Bulletin of GSMC MUHS International Chair Bioethics Unit

October 2021

World Bioethics Day
Informed Consent

Theme : 2021

INFORMED CONSENT

Seth G S Medical College and KEM Hospital, Parel, Mumbai -12
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GSMC - MUHS International Chair Bioethics Unit

Poster Competition on

'Informed Consent'

First Prize

Mrunmai Sunil Gaikwad

Introduction

Advances in biomedical sciences have made ethical lens imperative for medical practitioners, researchers and society at large so that adherence to moral values of beneficence, justice, autonomy in medical practice and research are up held.

Warren Reich's encyclopedia of Bioethics defines Bioethics as *'an area of interdisciplinary studies'* concerned with systematic study of human conduct in the area of life sciences and health care. Dr. James Drane calls the discipline paradigmatic because the dilemmas force the scholars to examine the essential life and death questions in the context of medical conditions. Scholars from diverse disciplines like philosophy, theology, sociology, law, biomedical sciences alongside medicine have contributed to development of the field. With their contributions to the development of bioethics core principles since 1960s, these streams have been instrumental in guiding medical practitioners towards rights based approach to health. So in way it is a union of the two trees of knowledge- humanities and philosophy on one side and medicine and biosciences on the other; that leads to growth of an integrated approach towards not only human but also environmental well-being and growth.

The Oxford dictionary defines the word *'Inarch'* as a plant graft created by connecting a growing branch without separating it from its parent stock. The term conveys the spirit of synergy between the two streams. Hence we chose this name for our bulletin which will bring to you articles on bioethical issues by medical faculty, students, ethicists, philosophers.

Our bulletin is intended for undergraduate, postgraduate students in medical, paramedical subjects and nursing as well as practitioners and teachers. It aims to open up discussion on ethics of practice, research, curriculum content and advances in biomedical sciences.

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GSMC MUHS International Chair Bioethics Unit.

Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra, India

NURTURING ETHICAL VALUES.....
ENRICHING MEDICAL EDUCATION.

Vision :

"Establishing highest level of ethical and professional standards in health professionals education, practice and research."

Mission:

"To inculcate the basic ethical, professional and humanitarian values in medical students right from the first day of training in order to make them not only expert clinicians but also compassionate human beings."

The 'GSMC-MUHS UNESCO Bioethics Unit' was formed in the month of August 2015. The solemnisation of the Unit under the MCGM Nodal Bioethics Unit and affiliation with UNESCO, Chair in Bioethics Haifa Australia was on 9th November 2015. The MCGM nodal unit was established at an event held in Topiwala National Medical College auditorium.

The objective of Bioethics Unit is to integrate the MUHS approved UNESCO Bioethics curriculum in the undergraduate and postgraduate students education and to train the faculty in effective implementation of the same.

1. To introduce and deliver bioethics and professionalism training in undergraduate and postgraduate curriculum.
2. To prepare an updated and modern curriculum, reflecting the need for integration of ethics during the training period and for its effective implementation in clinical practice.
3. To increase interest and respect to values involved in health care delivery and raising awareness for competing interests. To introduce various non-medical facets of medicine: sociology, economics, and public administration to students.
4. To add new chapters to present curriculum that will relate to new dilemmas, accommodating medical, technological and scientific progress.
5. To create training programs for teachers and instructors of ethics in medical institution.
6. To initiate, collaborate, facilitate and participate research related to bioethics.

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Editorial

Agreement is a given in any successful interpersonal transaction and a fundamental tenet of medical practice. In formal medical documentation, the same is called an informed consent and it is a mandatory document in most medical procedures as well as medical research. This year's World Bioethics theme is ' Informed Consent'.

Though bioethics as a structured curriculum in undergraduate medical foundation course as well as training was introduced by National Medical Commission as recently as 2019, the principles pertaining to consent administration have been in discussion for mean years. Ironically, the reason that the medical bodies and organisations discuss these are for safety of the practitioners rather than to uphold the patients' rights.

Movies and stories have always held a mirror to human mind and GOD complex described in the Hollywood movie Malice as well as in the a Marathi movie Aghat does show a mirror to the medical community. This complex is very dangerous phenomenon that not only erodes the ethical values of the practitioner but also sends wrong message to the budding physicians and surgeons who emulate their seniors and teachers. Only solution to this problem is a rigorous institutional oversight and internal regulation alongside Ethics training.

Postgraduate students, unlike the undergraduates, are the most important players in the real world of patients. They are the frontline providers who actually counsel patients and relatives, triage the emergent cases and administer consents. They must have a safe and dedicated space to discuss the ethical dilemmas in their work, with the experts in the field of ethics. Bioethics grand rounds that the GSMC MUHS Bioethics unit conducts for residents in various streams is an activity that must be mandatory across the residency. Writing Narratives and reflections enhances ethical insight of an individual. The unit has conducted workshop in Narratives and Reflections for the undergraduate and postgraduate students.

All professional bodies have ethical guidelines and codes in place, In spite of the codes, instances like Tuskegee Syphilis Study, HPV vaccine trial deaths have occurred. Both of these are examples of lapses in consent administration and students as well as practitioners must be aware of how these lapses cause a setback in research as well as practice.

This volume carries diverse standpoints; legal to personal. The article on women's vulnerability discusses why and how gender bias and gender blindness subverts autonomy and rights of women and the disabled. Special cautions in Informed consent document with regards to the vulnerable groups is important trainees to know and for practitioners to introspect on. Articles on Elements of Consent and consent In HIV and psychiatry highlight the legal provisions for the vulnerable.

In spite of choosing diverse topics, we have not completely covered the field of Consent. Topics like genetic consent, consent in public health research, end of life issues are yet to be covered. We hope to undertake educational events pertaining to these topics.

I hope this volume enhances our understanding of interrelationship of vulnerability, autonomy and consent

Dr. Padmaja Samant

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Message

I am delighted to learn that the GSMC MUHS Bioethics Unit is publishing the next issue of 'Inarch'. I offer my congratulations to the you and the members of the GSMC MUHS Bioethics Unit Mumbai India for this initiative. The last issue of Inarch was indeed outstanding and a great success. I am confident that this issue of Inarch and indeed the activities and programs under your leadership that I am aware continue to be of high quality.
Please convey my wishes to all then members and the active student wing / p[rogram of the Bioethics unit.
Sincerely

Professor Russell D'Souza MD
Melbourne, Australia

This year has been one fraught with pain, losses and exposed us to the good,bad and ugly.At the same time, this pandemic has taught us many lessons on resilience, kindness, giving and renewed hope. Let us move forward with new strength to be the best ethically, professionally and personally. I wish the Bioethics team the very best as you continue to do the good work that you began. Be positive and stay safe. Let the good shine over darkness.

Dr. Mary Mathew
Head, Indian Program
Former UNESCO Chair in Bioethics (Haifa)
Internationl Chair in Bioethics .

Municipal Corporation of Greater Mumbai

Seth G S Medical College and K E M Hospital, Parel, Mumbai

Dr. Hemant Deshmukh

Message

IIt gives me immense pride in writing this message for the yearly Bioethics publication INARCH by Bioethics unit of Seth G.S. Medical College.

This year's theme is 'Informed Consent' and it is a very apt choice of an ethics theme to be discussed as we are gearing ourselves up for the third wave of the COVID 19 pandemic. The pandemic has turned out to be an acid test of values and principles for clinicians and researchers alike. The global medical fraternity's ethical values of respect, autonomy and justice towards patients and research participants have been continually challenged for nearly two years now.

This volume contains articles discussing 'Informed Consent' from its evolution to utility of 'Informed Consent' depicted in popular media for teaching bioethics. The volume also has poetry, art and photography throwing light on the nuances of autonomy and consent.

The strong values, principles and creativity of our students and the commitment of our faculty have made this volume an interesting as well as informative read.

I wish them all the best in spreading the Ethics message among their co-learners.

Best Wishes,

Dr. Hemant Deshmukh

Seth GS Medical College and KEM Hospital, Mumbai

Municipal Corporation of Greater Mumbai

Seth G S Medical College and K E M Hospital, Parel, Mumbai

Dr. Milind Nadkar

Message

I am delighted to write this message for our yearly Bioethics publication INARCH.

The World Bioethics Day is celebrated on 19th October every year by all the Bioethics units of the International network of the UNESCO Chair in Bioethics.

The year's theme of 'Informed Consent' has thrown a spotlight on Autonomy, respect, veracity and justice with regards to clinical practice and research upon the diverse populations.

To some extent, COVID 19 has been a great equaliser, teacher and a challenge for not only clinical but also public health ethics.

I was happy to peruse through the volume containing art, poetry and articles by our students and teachers on this theme.

I wish them all the best in their endeavours in mainstreaming bioethics discourse in medical

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A Brief Glimpse of Evolution of Informed Consent from Ancient to Modern Times

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Introduction

Human participants are integral part of research which helps in advancement of various techniques and treatment modalities required for strengthening the healthcare system. In any medical research involving human participants, it is important to protect participants from harm. It is equally important for the researcher to obtain permission or approval of the participants to understand their willingness to undertake the risk.

Obtaining consent (meaning in Merriam Webster Dictionary "to give assent or approval" verb; "compliance in or approval of what is done or proposed by another" noun)[1] becomes obligatory to ensure that autonomy of the patient is exercised. Autonomy is one of the primary pillars of ethics which decides research participants' "right to selfgovernance, choice for care and the right to accept or refuse treatment;" and the only way to establish selfgovernance is to make sure that before expressing the willingness the participants have complete information about what to expect, the benefit/risk of the process, and the alternative options.[1]

The paternalistic attitude of physicians was evident in ancient India and during Greco-Roman period. The cases of abuse of research participants in history have influenced the development and regulation of informed consent processes.[2] Various factors such as socio-cultural diversity, vulnerability of involved people influence the principle of informed consent in medical practice and research involving human participants. Informed consent has evolved because of abuse/suffering of patients and research participants.

History of Informed Consent

Traditional systems of medicine during ancient times

In Ayurveda, Siddha, and Unani, it was as fiduciary responsibility of a physician to see that the patient did not come to any harm due to treatment. During ancient times, if the treatment involved high risk to the patient in the form of severe complications or death then the permission of relatives, community and the state of head used to be sought. But the permission or approval of patient was not considered. This was expressed in the same manner in all the classical texts of the traditional systems of medicine Sushruta Samhita & Charaka Samhita.[3 &4] The 'Arthasastra', the text of 3rd century mentions the capital punishment to physicians who have not taken prior permission before performing major surgery, which could result in death.[5]

In ancient Greece, the society was constituted of freeborn men and slaves. So, a doctor could have apprentices/trainees who belonged to either group. Although after training they too acquired the art of medicine to be called as "doctors". The societal status of patients affected the treatment given by the doctors.[6] The slave doctors treating slaves never explained the details of treatment to them. But freeborn doctors, who mainly treated freeborn patients, described the nature of their illness, but they did not reveal the whole truth regarding the condition or its prognosis, and prescribed medicine to them only after obtaining their consent. Even in the Hippocratic oath which is the first set of writings on medical professional conduct, the concept of consent goes unmentioned.[2]

Medicine and research during modern times

During modern times, there were many cases where the willingness/approval of patients/ research participants was not taken into consideration. The Father of Modern Gynaecology 'James Marion Sims' performed surgeries without anaesthesia on African American slaves. Some had several surgeries and died. Sims developed pioneering tools and surgical techniques related to women's reproductive health[7]. This was the prime example of 'progress in the medical profession made at the expense of a vulnerable population'. The Court hearing on case of Pratt vs. Davis (1905) stated that "Physician or Surgeon, however skillful […] [cannot] violate without permission the bodily integrity of his patient."[8] In a similar case in 1914, the verdict clarified that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body […]."[9]

During second World War, the German physicians carried out inhuman experiments on prisoners of concentration camps in the name of scientific research. The consent was not obtained from the prisoners and the end point of most of the experiments was death.

The U.S. Public Health Service (Tuskegee, Alabama, 1931-1972) studied the effects of untreated syphilis in poor AfricanAmerican land workers for over 40 years even after discovery of penicillin for treatment of syphilis in 1943.[10]

The HPV vaccine trial was initiated among tribal women of India (vulnerable population) under the pretence of "observational study" or "Demonstration project". The trial was started without taking mandatory permission from Drug Controller General of India. The trial resulted in the death of seven girls and in 2010 the Indian parliament's standing committee on health observed that "safety and rights of those children were highly compromised."[11]

Major developments in the evolution of informed consent

In 1900, the term 'Informed consent' was first used in Yellow Fever Study. The study participants were volunteers from Spanish immigrant community. Walter Reed developed a written consent document in Spanish, so the participants would be fully aware of the risks and would have signed the documentation which promises care and compensation.[12]

In 1947, the trial of 23 physicians and bureaucrats charged with crimes against humanity and war crimes for inhuman medical experiments conducted on concentration camp prisoners concluded in Nuremberg, Germany.[13] A trio of American set forth a series of 10 basic rules for the conduct of human experiments that has become known as the Nuremberg Code.[14] The emphasis was given on voluntary consent to regulate the ethical conduct of research experiments with human subjects. In 1964, the World Medical Association at a meeting in Helsinki, Finland adopted the 'Declaration of Helsinki' which outlines "a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects". It has been revised many a times and has been constantly updated till October 2013. The Tuskegee trial in US led to formulation of Belmont report (1979) by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for human protection. This report identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects. It mainly focuses on three principles: Respect for persons, Beneficence and Justice.[15]

In 1982, The Council for International Organizations of Medical Sciences published International Ethical Guidelines for Biomedical Research Involving Human Subjects (revised in 1993 and 2002). The "Policy Statement on Ethical Considerations Involved in Research on Human Participants" was released by Indian Council of Medical Research (ICMR) in 1980. Under the topic of informed consent, it states "the best way of obtaining informed consent is one that is difficult and one in which the norms and forms used in other countries are really not fully relevant to the conditions prevailing in this country."[16]

The central government in consultation with Drugs Technical Advisory Board (DTAB), Central Drug Standard Control Organization vide the Gazette of India notification dated 7th June 2013 proposed to make draft rule that audio-video (AV) recording of the informed consent process of individual participant by an investigator including procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record while conducting clinical trials in India.[17]

Conclusions

Despite existence of ethical principles & regulatory mechanisms there have been many instances of violations of informed consent worldwide. The paternalistic attitude of physicians has changed over time, mainly from 20th century. It is the duty and responsibility of the physician to share the required information and the risks involved in the treatment/ research with the patients/ research participants. Obtaining consent after providing required information and then shared decision making is very important to protect the autonomy of patients/research participants. The concept and process of informed consent is ever evolving. Various experiences and encounters between patients and physicians and between researchers and participants especially different emerging circumstances lead to appropriate modifications in guidelines.

