published in 1979, contains the recommendations of the United States’ National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. This commission was established following the passage of the National Research Act of 1974 by the American Congress, in response to the complaints which accompanied the revelation of atrocious inhuman treatments meted out to four hundred black American subjects during the syphilis trial experiment in Tuskegee Alabama, USA between 1932 and 1972.15 – 17 Three of the four key guiding principles of modern bioethics are contained in the Belmont Report viz - the respect for persons, beneficence and justice. Non-maleficence, which is the fourth item, is derived from beneficence. Three other principles – fidelity, veracity and scientific validity - have been added to the latter.

There are two levels in the principle of respect for persons – the autonomy of persons who are capable and the protection of persons incapable of autonomy. Autonomy upholds the patient’s right to voluntary informed consent and choice, on the basis of his or her comprehension of available options. Respect for autonomy requires that the physician respects the values and beliefs of the patient, including the decisions made by the patient such as the informed consent. The implication of this is that, informed consent is a pre-requisite to the autonomy of the patient. There are three elements of informed consent:

1. Disclosure - appropriate communication with the patient as to what he or she needs to know for good understanding of the situation in question.
2. Comprehension - a clear understanding of the information received by the patient.
3. Free consent - the freedom of the patient to freely decide whether or not, to give consent.

The protection of persons incapable of autonomy constitutes the second level of the principles of respect for persons. Three categories of persons are considered to be incapable of autonomy - the unconscious, the mentally sub-normal and the child. These three groups require the protection of their autonomy. The first consideration, particularly concerning the unconscious patient, is whether or not he or she has a living will. In the absence of this, the protection of the autonomy of the unconscious patient, along with that of the mentally sub – normal and the child, lies in the consent of a surrogate. Where there is no surrogate, the ethics committee of the health institution gives the consent, and where the latter is not available, a clergy or Imam, and in the absence of any of these, as a last resort, the law court, shall give the consent.

A surrogate decision maker is a person authorized to act on behalf of the subject when the patient is mentally incapacitated and lacks the ability to make decisions. The surrogate is an adult with the ability to comprehend information and make decisions on the basis of that information. Furthermore, the person is available and is willing to make medical decisions on behalf of a patient who lacks decisional capacity. Most surrogates are naturally drawn from family members. In recent times, the state enacted legislation which confers surrogacy for medical decisions on family members in order of priority. Surrogate decision making is aimed at arriving at the goal the patient would have reached if able to and not really, the preferred goal of the surrogate.

The over-riding of patient’s autonomy is known as medical paternalism. Strong paternalism is the over-riding of the autonomy of a capable person and it is not ethically permissible. On the other hand, weak paternalism is the over-riding of the autonomy of an incapable person, which is permissible if performed in the overall interest of the person. The ethical principle of beneficence enjoins practitioners to do and maximize good, emphasizing the practice of the optimal best for the patient in both preventive and curative healthcare. The ethical principle of non-maleficence enjoins practitioners to do no harm and cause no pain to their patients; harm or pain, in this instance, could be physical or emotional trauma meted out to patients during the course of medical care. The principle of justice connotes the ethical responsibility to ensure equitable distribution of health benefits and risks to patients without any considerations of sex, social status, ethnicity or religion. The principle of veracity enjoins the health practitioners to tell the truth all times.

The principle of fidelity refers to the ethical responsibility of health practitioners to honour whatever promises has been made to the patients, at all times. In addition, the principle of scientific validity enjoins health practitioners to uphold the highest standards of professional competence and scientific soundness in the care of their patients. Therefore, health practitioners should, at all times, desist from embarking on treatment which they are not competence to carry out.

There are four analytical levels of application of ethical
principles. Micro-ethical analytical level is individualized and refers to the relationship between the health practitioner and the patients. Much as the health practitioner has the ethical obligation to give the patient accurate and concise clear information to enable the patient make an informed decision, the patient, similarly has the ethical obligation to respect the health practitioner’s conscientious objection to carry out certain treatments that the patient may desire. Macro-ethical analytical level is more broad-based and refers to the relationship between groups or communities – between members of a community or between members of more than one community. A typical example of breach of ethical principles at the macro-ethical level is the inequitable distribution of medical doctors between the urban centers, where they abound in greater numbers, and the rural areas, where there are very few medical doctors, in spite of a relatively higher population in the rural areas.