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The consent of the governed is not consent if it is not informed
Edward Snowden. Legal and History

Philosophy of Autonomy and Consent

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Informed consent is a key element for protection of human welfare. Whether in the Greek or Roman era or ancient India, there has been a defensive paternalistic approach. Socio cultural differences existed then and are present now too. Sushruta Samhita mentioned permissions to be taken from State head (kings) but not from the patients themselves, Arthashastra mentioned capital punishment to the physician if prior permission was not taken before major surgery where death could occur. Kings offered sword to the physician before their operation, symbolizing that they not only gave informed consent, but also "informed request" to be operated so that the physician would be safeguarded.

Hippocrates stated that information needed to be given to the patient to enable her/him to cooperate with the physician to give consent. It was only after the shocking experiments of Nazi that gave rise to the Nuremberg Code. This was followed by Helsinki Declaration which stated the importance of an ethics committee review. An informed consent document was included comprising participant information sheet and informed consent form.

There exists a universality in vulnerability of patients or participants with reduced autonomy. Based on the Idea of popular sovereignty is the social contract and tradition of liberalism, a collective expression of rational choice. The roots of autonomy as self-determination are found in ancient Greek philosophy, in the idea of self-mastery. The ideal of humanity with self-sufficiency was associated by Plato and Aristotle and idea of moral autonomy developed further by Kant as having authority over one's actions. He connected the idea of self-government to morality; He felt one should be obedient to self- imposed law rather than an externally imposed law or religious precept. Moral autonomy was identified as the capacity to deliberate and Personal autonomy as the capacity to decide for oneself and pursue a course of action in one's life, often regardless of any particular moral content.

It is not what decisions we make but also what do we value while making these decisions. In bioethics, autonomy is a key value. Religious, traditional, or community norms and values are known to guide patients autonomously. Eg, the Navajo tribe in US believes knowing negative information could lead to harmful effects. Such cultural differences can influence decision regarding full disclosure. Though Negotiation of these diverse values and beliefs in decision making may be difficult, a patient's autonomous decision needs to be respected. This is irrespective whether it involves the negative right against interference or positive duties of moral reflection. Autonomous choice is said to be a right, not a duty of patients (Beauchamp and Childress 2001).

"Respect for autonomy" is the first principle for ethical decision making even though it is not intended to override other moral considerations and should not be constrained. There is a positive call for "respectful treatment in disclosing information and fostering autonomous decision-making" however where hierarchy in community still exists, in spite of constitutional freedom application of

autonomy to give consent out of free will does not apply.

Within the disability rights movement, the slogan, "Nothing about us without us" is a call for autonomy. A context of human relationships is applied which builds in a social component involving a dynamic balance between interdependent people. It talks about desire to recognize and empower as agents capable of self-determination and not merely rejecting having decisions made for people with disabilities by others.

As seen in the Belmont report (1979), the protection of subjects' autonomy is enshrined in the principle of "respect for persons" which states that participants in trials ought to be treated as autonomous, and those with diminished autonomy due to cognitive or other disabilities or illnesses are entitled to protection. This is applied as the principle of informed consent, as the Report presumes that this is the best way to protect autonomy.

The word "consent" has several meanings. It is considered fully informed when a patient or research participant who has the capacity to comprehend or is "competent" voluntarily consents after understanding fully the treatment or participation. It gives them the Veto power. Lack of informed consent can be used to establish negligence or malpractice and torts. The arguments for informed consent revolve around protection, autonomy, prevention of abusive conduct, trust, self-ownership ,non-domination, and personal integrity.

Protection from overzealous scientific researchers and neglectful clinicians is important for restoration of trust. The term "informed consent" received a legal standing in 1914 in US during the case Schloendorff vs. Society of New York Hospitals with the decision of court in favour of a competent Mrs. Schioendorff who had given consent for only abdominal examination under anaesthesia, however the tumour was removed by the surgeon without informing her about the possible adverse outcome. In order to see see if adequate information was given to the patient/participant,courts rely on 'prudent patient test'.

Clinical trials follow formalized process in which participants receive explanations of the purpose, methods, risks, benefits, and alternatives to study participation, as well as other matters, before they sign informed consent forms.

It may not be possible to "fully inform" if it was to include all facts that are material to physician decisions. Information pertaining reasonable standards implies what is reasonably pertinent to the patients and all relevant information in the event if abuse is suspected.

In clinical care, due to the theirbeliefs, biases and ignorance about medicine, patients refuse interventions that everyone including family and friendsconsiders best for them. An effort needs to be madeto explain the information again if healthcare providers discover that their patients do not understand crucial risks. Some patients may knowingly risk their own health in the name of religious or moral commitments like a protesting, fully-capacitated Jehovah's witness even when a much needed (though forced) transfusion would save the his or her life.

In emergency it is not always possible to obtain normal consent as patient may be unconscious and family specific preference may be identified, hence a presumed consent is valid. However when consent is not explicitly given silence does not express a yes.

Voluntary Consent has three barriers 1) coercion, 2) undue inducement and 3) no choicesituations. Coercion is defined by philosophers roughly, as a threat to make someone seriously worse off than she

is or should be, unless she consents. There exists a power of inequality between physician-patient relationship which makes consent involuntary. When the patient's fear is well-founded, or even intentionally instilled by the practitioner, the norm has been to consider consent invalid.

Undue inducement means something is being offered which affects the rational judgment, like cash in hand or material or a study participation. Attention is diverted to benefit to be obtained, not allowing a proper consideration of risks and rational decision making.

'No choice'situation is -not offering alternatives compelling to choose the offer or to undermine voluntariness otherwise. Eg for a poor person, the only way to gain access to an expensive life-saving drug may be by participating in a risky or very unpleasant study where the drug is provided free of charge leaving him with no choice, undue inducement and coercion.

The links between informed consent, autonomy, and the good life are more tenuous. A patient may refuse surgery which was for his benefit because he may have not understood it rightly hence making a wrong autonomous choice or there at times may be when choice is not available; eg. euthanasia.

Even today many patients would like to have physicians make decisions for them and such delegation seems acceptable, with an argument that autonomy is patients right not duty and since informed consent serves autonomy it ought to be autonomously waivable. Autonomy and Informed Consent are closely woven and require an understanding of the philosophy , rights, duties and legalities of various forms of consent; be it implied, tactic, verbal, written and also of the situation of those without capacity to consent.

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Elements of the Informed Consent document used in Clinical Research

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Introduction

A knowledgeable consent technique is acrucial tool of ethical execution of medical research studies. The effectiveness and satisfactoriness of the consent process depend on information comprehension, competence and voluntariness of the study participant.[1]Consent is a person's voluntary agreement primarily based totally upon adequate understanding and knowledge of applicablefactsto take part in a research study or to undergo a diagnostic ,therapeutic procedurein medical practice. The key information essential to decision making on the part of the subject regarding the participation should be presented(both written and verbal) in the consent form in simple non -medical, non- technical language best understood by the participant / patient[2].

This article the authors are focussing on informed consent document used in clinical research. The elements of this consent form are same in all the ethical guidelines for clinical research with some minor variations. The elements of the Informed consent form as per Indian GCP (2001)[3,] Ethical Guidelines for the conduct of Biomedical Health Research issued by ICMR (2017) [4] , ICH GCP guidelines (1996) [5] and WHO guidelines [6] are as follows:

1.Statement mentioning that it is research
2.Purpose and methods of the research in simple language.
3.Expected duration of the participation, frequency of contact with estimated number of participants.
4.Benefits to the participant, community or others that might reasonably be expected as an outcome of research.
5.Any foreseeable risks, discomfort or inconvenience resulting from participation in the study.
6.Confidentiality of records
7.Payment/reimbursement for participation and incidental expenses depending on the type of study
8.Free treatment and/or compensation of participants for research-related injury
9.Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled.
10.The identity of the research team and contact persons with addresses and phone numbers

In addition, the following elements may also be required, depending on the type of study

1.Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected.
2.If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pre-test and post-test counselling.
3.Insurance coverage if any, for research-related or other adverse events.
4.Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research.

Details to be provided under each elements of the Informed Consent Form

Introduction section

This section must include a statement that this study isresearchstudy and why the subject is being asked to participate the study. A valid rational is expected here for participating in the study for an individual subject. In addition statement of purpose of the research with expected duration of participation for individual participant must be stated. The total number of participants to be enrolled and the total duration of the entire study are also important elements of the ICD[7].

Procedure/Methodology section

This element is expected to include all procedures including procedures that are experimental and the rational to use such procedures. The details of the visit schedule and procedures to be done at each visit, time needed to complete these visits, need to written in clear lucid language. Participants should understand the importance of the procedure and how they are helpful and risky. This will help the subject to understand the details about the study and if he is able to give time for the study visits and voluntarily take the decision whether to take part or not in the study[6].

Risksection

This section should describe all the risks including physical and non-physical harm that the participant may face due to participation in this research study. Even if study is observational study and only data capture from records it must be stated that this will involve no risk. In questionnaire based studies sensitive questions may cause emotional or mental harm this statement has to be stated. In case of interventional drug trials the explanation of risk including all adverse effects stating their frequency of occurrence and intensity based on the data available. This explanation should be a reasonable and should not minimise reported adverse effect as this can be one of the important factor for participants to take decision whether to participate or not in the drug trial.[6,7]

Alternatives section

This should include a disclosure of all the appropriate alternative procedure or course of treatment that might be advantages to subject in case of interventional studies. This is to enable a rational choice about participating in the given research study. Subject should be aware of all the range of options available to him and not only the research intervention.[6,7]

Benefits section

This section must include the benefits to the subject and should be clear and not overstated. If no direct benefit is anticipated that should be stated. If there are no benefits to the participant but knowledge gathered because of this research study may benefit society and patient care it must be clearly spelled out. Do not include in the benefit section about free investigations or monetary allowances that are made for participation in the research study[6,7,8].

Studyrelatedinjury

This section must state about the provision of free medical management for trial related injury as applicable for interventional study. In addition provision of compensation for the same in case the injury is proven to be related to the study. There must be statement regarding whom to contact from the study team(name and contact details to be specified) in event of this injury and how will the provision of compensation be made (e.g., via trial insurance policy etc).[7,8]This information will give assurance to participants if any medical treatment required in event of injury they will be provided with due care.

Confidentiality section

This is one of the important sections as it explains how the confidentiality of the subject and subject records will be maintained. List all agencies (regulators, EC etc) who may access the study records.[ICH GCP]It explains where data will be kept and for how long. Explanation regardinghow this data will be used in future research or shared with other researchers, if applicable. It is mandatory to specify if specimens/ records are stored and whether they are coded or anonymised (not revealing participant identity) explaining the coding system used to identify participant subject data or specimen.[4,5]

It explains the system who keeps the coding key and for how long possibility of identification. It also states that the data may be published or presented but participant identifiers will be revealed.

Contactinformation

In this section and explanation whom to contact for answers to participant question about the research study and whom to contact in events of aresearch related injury. The names of the principal investigator and designated study team members with the contact numbers should be provided. For queries related to subjects' rights as research participant,the contact details (name and contact number)of ethics committee secretary / office needs to be mentioned.[5]

Voluntariness

This should include a statement indicating that the participation is completely voluntary that it will not involve any penalty or loss of benefit to which the subject is otherwise entitled and the subject may discontinue participation at any point of time without giving any reason. It must clearly state that his treatment at the concerned hospital will not be affected.[7,8]

Conflict of interest

When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study must be specified.[7]

Additional elements of the informed consent

If applicable

1) statement should be included that a particular treatment or a procedure involves risk to the subject embryo or foetus in the subject is may become pregnant.[4,8]

2) when applicable should be in form of circumstances under which their participation may be terminated / withdrawn by the investigator without the subject consent.[6,7]

3) the additional expenses if any that are to be borne by the participant need to be specified.

4) In case of interventional drug studies, the advice on contraception and what happens to the participant if she gets pregnant during the study needs to be clarified.[7]

5) if placebo is used to specify that it is inert substance and there will be no effect of the same in disease control.

In addition, ICMR Covid 19 guidelines have given due emphasis to E- consent which states that technology should be utilized to prepare interactive formats and using electronic tools such as text, graphics, audio, video, podcasts, interactive website, platforms to explain information related to a study and to electronically document informed consent the same. ICH GCP guideline and WHO Guideline for informed consent form includes details about the Randomization if applicable along with the subjects' responsibilities. The ICH GCP also includes the details to be mentioned about the anticipated payment or expenses if any to the participant. According to ICH GCP the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority (ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject also must be stated. According to the WHO guidelines it is must to include all the details about the trial drug as applicable).

Gene transfer DNA research

A separate informed consent document should be used for the gene transfer portion of a research project when the gene transfer research is an add on part of the main research study.[4]

Paediatric Participant

In case of clinical trials on paediatrics written informed consent should be obtained from the parent or legal guardian. However, all paediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand. Where appropriate, paediatric participants (age above 7 years) should additionally assent to enrol in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form having similar elements as in the consent form in more simpler language.[4,5,7]

Conclusion:

Taking an informed consent is a unique opportunity to build a trusted communication channel with trial participants. Knowledge assimilated through the trial participant has a massiveeffect on performance, compliance, and retention of the participant in a clinicalstudy. The informed consent activitycan beextrachallenging for developingcountries like India in which illiteracy and multiple languages may pose an issue. A detailed written informed consent document elaborating all the elements makes the consent process a valid, meaningful, and knowledgeableexperience for the research participant and assist him/her in the essential step of decision making to participate in a research study. In addition, designing a detailed consent form is acritical step toward inculcating "Quality and Ethics" in clinical research.

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The Good physician treats the disease; the great physician treats the patient who has the disease

William Osler

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Electronic Consent – New Wine in Old Bottle

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Introduction:

Digitalization has become the new normal, globally and is rapidly catching up in various fields; including clinical research. A vital element of clinical research – the 'informed consent' which has four critical elements, namely, complete information disclosure, voluntarism, decision-making and competence (including understanding), and authorization of voluntary participation has seen increasing use of electronic approaches. With the great deal of potential that technology holds, come the challenges in adapting/ replacing the conventional ways to/ with the digital platform. This review briefly discusses the electronic consent from the ethics perspective.

The FDA defines electronic informed consent (eIC) as "the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent." [1] There are multiple stakeholders in informed consent process. The direct stakeholders are the potential participant, legally acceptable representative and impartial witness (as applicable), the Investigator and Site, and the Sponsor while the indirect ones are the Ethics Committee (EC) and Regulators who have oversight of this process.

Requirements of eIC:

Lately, electronic consents have been used to document consents. These must also include all the essentials of informed consent in the language understood best by the participant. The interactive interface has facilitated the participant's ability to retain and comprehend the information during the consenting process. It can allow and inform any amendments affecting participants' continuation in the study. The choice to use either paper-based or electronic informed consent methods, completely or partially, should be with the participants, throughout the consent process. An electronic method of taking the signature of the participant or the participant's LAR may be a part of the eIC procedure. In addition to an electronic record, a hard copy of the informed consent is best kept for archival and future monitoring if applicable. [1-2]

A systematic review on various digital methods in e-consenting concluded that digital tools, especially the interactive multimedia tools, may be useful to enable the development of personalized informed consent that is tailored to an individual's socio-cultural characteristics. [3]

Translation of the ICD is fraught with errors and although back translation certification is in place, the issue of acculturation of technical and scientific terminologies is not resolved. Video and graphics augmentation obviates the need for translation. Errors in maintaining multiple versions, in administering the correct versions of the ICD and in re-consenting are lesser likely with the electronic mode. [4]

Review by ethics committees/ regulators and monitoring of electronic consent does not require sifting through multiple papers and makes the process relatively easier as all documents are stored in a single place – the web portal. Remote monitoring of the consent process becomes possible. The complete audit trail - including retention questions correctly answered by the potential participant, time and date of

signing of Informed Consent by all those involved is easily available. In case of multi-centric trials, this also adds to uniformity across sites.

Electronic consenting has become more relevant and safer method now due to restrictions created by COVID-19 outbreak. It has been proposed by ICMR in its 'National Guidelines for Ethics Committees Reviewing Biomedical and Health Research during COVID-19 Pandemic' to avoid direct interaction with the patient in isolation. [5] Whether it is for COVID or non-COVID research, e-consent, in this context, serves as an excellent measure to avoid the risk of exposure to infection for all stakeholders in research. This also prevents the need to travel and thereby inconvenience and time.

Challenges faced while implementation of eIC:

The benefits offered by the digital mode of consent come with its own set of concerns.

a. *Costs:* The pre-requisite for implementing procedures through the electronic mode is availability of necessary gadgets, technology and expertise. Investment in devices and software, systems to validate electronic documents, although one-time, may add to the budget. The costs of technical expertise in designing an electronic consent are much more than that for the conventional paper-based ICD. However, this increase in costs is justified if it helps in satisfactorily improving the recruitment, retention and compliance of participants in the trial.

b. *Training*: is essential to generate multimedia files and graphic materials and familiarize the staff with the use of new system and troubleshooting that may be required. There may be participants who are not gadget-friendly and would prefer to read from hard paper copies (e.g; low vision, impaired motor skills). Assistance from the site staff is essential to acquaint the participant not familiar with devices and their preference for one method over other should be respected.

c. *Recruitment Strategy:* Would only electronic literate population will be included in the trials?

d. *Communication*: Use of gadgets is prone to limit the discussion between participant and the research staff making the process impersonal. Prudent use of technology can be a solution and the participant should be encouraged to ask doubts, which is possible even remotely. Video chats can be yet another alternative.

e. *Authentication*: There is no way to verify the legitimacy of the signature and also the identity of the person actually signing (especially when it is done digitally and remotely) the consent leaving chances of misidentification, unless the informed consent procedure is done under video recording which is not always feasible. Similarly, one cannot be sure of the voluntariness and decision-making capacity of an individual signing the consent.

f. *Privacy and confidentiality*: One of the most important challenges is maintaining data security and confidentiality. Participants may feel threats to their anonymity and privacy. Although, restricted access and integrity of research personnel can serve to take care of these, but computer hacking and data leaks are a liability.

g. *Lack of regulatory guidance*: There is limited availability of a comprehensive regulatory guidance for all the stakeholders, especially in India. But US FDA guidance gives details for use of electronic consent in question answer format for easy understandability. [1]

h. *Legal validity*: According to a source, the most-cited concerns by multiple stakeholder

groups included those related to the security and legal validity of an electronic informed consent platform and usability for specific groups of research participants. [6] The digital platform is a relatively new advance in the informed consent domain and there is always hope and room for improvement.

Future Direction:

Research along with the data collection methods has evolved tremendously in the recent past. Social media and mobile devices are helping to recruit more participants and allowing "access" to participants remotely without the constraints of time or location. Such innovative study designs are being developed that are possible to be conducted entirely via internet or mobile applications and have new models of online and electronic consent. [7] During all this, the question remains how best to protect the right of choice to participate or not in the research, communicate information needed to make that choice, and an oversight system designed to safeguard these core values. Thus, today's need is choice based on transparency, partnership, and shared governance.

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Legal aspects of Consent

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Consent for the purpose of medical treatment means that a person must give permission before they receive any type of medical treatment, test or examination. This must be done on the basis of an explanation by a clinician. The principle of consent is an important part of medical ethics and international human rights law. Consent from the patient is essential whether it is for an examination or a procedure.

Valid Consent: For a consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. So,

Voluntary means not coerced or pressurized by clinician or family or friends.

Informed – means that the person should have been given all the information about the treatment including the risks and benefits, any alternative treatments available, and of what can happen if the treatment does not go ahead.

Capacity to make decision means that the person has understood the information provided and can use it to make a decision.

If an adult has the capacity to make a voluntary and informed decision to consent or refuse a treatment, their decision must be respected. This is to be followed even if refusing treatment would result in their death or death of an unuborn child.

If a person does not have capacity to make a decision about their treatment and they have not appointed a lasting power of attorney, the clinician can then provide treatment that they believe is in the best interest of the person, having discussed with relatives of the person receiving the treatment.

Before performing an operation, in the case of a minor the doctor should obtain in writing the consent from the parent or guardian or from the patient in case of young adult. In an operation that may result in sterility, the consent of both husband and wife is needed.

When is consent not needed?

There are a few exceptions when treatment can go ahead without the person's consent even if they are are capable of giving permission.

It is not required to obtain consent if a person

- needes emergency treatment to save their life
- needs immediate additional emergency procedure during an operation
- with a severe mental health condition has attempted suicide and needs hospital treatment
-is a risk to public health as a result of illnesses like TB, rabies etc

Therapeutic Privilege: The doctor's duty to disclosure of information is subject to the exceptions: (a) if the patient prefers not to be informed and (b) if the doctor believes the patient is so disturbed and anxious that the information provided would probably cause significant psychological harm. This is known as Therapeutic Privilege.

Autonomy: The patient has a legal right to autonomy and self-determination enshrined within article 21 0f the Indian Constitution. A doctor who treats without valid consent will be liable under the law of Tort and criminal law and also under the Consumer Protection Act. His licence to practice can also be cancelled or suspended by the MCI when found guilty for negligence. If a patient is touched without consent being sought, a charge of assault or battery may be instituted. An assault consists of putting a person in immediate fear of battery, without lawful reason.

A battery is an act of unwanted touching a patient in the course of an examination or carrying out surgery without consent. False imprisonment is keeping a patient under anaesthesia for which no consent was given

Consent and Capacity:

The law presumes that an adult is competent and competency is typically challenged when a patient disagrees with a doctor's recommended treatment or refuses treatment altogether. For a consent to be valid, the patient should have the capacity and competence to consent. The doctor responsible for the patient must decide on the balance of probabilities, whether an individual has capacity to make a particular decision. It is important to access capacity using the 2-stage test. It is necessary to consider in stage1:

1) Whether there is a temporary or permanent impairment of, or disturbance in, the functioning of the patient's mind or brain.

2) Whether that impairment or disturbance renders that patient unable to make the decision in question.

In the 2nd stage of assessment, the patient is considered to be unable to make the decision if they are unable to

a)understand the information

b)retain the information

c)use or weigh that information as part of the decision process

d)communicate the decision

It is recommended to do an advance care planning, eg appoint a power of attorney who can consent to medical decisions on behalf of the patient, make relevant advanced decisions or make advanced statement in case of those at risk of future lack of capacity, including those with fluctuating capacity

Inadequate information - Test for negligence:

There has been a shift over the years in the amount of information given to support the consent process. Patient's questions must be answered honestly, even though this might cause them anxiety. The test for negligence is based on the Bolam test and the Bolitho test. The Bolam test is used to determine whether a medical professional has acted negligently, in a way that falls below the standard expected of a responsible body of medical opinion. The standard of care expected of a medical professional is determined on the basis of evidence provided by medical expert witnesses. Recently following the Bolitho case, the judges are allowed to reject the evidence of an expert witness if they consider that it is not logically defensible. This modification in the ruling means that it is no longer possible for a medical professional to escape liability for negligence simply by finding a suitable expert to support his defence case.

Supreme Court's guidelines on Consent:

The Supreme Court in Samira Kohli's case enumerated the principles relating to consent.

1)A doctor before commencing any treatment on a patient has to seek and secure the consent of the patient. The consent so obtained should be from a patient who has the capacity and competence to consent; and it should be voluntary and should have to be given on the basis on adequate information concerning the nature of the treatment procedure.

2)The adequate information should include (a) nature and procedure of the treatment and its purpose, benefits and effect (b) alternatives, if any, available (c) any risks (d) adverse consequences of refusing treatment.

3)Consent given for a specific procedure such as diagnostic cannot be valid for conducting some other procedure even though it may be or therapeutic treatment. The fact that the unauthorized additional surgery is beneficial to the patient or that it should save considerable time and expense to the patient or would relieve the patient from pain and suffering in the future, are not the fgrounds of defence in an action in tort for negligence or assault and battery. The only exception to this rule is where it is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay the unauthorized

procedure until the patient regains consciousness and take a decision.

4) There can be a common consent for diagnostic and operative procedure or for any additional procedure that may be necessary during the course of surgery.

5) The nature and extent of information to be furnished by the doctor to the patient to secure the consent should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in that particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment.

Summary

Informed consent is basis to any medical or surgical intervention on a patient. All doctors should be familiar with the principles and practice of Informed consent which is enumerated in this document. Best practice in Informed consent will protect the doctor from potential litigation. Thus, in order to mitigate the chances of litigation, the doctor should explain to the patient in a clearly understandable way, the procedures which is likely to be performed. In India, the patient may be illiterate but not unintelligent. Hence, one must not deny them their right to information.

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Women's Vulnerability: An Impediment to Informed Consent

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Why should we discuss Women's vulnerability in a compendium of articles on the theme of Informed consent? The privilege of informed consent can be availed by those who have the capacity and competence. Competence is a legal term whereas capacity is clinically determined ability to make informed medical decision. Ironically even if women in our society have capacity to make informed medical decisions, they are neither offered that choice by paternalistic healthcare providers nor permitted by patriarchal families. This is why we should understand women's vulnerabilities in health matters.

The concept of vulnerability in medicine encompasses the extent to which a system or community member can be affected, attacked or harmed, either physically or emotionally in health system. Vulnerability is a subjective term and changes with time, geographical, sociopolitical context. The frameworks used to define vulnerability include demographics, level of education, social and financial factors. While the magnitude of vulnerable population cannot be clearly documented and understood, low socio-economic status exacerbates other vulnerabilities that people experience. Vulnerability being contextual, the involvement of community members who understand their context does aid in formulation of criteria defining vulnerability using characteristics that are easily recognised by them. It also ensures that the most vulnerable people are reached. This applies to children, sexual and racial minorities, the differently able people as well as women among others.