Meso-ethical analytical level refers to the disparity in the allocation of resources between various groups, whether in the public or private sector. It is also known as inter-generational justice; it falls between micro-ethical and macro-ethical analytical levels and violates the ethical principles of both beneficence and justice. Mega-ethical analytical level refers to issues which traverse national boundaries. Areas of concerns of this include reproductive health issues and its related impact areas such as, status of women and the environment.

Ethics and research

In the words of Sir William Osler, “Medicine arose out of the primal sympathy of man with man and out of the desire to help those in sorrow, need and sickness.” This, apparently, the premise under which medical research arose in response to the suffering that accompanied several epidemics of old such as plagues and tuberculosis. Apart from aiming to alleviate the suffering, this principle also ensures that even when deaths occur, it has to be with an attendant dignity and the satisfaction of health practitioners and researchers that enough care has been given, within every reasonable human capability.

Medical research has the noble goal of improving human well-being. However, the question arises as to how the rights of an individual can be reconciled with the demands of scientific ventures. Is it possible to ensure the protection of the right of the individual while seeking to achieve the laudable end result of research? Most researchers of the 17th and 18th century were unmindful of the need to protect the rights of human beings involved in biomedical research, and this continued even into the second half of 20th century. The Surgeon-General of the United States of America, in 1900, employed twenty-two Spanish immigrant workers in Cuba to prove that mosquitoes transmit yellow fever, and contract was substituted for informed consent. In the same year 1900, what was seemingly the first “National Guideline” on health research ethics was issued by the Prussian Ministry of Health as a ministerial directive in response to the work of Professor Neisser who, in 1898, while trying to develop anti-syphilis agent injected cell-free serum from syphilitic patients to other patients – most of whom were prostitutes – without their consent. Some of the subjects consequently developed syphilis. Professor Neisser was tried and found guilty by the Royal Disciplinary Court and was fined an amount equivalent to 25% of his annual income. The first true National Research Ethics Regulation - involving new therapy and human experimentation, was enacted by Germany on the 28th February 1931. Over the ensuing seven decades of 20th century, a good number of scandal-targeted regulations were enacted the world over, in response to inhuman experimentation meted out to human subjects, notable among these were:

1. Nuremberg Code 1947 – enacted following the revelations of atrocities and inhuman experiments carried out during the Second World War by the German Nazi and the following Nuremberg trial.
2. The Helsinki declaration – enacted by the World Medical Association in 1964 in Helsinki, Finland. This declaration consists of guidelines to protect humans, animals and the environment with respect to biomedical research.
3. National Research Act and the Belmont Report 1974/79 – this is the United State Congress’ response to the complaints raised following the revelations from the inhuman syphilis trial experimentation which was out on four hundred black Americans at Macon County, Alabama, between 1932 and 1972. The US Congress enacted the National Research Act of 1974 and then, set up the commission on the protection of human subjects involving biomedical and behavioral research in 1975. This commission produced the report of their finding in 1979 and this report is known as the Belmont Report in 1979.
4. The Council for International Organizations of Medical Sciences (CIOMS) Guidelines (1993/2002) - This council was jointly established in 1949 by World Health Organization (WHO) and United Nations Educational, Scientific and Cultural Organization (UNESCO) to serve the scientific interests of the international biomedical community through various activities such as the development of guidelines for ethical conduct of research. In 1993, CIOMS developed a set of guidelines entitled the International Ethical Guidelines for Biomedical Research Involving Human Subjects. Periodic revisions of these guidelines and others have gone off since 2002 including the revision of Helsinki Declaration in 2013.
5. Nigerian National Code of Health Research Ethics (2007) - In 1996, Nigeria witnessed the worst ever epidemic of cerebro-spinal meningitis (CSM) involving 300,000 people and causing 30,000 deaths. Pfizer drug company saw that epidemic as an opportunity to embark on a second phase therapeutic trial of their new antibiotic drug “trovafloxacine” (built for registration with the US FDA) for its efficacy in the treatment of paediatric CSM. This trial involved the recruitment of 98 children who received the new drug.
and another 100 patients who received an under-dose of another antibiotic drug, ceftriaxone, with case fatality rates of 5% and 6% respectively. It was discovered that the subjects were neither adequately informed about this trial nor were their consents obtained. The result of this study was an increased awareness on the need to observe ethical standards in clinical research, the training of health researchers, at the local and international levels, on ethical aspects of clinical trials involving human subjects. In furtherance to these, in the year 2005, the Federal Ministry of Health of the Federal Republic of Nigeria inaugurated the National Health Research Ethics Committee for the strengthening of a mechanism that will ensure the protection of Nigerians when they are enrolled to participate in research. The terms of reference of this committee included, the setting of standards and guidelines on health research including clinical trials, adjudicating on complaints involving breaches of ethical standards during research and reporting such breaches to appropriate regulatory bodies in addition to recommending appropriate disciplinary actions. The committee is also empowered to advice the Federal and State Ministries of Health on any ethical issues concerning health research.23