Women in each role in the healthcare system I.e. patients, doctors, nurses or associated healthcare workers, all have been vulnerable at some point or the other.

Gender and Health:

Women have been suppressed since ancient times and are thus preexistingly vulnerable. They have limited financial independence or at times are completely dependent on their families or male counter parts especially in developing countries. A low educational status makes them unaware of the need of adequate and prompt medical assistance, thus compromising their, and sometimes, their children's health, in majority of the situations. Lack of access to healthcare facilities like in rural areas, further deteriorates the above situation. Gender stereotyping decreases women's ability to challenge their doctors leading to inadequate demand for legally sanctioned healthcare rights. Systemic gender bias also reflects in the proceedings redressal fora leading to inadequate compensation.

Reproductive physiology of women subjects them to increased morbidity and mortality as compared to men irrespective of education, financial position or social protection- pregnancy related problems, anemia due to menstrual issues, sexual health issues and burden of contraception are some factors in addition to need of multiple hospital visits, contraceptive interventions, unwanted pregnancies, abortion related morbidity, maternal mortality due to hemorrhage etc.

Physiological changes in pregnancy and lactation lead to weight gain, bodily changes, operative morbidity, associated medical co-morbidities leading to stress and depression. Right from teenage up to

menopause women face hormonal changes affecting their social and emotional performance. Women are also more likely to go through diagnostic procedures exposing them to high dose of radiation whether as doctors, healthcare workers and patients. Unlike in males, major cancers in women are not lifestyle related. But due to the premium placed on women's reproductive ability and physical acceptability, these cancers take a toll on not only on their health but also self image. In the family, investment in woman's health is mainly restricted to reproduction and her other health issues are often ignored.

Reproductive health rights and biases against women's autonomy:

Autonomy should imply that when a mentally competent woman seeking abortion, need not produce authorisation from a third party. As per ethics guidelines in reproductive health research, the term "consent" is limited to the person who is directly concerned; and if partner is involved it is termed a "partner agreement".

India, is committed to ethical and professional standards in reproductive health services under International Conference on Population and Development 1994, that include personal reproductive autonomy and gender equality. Indian Population Policy, 2000, awards the right to voluntary and informed choice in contraception. According to the standards for male and female sterilisation of the Indian ministry of health and family welfare, the consent of the spouse is not required for sterilisation on a woman. The Medical Termination Of Pregnancy Act, 1971 (amended in 2002 and rules framed in 2003) espouses autonomy of and confidentiality for adult, mentally competent women seeking abortion. But the Supreme Court judgement in Ghosh vs Ghosh divorce case, on March 26, 2007 considered that abortion or sterilisation without either spouse's consent amounts to cruelty to the non consenting partner. At the same time, in various vasectomy campaigns run by the state, walk in services are given without seeking wife's consent.

Obstetric violence against women has recently been widely discussed and research shows it to be all pervasive and affecting the poor and the rich equally albeit in different ways- From disrespect and verbal abuse of the poor to staggeringly high cesarean section rates in the rich.

Mental Health and reproductive autonomy:

Mentally challenged women and girls suffer various forms of sexual violence and are left pregnant. The preemptive approach of families is to get these girls hysterectomised. Another reason for this demand is that the girls cannot manage their menstrual hygiene. Tragically the girls and women have capacity to decide neither on their reproductive rights nor the risks of major surgery. One can fully understand the pain and difficulties of parents, but stopping a physiological function which is only monthly is too severe a measure to maintain their dignity especially when minor surgeries like endometrial ablation are available. Worse, after hysterectomy, freedom from unwanted pregnancy makes these girls more convenient prey for the assaulters.

Shadow pandemic:

Lockdown and isolation have increased the rate of domestic and sexual abuse - termed as a shadow pandemic. The reported cases form just the tip of an iceberg with majority of cases being unreported.

It has also been reported that women healthcare providers with partners in a non-medical profession experience physical and emotional isolation from partners in the time of COVID 19 pandemic.

Responsibility of the health care providers:

As a part of the basic principles of medical ethics, all patients including women are entitled to autonomy, beneficence, confidentiality, non-discrimination and equity. Every woman deserves adequate opportunity and space to express her sufferings and also deserves due response by the healthcare workers.

A detailed explanation of the examination or a medical procedure to be performed should be offered beforehand, verbal permission or a written informed consent should be taken wherever applicable. This makes the patient and the relatives well prepared and secure. It also increases their trust in the doctor.

Though women's vulnerability is a known fact, it should not be used as an excuse for inefficient healthcare provided by doctors and institutions or as a reasoning for noncompliance on the part of women in acquiring health care services.

Only when these inequities reduce, will women be able to exercise autonomous and informed decisions for their health.

Informed consent is probably the most revolutionary, the most rudimentary, the most misunderstood and misused term in all of health law and bioethics

John D. Lantos
Mental health

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Informed Consent in Psychiatry

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Introduction

Persons with any psychiatric illness have to face stigma anddiscrimination and have been ostracized for a long time. The lower socio-economic strata are the worst hit. The situation is tricky when people who are illiterate, less educated, underprivileged, or are from remote and rural areas (India has around 65% rural population) have to choose access to basic health care over autonomy.

When it comes to autonomy, one of the most vulnerable groups is the Persons with Mental Illness (PMI). As mental faculties are affected, they may largely be unable to stand against discrimination on their own. Humankind has evolved from inhumane, coerced experiments by Nazi researchers on Jewish prisoners to the Declaration of Helsinki, upholding the rights of the patients. The doctor patient relationship is very important in ensuring that rights of patient. A sense of autonomy cements the doctor-patient relationship and ensures compliance. Ultimately it will impact all the health-related outcomes positively. Autonomy can be achieved by practicing Informed consent. Consent is voluntariness to undergo any procedure with free will, after being well equipped with relevant information and available alternatives.

India being a signatory of UNPRCD (United Nations Convention On Rights Of Persons With Disabilities) 2006 commits to safeguard the rights of persons with disabilities. For India, from the Indian Lunacy Act of 1912 to the Mental Health Care Act 2017, it has quite been a journey. With MHCA (Mental Health Care Act) 2017 into effect, it is necessary that mental health physicians are well aware of the concept of Informed Consent.

The concept of consent empowers both physician and patient. It empowers physicians to work without getting stuck in the web of legalities and empowers patients to make their own choices.

Elements of Informed Consent

According to Belmont Report, there are 3 elements of informed consent namely Information, Comprehension, and Voluntariness.

- Information: Individual needs to be given adequate information about the methodology, purpose, risks and benefits and alternatives available.
- Comprehension: The psychological sophistication - literacy, language, and culture needs to be taken into consideration while providing information. These factors may affect the understanding of the information by the patient. The context of the information is as important as the information itself.
- Voluntariness: The consent given by the patient should be under free will. There should be no use of coercion or undue influence.

Assessment of capacity to Consent

Consent is not an all or none phenomenon. It is task-specific and time-specific, especially in Persons With Mental Illness. It's dynamic. A patient with psychosis cannot always be considered to not have the capacity to consent.

In a landmark judgment dating back to the 1870s, the court endorsed that just having a mental illness does not make the person unfit to take every decision. John

Banks was a millionaire before he succumbed to mental Illness. The will he had in his niece's name was challenged citing his mental illness. In Banks v Goodfellow (1870) LR 5 QB 549, the courts legitimized the will stating that at the time of making the will the patient had a complete understanding of his actions and that his symptoms did not affect the decision making.

Under MHCA, a person is presumed to have the capacity to consent until proven otherwise. It requires establishment of understanding, appreciation, and communication for capacity assessment:-

a) UNDERSTAND the information that is relevant to decide the treatment or admission or personal assistance

b) APPRECIATE any reasonably foreseeable consequence of a decision or lack of decision on the treatment or admission or personal assistance;

c) COMMUNICATE the decision using speech, expression, gesture, or any other means.

Types of Consent

There are majorly 2 kinds of consent: -

1. Implicit: The consent is implied through an act. For example, when a patient presents himself for an appointment with a doctor, consent is implied that the patient wants to be treated by the doctor.

2. Explicit: Consent needs to be taken explicitly or clearly- verbally for things like abdominal or chest examination or in written form for procedures like administering anesthesia or surgical procedures.

Informed Consent and MHCA 2017

According to MHCA, "Informed consent" means consent being given for a specific intervention without force, misinterpretation, or mistake. Such consent can only be given after the patient is well informed of the risks and benefits of the intervention and alternatives available. The patient should be made aware of the information in the language and the way he/she best understands. A person belonging to the village or a person who is less educated can be explained about the procedure by simplification rather than using complex medical terms and jargon. Highlighting the rare side effects may unnecessarily scare the patient while the risks with higher incidence need to be necessarily informed. Health care practitioners need to display sensitivity in this regard.

For example- the most commonly encountered procedure in psychiatric practice where consent is of prime importance may be ECT. It is necessary to explain to the Nominated Representative and the patient (if in capacity) about the procedure like – use of anesthesia, muscle relaxant, inducing agent, and mouth gag. Common side effects like headache, body pain, post-ictal confusion, and temporary anterograde amnesia can be explained. The case-specific need for ECT like rapid improvement and fewer side effects might be explained alongside risks. Alternatives if available may be offered.

MHCA has also made provisions for emergency and psychosurgical procedures. In case of emergency when there is harm to the patient or others, the capacity assessment may not be feasible. In such a scenario, emergency treatment can be provided by any registered medical practitioner up to 72 hours or till the patient is assessed at a mental health establishment; whichever is prior.

MHCA has also taken care of homeless Persons With Mental illnesses. All of us have encountered persons with mental illness across the street some or the other time. Most of them may not have mental capacity. According to section 101 of MHCA, such a person can be brought to the attention of the police governing the area. The police presents the patient to the magistrate. The magistrate may then direct the placement of the patient in the state-run mental health institutions.

As per MHCA, for minors suffering from a mental health disorder, consent needs to be taken from the

Nominative Representative. Two independent psychiatrists or one psychiatrist and mental health practitioner/medical practitioner who have assessed the child in the last seven days independently should give affirmation.

MHCA has also provided guidelines for research in psychiatry. Patients with psychiatric illness constitute a vulnerable population .Consent for research needs to be free and informed in these patients. A Nominated Representative can be authorized by a State authority in certain conditions. The patient or Nominated Representative can withdraw consent at. any time during the period of research

CONSENT IN INTELLECTUALLY DISABLED

Rights To Persons With Disability Act 2016 has laid down the concept of "limited guardianship" for a person with an intellectual disability. Shared guardianship means that the decision-making will be shared mutually between the patient and guardian. The guardians' role is to assist in decision-making. The guardian cannot exercise absolute autonomy over the patient. Also, this guardianship is time and task specific.

ASSENT

Affirmation given by a child is assent. The assent should be formulated taking into consideration the developmental level of the child. For a child between the age of 12 to 18 years, written assent of the child along with written consent of legal guardian needs to be taken into consideration. For a child between the age of 7 to 12 years, verbal assent needs to be taken along with the consent of the parent /guardian. For a child, less than 7 years of the consent of the parent/guardian suffices.

CAPACITY ASSESSMENT FOR MEDICAL/SURGICAL TREATMENT AND PROCEDURES

Capacity assessment may be needed for Renal transplant donor/recipient, Liver transplant donor/recipient, to give up a child for adoption and also to make medical or surgical decisions in Person With Mental Illness.

The patient should be assessed for comprehension, appreciation, and communication. Serial Mental Status Examination (MSE) and objective psychological tests like Rorschach Test and MMPI provide supportive evidence. Various scales for assessment of capacity include MMSE, standardized Silberfeld questionnaire, MacArthur Competence Assessment Tool-Treatment (MacCAT-T), the Aid to Capacity Evaluation, Hopkins Competency Assessment Test (HCAT).

CONCLUSION

Consent is an integral part of the treatment process. While it upholds the autonomy of the patient It safeguards the doctors from legal hurdles. Digitalized and standardized procedures are the need of the hour. In the end, we need to remember that "Some values must be universal like human rights and equal worth of every human being" - Bjorn Ulvaeus

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To Consent or Not to Consent

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'Consent' - the word is derived from the latin word 'consentire' where 'con' means 'together' and 'sentire' means 'feel'. If we combine, it is 'feel together' which implies that all our bodily senses come together to possess that one particular affirmative or negative feeling. In the medical field as at least some of us would have experienced there is a document that we are made to sign as a patient or immediate legal representative of the patient before we are to be examined, treated or subjected to a diagnostic test. Such a consent is known as a General Consent. There is another which is an Informed Consent, it is drafted by a researcher who would be in need of participants fulfilling specific criteria to be enrolled in his/ her research and needs to not only sign but also comprehend the risks and benefits.

One of the many documents in a Research Study is an Informed Consent Document. Breaking the words here is what we get; 'informed' is possessing knowledge while 'consent' is permitting to perform an action. Now, we go to the term 'informed consent' together only to understand that in medical research; informed consent is a process of communication between us and our health care provider researcher that would either lead to an agreement or disagreement toward being a part of the research study.

Considering, me to be a lay person who could be a subsequent participant. I may be educated which necessarily does not imply that I am familiar to the medical/ scientific terms. As a patient, my thoughts could be preoccupied and as a volunteer also, I would have certain other things to attend to. This calls for the consent to be simplified and hassle free in such a way that the reading level of an informed consent document should be that of an 8th grade. Also, In a country like ours with linguistic diversity, all regional languages need to be considered for comprehension.

An informed consent should educate me about not only the purpose and detailed information about the research procedure but also the involved risks, benefits, alternatives and principally my rights and duties while participating in the research study. Keeping these required elements in mind, an informed consent should be crisp, simple, in a comprehensible language, non coercive and totally non inductive.

It is of utmost necessity that I as a participant must possess the ability to make the decision after considering the options that I have, evaluate the consequences of choosing each of the options and further analyse the cost and benefit of each of these. In case, I am illiterate, it is my right and the researcher's duty to make sure that there is an impartial witness to the entire narration of the Informed Consent document with the explanation. If I am medically unfit to hear, understand and sign the document, I am very vulnerable. I deserve utmost protection and a Legally Authorized Representative (LAR) possesses equal rights to be given all necessary information before signing the document on my behalf. Signing, thus implies that; I have not only received all the information but also understood the same and thereby I grant the researcher the permission to perform the research study on me.

As a lay person / participant, some parts of the document are very important to me. Also there may be some questions that I really may not understand the

importance of at the time of signing consent. So I require enough time between signing and the beginning of study.

Description/ Purpose of the Research

The study for which research is going to be carried out along with its expected results needs to be clearly written in detail and in an extremely simple language. All medical terms should be explained in an ordinary man's language for me to understand carefully what I am likely to experience when in the study.

Risks and Discomforts

The risks and discomforts which could occur on account of the research have to be openly shared and it would be even better if the same are compared with the standard treatment options that I might forgo to enrol for the research study. This would help me to make up my mind about possible suffering. Also, as a woman it becomes the duty of the researchers to elaborate on the risks if any; on me being impregnated.

Benefits: Other than drug trials, very few studies have actually any direct benefits to us. The comparison between the benefits from the standard treatment and the research treatment would throw light on the possible benefits and I would be in a position to figure out if I would really want to participate in this research study.

Confidentiality

This clause is of paramount importance to me. I have to be legally assured that my identity will not be revealed under any given circumstances. Also, I would like to be consulted if the provided samples or results need to be used for further research or some other research study.

Study Duration and Sample Size

I would not only like to know the amount of time we would be spending to be a part of the study but also the total duration of the entire study. Also, I should be aware of among how many number of people/ participants am I.

Somethings that I really need to understand:

a. Placebo

Placebo is a foreign word, not in common use. I may not understand what placebo controlled trial is. I really wish a researcher spends more time explaining to us what it means to be in a placebo controlled trial.

b. Post trial benefits:

This is the most relevant aspect to me. Pharmaceutical companies make profits from the drugs that come into the market after being tried on us. I would be glad to have some benefits as in many conditions, the drugs are required lifelong and are costly too.

c. Trial Procedure

The procedure of the research study has to be described in detail in a non medical and ordinary man's language elaborating every minute detail of the procedure we are about to undergo. I would like to know what happens to my blood, tissue, genetic samples, reports and such in future, how long and where they would be safely stored.

d. Compensation for Participation

In case the research does not involve a standard of care treatment or it involves visits only for the purpose of the research, either I or my accompanying person stand to lose wages and spend from our pocket for the visit. We need to be financially compensated for but at the same time it should not be an inducement due to which I might be tempted to participate ignoring the risks involved.

e. Compensation for study related injury

Particularly as a patient, I am more vulnerable to various forms of study related hazards or injuries, such as side effects of study drugs, procedures. I may lose out on vital standard treatment in a study of new procedures. This would result in huge physical losses too. Hence I expect compensation commensurate with my earning capacity and free treatment of any complications arising out of study participation. Even if participation is not compensated, I expect that any study related injury must be compensated.

f. Unforeseeable risks

Any risks on account of the research study, even if not practically proven but theoretically expected, should be mentioned for me to not be surprised if and when they occur.

g. Right to Withdraw

I must have the freedom to withdraw whenever we wish. There should also be a mention of what the researchers would be doing with my samples and documents in such a case and also assure me that my further treatment will be unaffected.

Contact

Having the contact number of the researcher and the team members who would be available at all times to answer not only any questions that spring up but also trial related complications is a necessary requirement.

Consent

After signing I also require my signed copy of the consent document for my personal record.

I may be required to consent in any of the following formats.

1. Written - which is a document in a written format.
2. Oral - which is done orally but an audio-visual recording is maintained as proof.
3. Online - is virtual and the analog is such that if I select 'No, I do not agree to participate' it does not take me to the next page.

A young participant of 7 to 18 years signs an assent form that is simplified for the younger person's understanding and guardian's consent needs to be taken too.

Conclusion:

In conclusion, transparency is the key to a healthy research study when there is an involvement of an external force on account of which we have laid down our expectations and look forward for the void to be filled by the other side. Informed Consent thus becomes the most salient document in a medical research study illustrating a complex relationship between a researcher and participant and makes a difference between consenting and not consenting by the participant.

For all reasons , all government without the consent of the governed is the very definition of slavery.

Jonathan Swift

GGG

Movies for Bioethics Teaching: A Case Study on Informed Consent

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Introduction

Movies are a mirror of the individual and also societal thought processes and culture.

The silver screen strives to remind us of human follies by telling us stories of deep dark secrets of human aberrations and cruelty. The movies portray people's experiences, aspirations and give voice to their fears, needs and demands. As students of Medicine we get to learn the bioethical issues from these stories.

It will not be far from truth to say that the whole movement in Bioethics evolved after the World War II Nazi atrocities in concentration camps came to light. These events led to formation of Nuremberg code and Declaration of Helsinki. Numerous movies have been made on the theme.

Here we discuss how human vulnerability, agency over body, autonomy and consent in general and medical consent are depicted in Indian and western movies. We spell out the bioethical principles that are crystallised through the movies and that the movies can be used to discuss these principles with students.

Human vulnerability, agency and autonomy:

Social evils and vulnerability of women are portrayed in **Water** which is a tale of widows abandoned by a regressive society. It is set in India of the early 20th century, during which widows were considered an economic burden to families and were abandoned. They had a choice between marrying the deceased husband's brother, burning on the pyre with the husband's dead body, or shave their heads and atone for their 'sins'. In the film, a young eight year old girl is widowed and left by her father in a widows' ashram in spite of her gut wrenching protests. In the ashram, all the widows had to shave their heads except Kalyani, a beautiful young woman who is pushed into prostitution by the woman who runs the ashram. Leave aside respect and autonomy; human comforts are denied to the widows portrayed in the film. Water is time specific, and depicts a grim reality of the past and vulnerability of widows.Another movie **The Last Colour** and a documentary **Widows of Vrindavan** alsodescribe the situation of the widows outcast by the society.

Unfortunately, rather than introspecting on the social evil, some sections of Indian community protested against **Water** considering it a statement on religion.

A movie that portrayed agency over body is **Million Dollar Baby.** In this widely acclaimed award winning movie, a young woman boxer Maggie becomes quadriplegic in a vicious boxing bout. She has to undergo amputation of a leg too due to gangrene. Frustrated with her own state, she pleads with her mentor and trainer Frankie to kill her; she also bites her tongue off in an attempt to commit suicide. In the end, Frankie assists Maggie to relieve her of her suffering. Was she asserting her agency over her body? Was she making an autonomous decision to make a dignified exit? Probably so.[1]

Pink is a courtroom drama telling story of three young women who are in a legal battle against a group of well connected men who flirt with them at a pub. They are accused of soliciting sex and blackmailing the men. They are judged by their clothes and by the drinks they chose to have. They are not supported even by their own families. A lawyer Deepak Sehgal argues the girls' case. The highlight is a speech by the Lawyer - A NO IS A NO. 'No in itself is

a statement. It does not require an explanation or definition.' And 'When someone says so you STOP!' suggests respect we must have for a person's autonomy.

The movie makes a statement on the patriarchal attitude of the society towards women which makes even the modern, educated and independent women doubt themselves. It roots for women's right to self determination in sexual matters.

Consent in medical research

After the fall of Germany in WW II, the Allies conducted legal proceedings against the German doctors, politicians and members of Gestapo who were guilty of war crimes. More than seventy medical trials were conducted on concentration camp inmates from 1939 to 1944, with tacit agreement and even under supervision of physicians who took orders from the captors. These projects were aimed at improving the survival of German army, testing medical procedures and drugs and experiments to affirm Nazi racial ideology. The available lists of victims include Jews, Poles, Gypsies, political prisoners, Soviet prisoners of war and homosexuals. **Judgment at Nuremberg** is a 1961 American film on the theme. Every possible ethical principle was violated in these experiments. Principles of racial nondiscrimination, autonomy, consent, non-maleficence, human dignity and human rights, protection of the vulnerable were all flagrantly violated.

Interestingly, in the movie, the German attorney for defendants brings up the judgement of 1927 by Justice Oliver Wendell Holmes Junior in 'Buck v. Bell', where compulsory sterilisation of the unfit and intellectually disabled did not violate the fourteenth amendment to the United States Constitution.

Incidentally the critics of the actual trials suggest that the bioethical principles are not in existence when the guilty were tried.

Diverse vulnerabilities and organ retrieval

Human Harvest is a documentary film which follows the investigative work by Canadian Nobel prize nominees on organ harvesting from live political prisoners- Falun Gong members who are being victimised by the Chinese state for their religious ideology.

Another award winning documentary **Tales From the Organ Trade** examines the shadowy world of black market organ trafficking. It brings to us the plight of the poor who are lured into donation of organs so that they can sustain their families. It also puts forth the plight of the recipients who have no chance of survival without organ transplant. The ethical dilemma described here has few solutions.

In these two stories, justice, protection of vulnerable and non-maleficence are the ethical principles that are highlighted.

A Marathi movie **Ventilator** speaks about organ donation. The movie was a commercial success but received criticism from organ transplant advocacy groups about the perceived trivialisation of the consent for organ retrieval.

To sign or not to sign

Anumati was a 2013 award winning movie in Marathi that dwells on relational autonomy of an old man of moderate means whose wife is in coma. The doctors suggest that the family signs a DNR (Do not resuscitate) form. The son agrees; but the father doesn't. Besides conflict in consent, possible ethics discussion points are justice, relational autonomy in end of life and medical futility.

Racial discrimination in medical research

Coming back to medical research consents, even as the USA was sitting in judgment of the nazi army, doctors and politicians for warcrimes, a federally sponsored trial was taking place with flagrant violation of the Helsinki Declaration of 1964.

This was depicted in a movie '**Miss Evers' Boys**', based on Tuskegee trial that took place in Tuskegee, Alabama from 1932 to 1969. The filmportrays the conversion of the government

sponsored syphilis treatment program into a clinical research project in 1932 in which existing treatments were to be withheld for a very long time. Even when penicillin was available in the lates 50s, it was not offered to them. In the movie, Miss Evers' services are sought to enrol participants. She accepts the idea that not telling the men that they are participating in a study and not receiving treatment is justified because they may be afraid to participate.

The monograph 'Bad Blood' by James H. Jones that gives an account of the actual study states, and I quote, "More than any other person, she (Miss Evers) made them (the participants) believe that they were receiving medical care that was helping them.

The struggle and outrage of Dr. Brodus is also evident in the movie when it is proposed that the existing treatment is replaced with a placebo. He also rebuts Dr. Douglas regarding the proposed title, where he (Dr. Brodus) insists that words 'Tuskegee' and 'untreated' must be included in the title.

Bioethical principles violated as shown in the movie are veracity, beneficence, non maleficence, justice, nondiscrimination, disclosure, fiduciary duty, respect for diversity and protection of the vulnerable. Donald Herman's exhaustive account of the Tuskegee study is a detailed reflection on ethical and legal lapses in the study.[2]

GOD Complex

Malice and Aghat are two movies that paint arrogance of the surgeons and utter disregard for human life in respective stories.

Malice hits home hard because of one dialogue of the surgeon who is facing an enquiry for removing ovaries of a patient without consent and valid indication, "I am GOD". The force and conviction with which Dr. Jed Hill justifies his action is shocking. his belief that when it comes to medical decisions, he is God and the conviction with which he he expresses what he believes are scary. They are scary because it is very believable that doctors have all the temptations to think that they can play God. Dr. Hill's belief is scary because his act of doing oophorectomy without informed consent cannot be seen as an aberration of one individual. The sense of power a physician feels in saving lives is almost heady. Some proxy decisions taken by a doctor may be justified as an act in good faith in the given circumstances; but consent, right to full information, truth telling and disclosure are non alienable rights of patients. Neither is relational autonomy is respected by Dr. Hill though the patient's husband is his friend.

Aghat has similar issues where, without a shred of supportive diagnosis, a senior gynecologist orders bilateral oophorectomy in a 22 year old woman (who is about to be married soon) even as his pathologist colleague and a junior gynecologist team member opine against it. He dismisses evidence based approach and victimises the female junior who refuses to perform oophorectomy. Arrogance of the senior gynecologist is appalling. When the patient and her mother ask him about future, the doctor is dismissive. He also falsifies the records. It s aptly said that bad science is bad ethics. The junior gynecologist fulfils her fiduciary duty on all counts.

Veracity, consent, disclosure, relational autonomy are the issues besides fiduciary duty. Truth telling and disclosure are related to informed consent as they involve placing autonomy above paternalism.

Medical emancipation

My Sister's Keeper is tale of a young girl Anna approaching the court for her emancipation and right to dissent. Her mother Sara, fighting for her elder daughter Kate's life, is a respondent. Kate has a blood cancer. Neither parents nor brother are genetically compatible donors for marrow, blood or tissue. So on the oncologist's suggestion, 'a saviour child', a genetic match is conceived through assisted reproduction. Even as a child, Anna keeps donating tissue and blood as required on parental consent. As Kate's kidneys fail, Anna is required to donate a kidney. Here she sues

the parents, petitioning for withdrawal of parental rights, and her own medical emancipation. In reality, Kate has been frustrated during protracted grave illness and treatment, and has asked Sara to stop donating tissue, blood.