Ethical issues in perinatal medicine

Perinatal medicine is replete with important issues that elicit ethical concerns. The knowledge of this fact has heightened the inevitable need to develop and include ethics in the curriculum of undergraduate and postgraduate medical education. Admittedly, this inclusion is believed to be coming relatively late in the field of obstetrics and perinatal medicine compared to other specialties such as medicine, general pediatrics and psychiatry.24 Nonetheless, a lot has been done in the sensitization of practitioners of perinatal medicine as to the ethical imperatives associated with their practice in the areas of education, research and clinical practice. Some key areas and their ethical associations need to be highlighted. Perinatal medical research, because of its sensitive nature, should be associated with protocols that conform with laid down ethical guidelines in order to ensure that appropriate benefits, rather than harm, accrues to the fetus or neonate, the mother and indeed the society.25

Medical decision making and materno-foetal conflict

Medical decision was, over a long period of time, paternalistic, with decisions made solely by the medical practitioners and handed down to the patient without questions. However, in recent times, decision-making is shared between the patient and the doctor, with patient’s autonomy occupying a more prominent place, even if, it conflicts with the doctor’s recommendations. It has become the responsibility of the doctor to present information, together with alternatives and options, to enable the patient make informed decision as to what management option to accept.

Materno-foetal conflict arises when a pregnant woman refuses to accept medical treatment or intervention considered necessary to optimize the safety of her life and that of her unborn child. For example, when a pregnant woman with Type 4 placenta praevia vehemently rejects an offer of caesarean section, or as does also, a woman with severe pre-eclampsia causing intra-uterine fetal growth restriction. The conflict in these cases lies between the physician’s recommendation and the pregnant woman’s autonomous decision to reject the recommended intervention. In these cases, it is ethically expedient that the physician examines the reasons for the patient’s refusal to accept his medical advice to guide his next line of action. It is true that, for the pregnant woman, her duty of beneficence to the foetus may override her right to autonomy. However, the resolution of any associated conflict must be her choice. In materno-foetal conflicts, therefore, the pregnant woman’s autonomy takes the center stage. If the pregnant woman has decisional capacity, ethics demands that her autonomy and choices, even ‘bad’ choices, be respected. A pregnant woman’s autonomy and informed refusal should be respected. These viewpoints have become the standard responses to the vexed issues of “court ordered caesarean section”.26

“The foetus as a patient” concept

Perinatal medicine has recently promoted the concept of a foetus as a patient. In their review of this subject matter, Chervenak and McCullough posited that the foetus becomes a patient when the foetus has a problem requiring medical intervention which will considerably determine the well-being of the foetus and aid her development into a healthy child.27 Before the age of viability i.e. 24 weeks gestation, the foetus is not considered to be a patient that is independent of the mother’s autonomy in so far as it is incapable of independent survival ex-utero. The implication is that the pregnant woman can bring her values to bear on her attitude towards the status of the foetus as a patient. She may, therefore, decide to uphold or withdraw the patient status of her pre-viable foetus.19 The situation is different for the viable foetus (gestational age 24 weeks or more) which is considered to be capable of surviving outside the womb of the mother; this independent survival confers on it the autonomy status that is independent of the mother.27,28

The foetus, as a patient, can be understood in relation to the two ethical principles of beneficence and respect for person. The treatment given to the pre-viable foetus must uphold the ethical principles of beneficence to the foetus, albeit subsumed within the autonomy of the mother, while the treatment given to the viable foetus upholds the two ethical principles of beneficence and autonomy of the viable foetus. Both ethical principles should be upheld in the mother.28,30 Therefore, it is clear that the physician has maternal autonomy-based and maternal beneficence-based obligations as well as foetal beneficence-based obligations, which must be balanced. The pregnant woman’s autonomy has priority. If maternal autonomy is at variance with the interests of the foetus, her interests, which in-
clude her autonomy, takes precedence over that of the foetus irrespective of whether the foetus is at increased risk or not.  

**Medical Futility**

Medical futility is a situation where medical interventions for the mother or foetus are considered to be of no benefit. It is commonly encountered in situations of extreme prematurity, severe congenital anomalies and other situations of severe newborn complications requiring resuscitation. It is a terminology presently considered to be unpopular because of its semblance of hopelessness which could discourage health practitioners from putting their best forward towards the salvage of the patient. Futility conflict arising from treatment options should balance the values and feelings of the patient’s relatives who will care for the patient with that of the default position of maintaining life in ordinary terms.