The movie has dealt with complex ethical and legal issues like consent and dissent, medical emancipation, medical futility, relational autonomy.

Gómez-Vírseda and colleagues have given a philosophical insight into relevance of relational autonomy in end of life medical decision-making and how it could enhance individual autonomy and consent.[3] It is also relevant to cultures where family holds immense importance to the patient. Dichotomous,with the physician's paternalistic approach and institutional encouragement of spousal consent in reproductive health interventionson one side and, Stress on individual autonomy adding to complexities of mental healthon the other side should be reviewed so that a via media is found.

Psychiatric vulnerability

55 steps is based on real life legal battle of Eleanor Riese in Riese v. St. Mary's Hospital & Medical Centre. Riese who suffered from chronic schizophrenia, apparently due to past meningitis was institutionalised and treated. Later when she had relapses, she was treated without her consent. She had severe side effects of her medications and periodically those were stopped and restarted on divergent medical opinions. Voluntary in-patient's consent for antipsychotic medication as against involuntary administration of allegedly medication (with reported adverse effects) was the point of contention.

Eleanor's struggle to get justice, defendant institution's interpretation of Lanterman-Petris-Short Act, the appellant's argument on the right to refuse medication and, issue of involuntary confinement of psychiatric patients are depicted in the movie. Eventually, Eleanor Riese dies due to long term effects of the drugs. In 1987, in Riese v. St. Mary's Hospital and Medical Centre, the California State Court of Appeals declared that psychiatric patients had the right informed consent and before involuntary treatment their competency to make decisions should be judicially determined.[4]

The highlighted ethical issues are those of human dignity and rights, right to consent, beneficence, non maleficence, disclosure and veracity, fiduciary duty.

Movies- a potent material for bioethics discussion

As long as Movie medium has been available; sociocultural, medical and political stories or news with strong individual and social impact value have drawn producers to the them. A well written script conveys real, raw but unexaggerated human emotions. The silver screen characters talk to the audience and leave a lasting memory of their story. Incidents come alive for the audience with much more intensity than those on paper. Interactions between the characters lend a greater appeal to the story and message. They can also be played and replayed.

There are commentaries on depiction of psychiatric patients' treatment in Indian cinema by psychiatrists.[5] It is felt that dramatized depiction is more likely to earn box office success as compared to technically correct version. This probably applies to many movies (Not necessarily psychiatric). This small drawback notwithstanding, movies can be a very good material for ethics discussion.

Conclusion

As said by Angelo Volandes, film vignettes help medical students in early years to fill the imaginative gap in understanding of clinical realities.[6] Of course, the efforts and interest taken to discuss the ethical aspects will decide the success of use of movies to teach bioethics.

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Because the work that doctors do has moral urgency, doctors have a highly refined, professionally reinforced sense of right and wrong.

-John D. Lantos. After Movies for Bioethics

GGG

Informed Consent with Reference to HIV

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Mr. Subhash came to the general medicine department at a medical college hospital after he tested HIV positive in a private clinic. The patient was a 24 year old male who had been selected for a new job where it was mandatory to submit an HIV test report as a part of a pre-employment health check-up. He has never engaged in any high risk behaviour and therefore believed that couldn't be infected. There was no pre-test counselling procedure carried out by the clinic. He was given a consent form to sign without any discussion after which the test was carried out. When the positive result came back, the physician disclosed the test result to Mr. Subhash but no other explanation or no counselling with regard to HIV infection was done.

At the second hospital, he requested a physician, Dr. Gupta, who examined him, to repeat the HIV antibody test in order to confirm his status. The test was performed.

On the day of the appointment for the report, the patient did not report to the clinic. Dr. Gupta checked the test result and found it positive. A few days later, when Dr. Gupta was out of the hospital, his brother visited the clinic and was seen by one of physicians who was working there. He asked the physician about the test result. He explained to him that he could not inform him of the test result and was obliged to disclose the result to the patient himself.

Dr. Gupta called the patient and asked him why he did not show up. Mr. Subhash replied that he was too busy to come to the clinic and asked Dr. Gupta to disclose the result to his brother. Mr. Subhash's brother came to the clinic next week and was disclosed that his brother has been infected with HIV virus.

What were lapses in the ethical principles in this case? Were the principles of informed consent, autonomy and confidentiality maintained in this case?

Introduction:

Informed consent and refusal of consent for diagnosis or treatment are important legal and ethical rights of patients.[1,2,3] Physicians have the right to make diagnoses and recommend treatment but individual patients have the right to decide whether the proposed interventions/procedures are acceptable to them. Informed consent is one of the most important fundamental right of patient in medical decision making especially in conditions like HIV. [3,4] The process should include the delivery of information regarding the procedure, its risks and benefits, voluntary agreement to undergo the procedure, and documentation of the agreement.[2,3,4]

Pre & post-test counselling -'Informed' consent & autonomy:

Pre- and post-test counselling with a detailed discussion regarding the procedure, related risks, benefits are carried out and are key components of HIV testing consent requirements. This forms the "informed" portion of written informed consent.[5] Doctors must ensure that patients are provided with all information necessary to decide to undergo an HIV test. This is a critical part of a doctor's obligation to his patient and can be done by either the doctor or by proxy.[5]

In this case, a pre and post-test counselling was not carried out and the doctors can be sued for a) not carrying a pre-test counselling or what is an informed

consent, b) Not carrying out a post-test counselling as a positive HIV diagnosis is a life-altering event, not something that can be treated. HIV remains an incurable disease that requires adherence to a specific and often challenging treatment regimen. HIV is still associated with significant social stigma and discrimination. A proper post-test counselling with explanation of the various treatment options, linking with the ART centre and providing moral support is an essential part of HIV testing, c) In the above case, the client's autonomy was lost as he was mandatorily made to undergo the test which is against ethical principles.[6]

Confidentiality:

Report was given out to a relative which is not ethical as confidentiality of a positive diagnosis has to be maintained.

Valid informed consent should include: [7]

(1) Disclosure of information,

(2) Capacity /competency of the patient (or surrogate) to make a decision, and

(3) Voluntary nature of the decision.

A proper informed consent has the following requirements [2,8]:

1.Language should be understandable to the subject or the legally authorized representative – In a research setting, informed consent document should describe the study's purpose, the duration of the subject's participation, a description of the procedures, reasonably foreseeable risks, and benefits that may be expected from participation. It should also mention that participation in the research study is voluntary and will not result in any penalty if the participation is withdrawn or not given. In clinical setting, in case of pregnant and lactating women, neonatal implications of feeding choices should be clearly informed. Not only the best but a viable option should be also clarified. AFASS (acceptable, feasible, affordable, safe and sustainable) is the watchword that implies autonomy in making feeding choices.

2.Voluntary Participation: Consenting process should inform that it is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject/ client is otherwise entitled.

3. Adequate Time to be given to decide: Sufficient time should be given to read the consent form, to question and discuss the information and to carefully decide whether or not to volunteer for the study.

4.Adequate time for questions: Subject / client should be offered the opportunity to ask questions. Research subjects should be informed about the selection process, person(s) responsible for the research and the mechanism(s) by which their comments and/or complains will be received and acted upon.

5.Exculpatory Language: No informed consent, whether oral or written, should include any culpatory language that places blame or liability on the client. It should not be such that the subject or the representative is made to waive or appear to waive off any of the client's/ subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. [2]

6.Research on children: Especially in case of HIV, the healthcare provider should also seek the assent of older children and adolescents by providing age appropriate information to these children to help empower them in the decision making process. An exception to this rule is a legally emancipated child who may provide informed consent for himself. Some, but not all, examples of an emancipated minor include minors who are (1) under 18 and married, (2) serving in the military, and (3) able to prove financial independence.[2]

7.Confidentiality: A statement describing the extent, if any, to which confidentiality of records identifying the subject has to be maintained. Shared

confidentiality is an ethical justification for exchange of information regarding certain conditions like HIV/ mental illness in a treating team or if required by law. Some state statutes make exceptions to confidentiality with regards to the spouse/ sexual partners. The decision to breach confidentiality lies with the physician and is not imposed by law. [9]
In the USA, there is a clause of 'Duty to Warn' under which third parties are informed about their risk with anonymity in place.

8.Documentation: Appropriate documentation of the informed consent process is required unless that documentation has been waived off by the institutional review board. The informed consent document should be signed and dated by the subject or his/her legally authorized representative and by the person obtaining consent and/or a witness who attests with his/her signature to the appropriateness of the consent process. In research, the principal investigator is responsible to ensure that the requirements of informed consent are fulfilled. There must be a witness present during the entire consent process who must attest to the accuracy of the presentation and the apparent understanding of the subject.[2,8]

9.Exceptions to mandatory Informed Consent: Several exceptions to the requirement for informed consent include a) if it is by order of a court b) Organ or body donation and 3) voluntarily waived consent.

10.Exposure related tracing of source: In case the source denies consent and blood sample is available, it may be tested and the source may decline to be informed of the result. In case the source denies consent and blood sample is not available, at the request of the exposed, the test may be carried out and the source may decline to be informed of the result.[9]
With the above mentioned consent related guidelines, it is ensured that the autonomy and rights of the clients are protected in case of HIV.

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Informed consent- A Nurse's Role

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Introduction:
Informed consent is a person's agreement to allow something to happen based on full disclosure of facts needed to make an intelligent decision. Nurses need to ensure that the patient or a competent and responsible adult relative of the patient sign the consent form of the hospital.

Purposes of informed consent:

1. To ensure that the patient understands the nature of treatment including the potential complications.
2. To indicate that the patient decision was made without pressure.
3. To protect the patient against unauthorized procedures.
4. To protect the hospital staff and the hospital against legal action by a patient who claims that an unauthorized procedure was performed.

Key principles of informed consent:

1. The consent must be given voluntarily by a mentally competent adult. The patient should not coerced be into giving consent.
2. Patient must understand exactly what he/she consenting to. If a patient speaks a foreign language or is deaf, an interpreter must explain the consent.
3. The consent should include risk to the procedure, alternative treatment available, and prognosis if the treatment is refused.
4. The consent is usually written, to provide a record of the transaction.
5. Consent to the treatment a minor is usually given by the parent or the legal guardians(Assent).

The "thin" conceptualization of informed consent:
In medicine, the form of valid consent is "thin", as to enhance simplicity and transparent administration. According to the thin conceptualization of consent, a person giving consent must be mentally competent, free from overwhelming duress, and properly informed about the decision in hand.
Law and regulation often set additional formal requirements, such as a dedicated form of informed consent signed by the patient, a second signature by a witness, and the communication of the information by the responsible physician. A patient's expressed choice, made in the specified conditions, is considered a valid informed consent. Elements of informed consent in Nursing research are similar as in medical research. In addition, in research, nurse on the team has an advocate's role to fulfil.

Role and responsibilities of research nurse:
The research nurse's job is complex, and multidimensional. The research nurse who coordinates its day-to-day management of the research project. She requires leadership and organisational skills and a flexible and adaptable approach. The nurse also needs to prioritise and to make decisions. The nurse member needs an extensive knowledge of the research process and research-related legislation. In addition, they need IT skills, proficiency in use of word processing, spreadsheets, database and presentation software. A nurse member should also be able to undertake internet search.

Consent for operation and other procedures:
Professional nurses always strive to ensure informed consent. Exercise of clients' rights by them and and full communication are ensured. The consent should be taken in written form specified in the respective institution or government.
A patient coming into hospital still retains his rights as a citizen and his entry only denotes his willingness to undergo an investigation or treatment of a serious nature, or an operation that requires written informed consent of patient and next of kin.
Treating a patient without obtaining proper consent can lead to a charge of assault and/or battery.

Conclusion: When a nurse is administering treatment, she has to ensure that the patient or family member who has to sign the informed consent document, understand aspects of the treatment. A well trained nurse can explain the consent form to the family and solve their queries too. Hence she is a patient advocate.

Delayed Consent in Surgery

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Once based on unswerving trust, medical practice today, is embroiled by litigations, stemming from changing patient perception fuelled by increasing scepticism. Now more than ever, it is prudent for all medical practitioners to acquaint themselves with the diverse aspects and intricacies of the consent taking process.

The concept of consent in medical practice is centred on the tenets of patient autonomy and self-determination. While the basic act of patient presentation to the doctor implies consent for general (not intimate) physical examination, consent for any procedure beyond routine examination must be explicitly expressed by the patient, either verbally or in writing, and in the presence of a witness, who should not be a part of the operating team. The exceptionally invasive nature of surgery makes a written informed consent indispensable in the practice of Surgery. For a consent to be valid, it must be an 'informed' consent, given 'freely', by an individual who is 'competent to contract'. Free consent is one which is given voluntarily, without any kind of pressure, misrepresentation, mistake or misunderstanding pertaining to any aspect of surgical treatment.

'Informed' consent implies that adequate information be given to the patient regarding the disease, the foreseeable prognosis and the treatment modalities available. Armed with knowledge of all reasonable eventualities, the patient can then give a consent, which is truly 'informed'. It is worthwhile to remember, that the consent taking procedure is a dialogue between the surgeon and the patient, and not a one-sided discourse of information.[1] At every step, ensuring patient understanding of conveyed information is paramount. Patients must be given the opportunity to ask any questions they may have, along with the freedom to withdraw consent at or review their decisions, as long as they have the capacity to do so. It stands to reason that adequate redressal of patient queries can be best done by the operating surgeon; It is therefore prudent that consent be taken by the operating surgeon, or at the least, by a surgical team member who is well versed with the said surgery, and is therefore better equipped to explain any complications that might accompany the suggested surgery and answer patient's questions. While this holds true in elective surgical interventions, the scenario often differs markedly in surgical emergencies. Patients undergoing emergency surgical procedures may be incapable of giving consent or comprehending the repercussions of the same, or the surgical crisis may be such that the intervention carried out would be based on/ influenced by intraoperative findings and therefore cannot be possibly explained beforehand. In this context, there is no time available between patient presentation and surgical intervention and patients often grasp the gravity of the intervention carried out, after its occurrence. Consent in these cases, therefore is a 'delayed' consent, with which the patients come to terms with, only after the said procedure has been performed.

Patients requiring emergency surgery are often obtunded. If a patient in need of emergent lifesaving surgical intervention is unconscious and no surrogate decision maker is available, then consent may be waived[1]. In this situation, it is the duty of the surgeon to operate in good faith to save the life of the patient, and not delay a necessary intervention in lieu of legislative safety. Such waiver of consent is protected by the Supreme Court of India and the National Redressal Commission[2]. In fact, failure to perform a lifesaving surgery whilst awaiting procedural formalities amounts

to negligence, as highlighted in the case of Dr. T.T. Thomas v. Smt. Elisa and Others[3], where a patient diagnosed with perforated appendix with peritonitis requiring emergent surgery was not operated upon due to lack of consent. Herein, the Kerala High court held the doctor to be negligent and observed that 'consent is important in cases of operations which may not be imminently necessary to save the patient's life. But there are instances where a surgeon is not expected to say that "I did not operate him because, I did not get his consent". Such cases very often include emergency operations where a doctor cannot wait for the consent of his patient or where the patient is not in a fit state of mind to give or not to give a conscious answer regarding consent'. The Law therefore explicitly states that absence of consent for an emergent surgical intervention will not be called in question.Sometimes in cases like mutilating surgeries such as limb amputations, an independent physicians consent or consent from administrative medical officer can be obtained.

In surgical emergencies, uncertainty is compounded by the limited time available for accurate diagnosis preoperatively. It is not practical to subject a hemodynamically unstable patient to laborious and time intensive preoperative tests. Furthermore, surprise findings in the context of emergency exploratory laparotomy are not uncommon. Decisions may vary from the standard, depending upon the findings and patient's condition.. No amount of preoperative comprehensive counselling can cover all eventualities, and therefore the obtained consent, although valid, may still be incomplete. Often surgeons may find themselves in the operating room with an unsuspected finding. Postoperative discussion with the patient of the reasoning behind the decision and proper documentation of the same is mandatory.

In special situations like mass casualty incidents, the patients are triaged and treated on an urgent basis. Many of them are not even in a condition to tell their names or understand the details of procedure. Surgical procedures may be required to be done expeditiously in order to decongest the emergency area. Often major surgical interventions may be needed urgently, without extensive investigations. In most of these patients, surgical plans may need intraoperative review based on a thorough exploration of the surgical site and consideration of other pertinent factors. Similar intraoperative findings may lead to different decisions based on patient factors. The decision to repair immediately, to excise a bleeding organ, or to merely perform a damage control surgery with subsequent re-exploration; need to be made quickly and may change dynamically with the intraoperative events. While these lifesaving procedures are medicolegally safeguarded, it is wise to remember that such decisions still affect the quality of life. A preoperative conversation may not be possible in mass disasters. One significant example is the creation of an intestinal stoma, perhaps one of the most commonly performed enteric emergency surgeries, and one with a remarkable impact on the patient's quality of life. The gravity of the emergency decision is seldom appreciated until later when the patients face daily inconvenience along with physical and social strain of managing a stoma bag, which can lead to growing resentment. A thorough discussion of the operative findings and reasoning for the decision making should be communicated to the patient postoperatively.

Despite the advent of modern investigations, numerous times a surgeon is faced with an intraoperative surprise like an anatomical anomaly, or a missed pathology. The finding of a Meckel's diverticulum is a common occurrence, and the decisions to treat it may differ widely and from surgeon to surgeon. One may take up a patient for surgery for a particular pathology, however the intraoperative findings may preclude the decided plan. Tumours deemed operable on preoperative investigations may turn out to be unresectable. Benign obstructions may feel malignant. A resectable malignancy may have peritoneal metastases. It is important to remember in such situations that while life-

saving intervention may be performed, no other intervention, even if the surgeon perceives it to be in the "best interests" of the patient, can be carried out, without preoperative consent. This can be elucidated in context of the common occurrence of finding of a second pathology intraoperatively during an unrelated surgery. For example, finding a malignancy in a uterus or a gall bladder in a patient undergoing surgery for an unrelated pathology. While the intent may be to cure, it is not endorsed by the law and exposes the surgeon to litigation. This is where things go wrong despite everything being done in keeping with the principles of good practice. An important case in this regard is that of Samira Kohli v. Dr. Prabha Manchanda and Others[4]. In this case, a 44-year unmarried female, was advised to undergo diagnostic laparoscopy. Preoperative consent gave the doctor an allowance to carry out a "diagnostic and operative laparoscopy" and there was an additional endorsement that a "laparotomy may be needed." Upon the intraoperative discovery of a uterine pathology, the consent of the patient's mother was taken, and the patient's uterus, fallopian tubes and ovaries were removed whilst the patient was under the influence of anaesthetic medication and therefore unable to give consent. Post-surgery, however, when litigation was sought by the patient, it was held that the operation was conducted without real consent and the doctors were held liable. For the first time in India, the Supreme Court ruled that however broad consent might be for diagnostic procedure, it cannot be used for therapeutic surgery. The court observed, "where a surgeon is consulted by a patient and consent of the patient is taken for diagnostic procedure/ surgery, such consent can't be considered as authorization or permission to perform therapeutic surgery either conservative or radical (except in a life-threatening or emergent situations)". Furthermore, the court observed that "… where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorized additional procedure involving removal of an organ only on the ground that it is beneficial to the patient or is likely to prevent some danger developing in the future, where there is no imminent danger to the life or health of the patient." It therefore follows, that while a delayed consent is applicable in the context of interventions done for saving a life, it is not justifiable for surgery procedures when not required for saving a life, no matter what the underlying intent.

Delayed consent in surgery is also applicable in the context of aberrations noted during surgery necessitating a revision of plan. Sometimes, the surgical field after excision of a malignant tumour may turn out to be bigger than anticipated necessitating a revised reconstruction. Other aberrations may result from pathological processes such as frozen surgical fields, or may be iatrogenic in origin. These include loss of surgical materials (mops/ needles) in the patients' body cavities, which may lead to a prolonged search for the same. Rarely a mop may be missed entirely and a gossypiboma detected postoperatively, may require a second surgery. Preoperative consent cannot practically include cautioning of these far-flung intraoperative deviations. The documentation of such an event and due diligence shown in trying to find the said foreign body are vital. These are the times where a good rapport with the patient and relatives and their trust, can salvage the situation post-operatively. This is the most important aspect of delayed consent taking, and requires good communication skills on the surgeon's part, to be able to explain the events and obtain their approval, after the said occurrence.

The very act of submitting oneself to surgery signifies an unparalleled level of trust placed by a vulnerable patient in the operating surgeon. In emergency situations in particular, where surgical decisions may not find mention in a preoperative consent and need post-operative "delayed" disclosure, preventing the breach of this trust by ethical actions directed by the legal norms, is of paramount importance.

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The patient's autonomy always , always should be respected, even if it is absolutely contrary - the decision is contrary to best medical advice and what the physician wants.
the disease

Jack Kevorkian

GGG

No Life Unworthy of Life

Ms. Anushka Kantak

Have you ever heard, of the Nuremberg trials?
Nazi experiments that killed the “undesirables”?
Jews, political prisoners, and outcasts of society
Lives sacrificed to save the high and the mighty.
Or perhaps, the German Aktion T4 programme?
A method infamously transferred to the Nazi concentration camps;
Mass gassing and murder of the disabled and mentally ill,
Financial and genetic burdens to society, easy to kill.

The Tuskegee Syphilis experiment was an ethically abusive study,
Infected African-American men were told they needn't worry
Free health care was promised, information about the study wasn't given
Not one infected man was treated with a dose of penicillin.
The Blacks, the Jews, the disabled and vulnerable
Were all treated with methods painful and intolerable
Experiments performed in the name of the greater good
Performing acts of injustice, that no one ever should.

They say, amid clash of arms, laws are silent,
But to make decisions uninformed itself is violent
But who are we to care for the oppressed and dying?
Why give them a choice; what if they start denying?
Aren't we doctors, bound by duty?
To protect and preserve the health of humanity?
To help the wounded, and aid the healing,
to reverse the tide of diseases unyielding?

Before you treat the ill, do well to bear in mind,
Within you, it is care and hope they find;
They turn to you for help, exhausted, defeated.
Treat them how you yourself would like to be treated
Respect and empathy are necessary, discrimination is a sin
Information must be provided and consent must be written
Do no harm, make sure to give them a choice,
Be just and fair, lest they have to pay the price.

सूचित संमति पत्र

जीवनमरणाच्या प्रवासात

रुग्णालयातल्या रहिवासात

मृत्यूच्या उंबरठयावर असतो,

डॉक्टर आणि परिचारिकांचा साथ।।

प्राण वाचवणं असल जरी डॉक्टरचं कर्तव्य,

निर्णय घेण्यासाठी घेतली जाते नातेवाईकांची स्वाक्षरी,

असते ती दोनच शब्दांची, पण ते कायदेशीर लेखी वक्तव्य।।

कायदेशीर ही बाब आहे सूचित संमतिपत्र घेणे,

होकारार्थी किंवा नकारार्थी असते हे माहिती पत्र,

नाजूक अवस्थेत नातेवाईकांना कायदेशीर आश्वासन देणे,

जीवन प्रवासात असते हे परिचारिकेचे सत्र।।

जीवन आणि मृत्यु या दोन बाजू नाण्याच्या,

प्रतिमा या कुटंबातील भावुक क्षणांच्या

रुग्णाला वाचवणे हे ध्येय परिचारिकेचे,

ह्यातच यश तिच्या अग्निपरीक्षेचे।।

कष्टांची ही माळ आहे वैद्य आणि परिचारिकांची,

रुग्ण वाचण ही गरज आहे कुटुंबाच्या भवितव्याची,

रुग्णांसोबत घातला जातो हा भावनेचा मेळ,

रुग्ण आणि नातेवाईकांसोबत परिचारिकांचा आनंदमय वेळ।।

ऐश्वर्या आदमाने

प्रथम वर्ष विद्यार्थिनी नर्सिंग स्कूल

Reflection

Pratik Debaje, Mahima Bhuta
Intern
Seth GS Medical College and KEM Hospital,

My first year at KEM, as an MBBS student, a new journey and experience, not knowing what awaits ahead I entered for an interview in the hope of becoming a student wing member of the GSMC MUHS UNESCO Bioethics. What I thought would be a small, general talk turned to a long and interactive interview which paved the path of what was to come in the next five years.

Being a novice in this field, I was totally unaware about Bioethics but once I got the news of my selection in the team there was no looking back. The unawareness about the subject changed to knowledge in no time under the guidance of all faculty members and other student wing members. To the extent and satisfaction that I could really understand and apply the Bioethics principles while dealing with my patients during my entire duration of education and internship. These principles have always served as the baseline for me in all the uneasy situations that I have come across be it medical or personal.

My journey as a student wing member began in the year 2017. I had the opportunity to be a part of the organising team for the Street Play event in the annual World Bioethics Day celebrations. The theme for the year – Equality, Justice and Equity was another learning lesson for us as students and humans. What stayed with me that year was a Street Play focusing on Gender Equality, urging us to be more thoughtful regarding the transgender community. This pushed me to help the transgender community by providing them with essential goods for their daily use.

The next year, 2018,was another motivator for me. To begin with,'ETHOSCOPE'– a name suggested by me for Short Film Making competition, was accepted. In the same year, my team and I made a Short film- 'हतबल (Hatbal)'. It was revolvingthe theme of the year- 'Solidarity and Cooperation' and which won the Second Prize in the competition. Various activities carried out by us as a team made me realise the importance of Solidarity and Cooperation in the medical profession. Starting from 'Mama (ward boy),Sister (nurse) to ajunior, it's our unity and cooperation that delivers a quality healthcare to a patient.

In 2019 with the theme 'Cultural Diversity' I learnt to respect the Cultural values of patients while providing them care and before performing any procedure. And needless to say, I was extremely thankful to the entire team for awarding me with the Best Student wing member award that year.

Year after year, Bioethics has never failed to enrich me. Even in the year of the pandemic-2020, with lockdown everywhere it was decided to host all the activities on an online platform and this was something really challenging. Being a part of Poster Competition organising team, I realised that this yearwas like no other. But withprecise planning everything was managed smoothly.

INARCH, has always had my heart and sweat. Working towards making INARCH better and better, I had the chance to read some great articles which aided me to relate to real life situation in Wards and Triage. It has also helped to improve my editing skills and made me tech-savvy using Corel and Photoshop.

These are only highlights of what I have gained from Bioethics. Bioethics has made me a better doctor and even more a better human being. Bioethics has been a part of my MBBS journey throughout just like KEM and means no less. With this being my last year as a part of it, it is going to be really difficult to bid adieu and move forward. But what I always will carry on with me are the experiences, learnings and principles!