**Prenatal diagnosis and interventions for severe congenital malformations in the foetus**

Perinatal diagnosis is an essential procedure in modern obstetric care. It provides information on foetal diseases which may require termination of pregnancy in countries where such is legally permissible. The procedure should be preceded by counseling and informed consent should be obtained. Ethical questions arise on what degree of abnormality warrants the termination of pregnancy. In general, the decision on whether or not to terminate the pregnancy should be made by the parents and relations of the patient, who are appropriately guided and not coerced. Where abnormalities are compatible with life, parents are discouraged from opting for pregnancy termination.

It is ethically appropriate for a woman carrying a severely malformed foetus to seek pregnancy termination. Where termination of pregnancy is not possible on legal and religious grounds, such pregnancy should be subjected to prenatal diagnosis procedures to ascertain the extent of abnormalities. The pregnant woman must be appropriately counseled before and after the procedure to allow informed decision with regards to pregnancy process and termination of pregnancy should never be carried out on the ground of foetal sex. Where a disagreement exists between couples on the fate of the abnormal foetus, the decision of the mother takes precedence. Where the couple disagrees with the advice of the attending physician, the physician is ethically bound to encourage them to seek the opinion of another physician. It is ethically appropriate for the physician to seek consent to confirm and appropriately document the nature and extent of foetal malformation following termination. In addition, the physician must inform and counsel the parents on the magnitude of the problem, and the action required.

**Safe motherhood**

The key indicators to safe motherhood are maternal and perinatal mortality as aptly captured in the fourth and fifth goals of the United Nation Millennium Development Goals. Most causes of maternal and child deaths are preventable and, therefore, constitute a violation of key ethical principles in obstetric and perinatal care. Lack of access to family planning services, abortion services, good antenatal care, emergency obstetric care, safe and clean delivery by skilled birth attendant, postnatal care services and good neonatal care – all constitute a violation of the ethical principles of respect for persons, beneficence, non-maleficence, and justice which may occur both at micro-ethical or macro-ethical level.

**Cord blood collection and newborn care**

The umbilical cord blood is a good source of haemopoietic stem cells which can be used in the treatment of certain blood-related disease conditions such as leukaemia. At the point of birth, the cord blood can be collected, pooled and stored in cord blood bank for dispensing when required. The storage and collection of umbilical cord blood requires informed maternal consent. Early clamping of the umbilical cord at birth has been shown to cause a reduction in the circulatory volume of foetal blood by 30% which may tip the foetus into circulatory collapse. Therefore, obtaining an informed consent from the mother including an explanation of the procedure and a promise to avoid early clamping of the umbilical cord, should be a pre-requisite for the collection of cord blood for pooling and storage.

Newborn resuscitation is also an integral aspect of good perinatal care. Newborn resuscitation requires that the medical practitioner upholds the ethical principles of respect for person and non-maleficence through a pain-taking, careful and non-traumatic resuscitative practice. The neonates undergoing resuscitation constitutes a person incapable of autonomy but whose autonomy, nonetheless, needs to be protected. It is therefore ethically appropriate that the parents of the newborn, serving as the surrogate, be appropriately informed on any resuscitative measure or intervention that needs to be carried out on the newborn and consent appropriately obtained. Counseling of the parent surrogate requires that the medical practitioner be vast with the knowledge of the clinical condition and diagnosis, management and prognosis of the infant under care, to enable him give accurate information to the parents otherwise, consultation with senior members of the team may be necessary. Where the parents disagree with the advice of the medical practitioner, an independent adjudication may be sought and in extreme cases, the views and intervention of the institution’s ethical committee.
Conclusion

The development of perinatal medicine over the years has been targeted at the improvement of newborn survival from prematurity and other morbidities associated with the newborn. Bioethics has inevitably developed alongside to address ethical issues associated with the obstetric care, perinatal research and newborn intensive care necessary to ensure the survival and well-being of newborn infants. The implication of this is that, healthcare professionals caring for the pregnant mother and her newborn should be conversant with bioethical challenges involved in such care and the response necessary to achieve success. Therefore, health professionals should be aware of the ethical issues concerning foeto-maternal questions arising pre-conception, during pregnancy, at delivery and during the post-partum period, in order to optimize positive outcome of care and interventions involving the mother and newborn during these periods.

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References