GSMC MUHS International Chair BIOETHICS UNIT
ANNUAL REPORT – 2020 -2021

I.Highlights & Achievements:

WORLD BIOETHICS DAY CELEBRATIONS 2020

The GSMC MUHS FORMER UNESCO Bioethics Unit celebrated the 'World Bioethics Day' on **Monday, 19th October 2020** along with a weeklong celebration prior. This year the pandemic led us in a new normal way of celebrations with a lot of new learning and resilience. The World Bioethics Day 2020 began with the strong student wing that carrying out various activities based on the theme of World Bioethics Day 2020 'Benefit and Harm'.

Due to the current situation of COVID 19, all competitions were held online/offline mode on virtual platforms. The students were involved in planning, organizing and execution of these events. Experts from outside and within the institute were invited as judges.

As a part of World Bioethics Celebration 2020, Poster, Photography, JIGYASA 'Ethical Reflections on the COVID 19 Pandemic', IDEON 'Ideas Combating the Pandemic', Storytelling competitions were held on theme "Benefit and Harm'.

❖GUEST LECTURES:

Guest lecture on **"Ethical Issues in cancer therapy and Research"** was taken by Dr Sewanti Limaye who is currently working as Consultant - Medical Oncology, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute and Director Clinical and Translational Research, Oncology. She spoke on ethical issues by taking a case of women with breast cancer.

Dr Akash Shukla, who is currently working as in charge and Head of Medical Gastroenterology – KEM Hospital and Hepatologist at Global Hospital delivered a talk on **"Ethics of Transplant Medicine".**He narrated the story from history to types of transplant.

THE MAIN EVENT: WBD 2020 CELEBRATIONS

The main event was organized on 19th October 2020 in the afternoon. Dr Mariya Jiandani, Head of the Unit welcomed all, introduced the theme and spoke about the events planned to celebrate the World Bioethics day. Dean Dr Hemant Deshmukh addressed the audience. Following the speech, the annual bulletin of the Bioethics Unit 'Inarch 2020' was released by the Dean Dr. Hemant Deshmukh. Subsequently Dr Anjali Telang, secretary of the unit presented the annual report.

RELEASE OF 'INARCH' BULLETIN 2020

The annual bulletin of the Bioethics Unit 'Inarch 2020' was released by Dean Dr. Hemant Deshmukh. Dr. Padmaja Samant, the editor of Inarch spoke about the unique title of our bulletin and also about this year's issue of Inarch which has covered a range of topics related to the theme of this year.

KEY NOTE ADDRESS BY DR VASANTHA MUTHUSWAMY

The key note speaker Dr Vasantha Muthuswamy, renowned Senior Deputy DG & Scientist G (Retd.), Indian Council of Medical Research who is also President, Forum for Ethics Review Committees in India (FERCI), Chair, Ethics Advisory Committee & Central Ethics Committee on Human Research, ICMR, Member, National Apex Committee for Stem cell research & Therapy (NACSCRT), President,(Former) Senior Deputy Director General, ICMR, New Delhi, India. After explaining the basic tenants of ethics, Dr Muthuswamy highlighted the guidelines of ICMR research, basic concept of stem cell research, how it evolved, present scenario and its applications.

International SEMINAR SERIES OF "BIOETHICS AND COVID 19"

GSMC MUHS FORMER UNESCO Bioethics unit organized international seminar on **'Bioethics and Medical Education'** in collaboration with Department of education, UNESCO (Haifa) on 23rd November 2020 from 1:00 pm to 3:30 pm on zoom platform. The Dignitaries were Honourable Vice chancellor Maharashtra University Nashik, Dr Dileep Mhaisekar, Prof Russel Dsouza Prof Mary Mathew , Dr Ved Prakash Mishra, Prof Gibbs. The following eminent speakers delivered talk

- Professor Russel Dsouza- Covid 19 : Ethical issues with Human challenge trials
- Professor Vedprakash Mishra: Bioethics in medical curriculum
- Professor Trevor Gibbs: Why faculty development is important in medical Education
- Professor Salagre: Health Professional education: Opportunities and challenges

FACULTY SENSITIZATION PROGRAMME ON BIOETHICS & AETCOM MODULES FOR GSMC TEACHERS

The introduction of AETCOM module in the CBME curriculum has necessitated that the faculty members training the students understand the scope, contents, resources, teaching learning (TL) methods including assessment of the AETCOM modules assigned to each phase of CBME curriculum.The faculty sensitisation workshop for the faculty members of the Department of Pharmacology and Therapeutics, Department of Microbiology and Department of Pathology was conducted by the unit members.

Dr Kavita Tilwani & Dr Vivek Tilwani, medico legal experts were the guest speakers for two sessions of Microbiology workshop. All Sessions were appreciated by faculty members of three departments

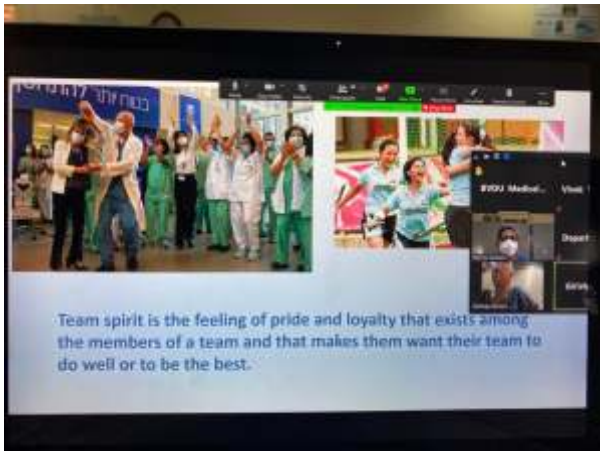
DEPARTMENT OF PATHOLOGY

DEPARTMENT OF PHARMACOLOGY

DEPARTMENT OF MICROBIOLOGY

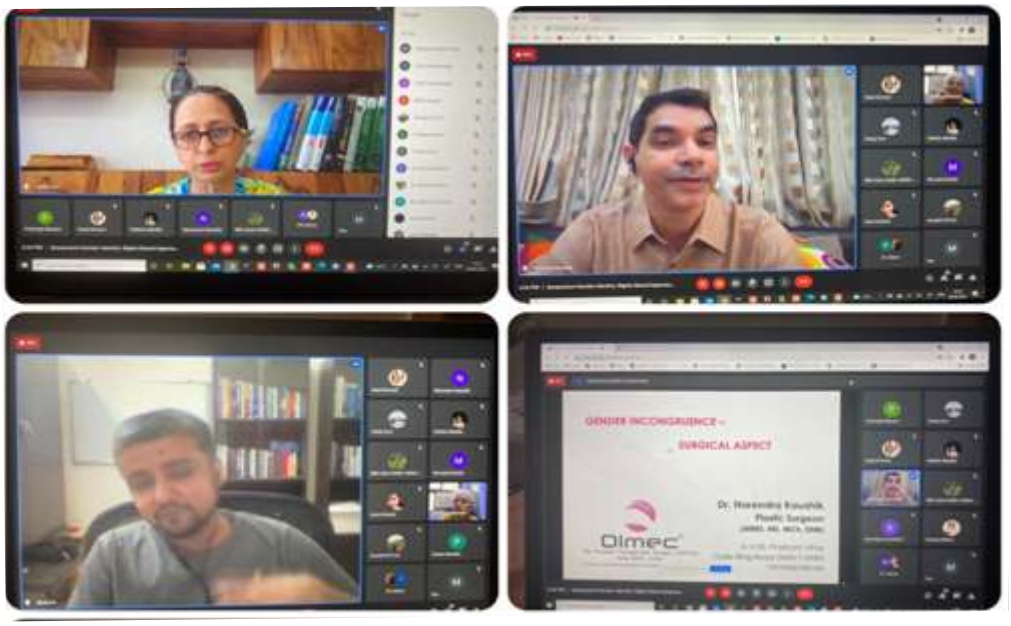
FACULTY SENSITIZATION PROGRAMME ON BIOETHICS & AETCOM MODULES FOR FACULTY MEMBERS OF BHARATI VIDYAPEETH (DU), SANGLI, AND PUNE INSTITUTE

The faculty sensitization programme was planned on virtual platform on 28th & 29th May 2021



GENDER IDENTITY - A RIGHTS BASED APPROACH' SYMPOSIUM 30th JUNE 2021

A symposium titled 'Gender Identity - A Rights Based Approach' was conducted by the GSMC MUHS Bioethics Unit on 30th June 2021. Dr. Sudha Rao, head of the department of Pediatric Endocrinology at Jerbai Wadia hospital spoke on 'Late Presentation of Disorders of Sexual Development and Gender Identity'. Mr. Mridul Dudeja spoke on 'Rights Based Approach to the Needs of Sexual Diversities'.
Dr. Vinita Puri, head of the department of Plastic Surgery, Seth GSMC & KEMH and Dr. Narendra Kaushik, Plastic Surgeon from New Delhi and alumnus of KEMH, spoke about surgical interventions in the disorders of sexual development. The talks were followed by question answer session.



I

- **Publications –**

- Annual bulletin of the unit, “INARCH” based on the theme "Informed Consent” will be released during the World Bioethics Day celebration on 18th October 2021. Dr Padmaja Samant is the editor of this bulletin.

- Obstetric violence: a health system study' an article by Raksha K. Shetty, **Padmaja Y. Samant**, Priyanka U. Honavar was published in the International Journal of Reproduction, Contraception, Obstetrics and Gynecology in March 2021 [S.l.], V 10, N 4, p. 1551-1560.

II

Education: GSMC MUHS International Bioethics unit conducts training for undergraduate students across various disciplines in accordance with the syllabus designed by MUHS. The following topics were covered for various disciplines:

Date	Discipline and Batch
October 12, 2020	18 Interns attended this session
Feb 2021 to June 2021	First MBBS students 2020-21 Batch
16th & 17th March 2021	194 First year nursing students attended this session
6th May 2021	For new batch of interns

INTERNS ORIENTATION PROGRAMME
12 OCT 2020

FOUNDATION COURSE
FIRST MBBS BATCH 2020-2021

III. Student wing Activities: The unit has a strong students' wing that carries out various activities. The theme of World Bioethics Day 2021 is 'Informed Consent'. The poster making and photography competitions were based on the same theme. Due to the current situation of COVID 19, all competitions were held online/offline mode on virtual platforms. Students were involved in planning, organizing and execution of these events. Experts from outside and within the institute are invited as judges.

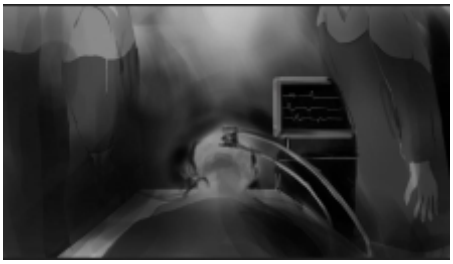
Shreya Shah
First Prize Winning Photograph

31 Breaths Per Minute

Director-Animator: Kingshuk Sarkar
Assistant Director: Ansh Agrawal

Script: Kingshuk Sarkar, Ansh Agrawal, Tanmay Gholap

Voice cast
Doctor: Raghav Paranjape
Girl: Manali Jagtap
Mr Ashok: Ansh Agrawal
Other patient: Kingshuk Sarkar



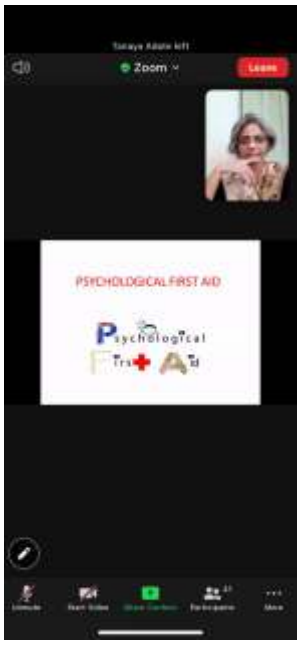
First Prize Winning Short Film

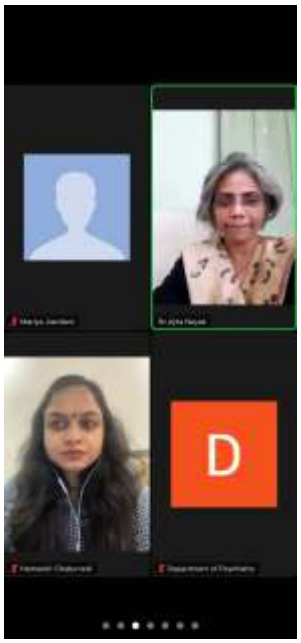
COMBATING VACCINE HESITANCY WORKSHOP
17th September, 2021

Considering the current situation of COVID 19 pandemic and the apprehension about COVID 19 vaccines, the Students' Wing of GSMC MUHS International Bioethics Unit had organized a workshop on 'Combating Vaccine Hesitancy' on 17th September, 2021. Twenty-two undergraduate and postgraduate students attended this workshop. Dr Shreeraj Talwadekar, Assistant Professor of Microbiology, Dr Deepika Sadawarte, Assistant Professor of Community Medicine, Dr Shilpa Adarkar, Associate Professor of Psychiatry were the faculty for this workshop.

PSYCHOLOGICAL FIRST AID IN MEDSCHOOL WORKSHOP
5th October, 2021

Considering the current situation of COVID 19 pandemic and the apprehension about COVID 19 vaccines, the Students' Wing of GSMC MUHS International Bioethics Unit had organized a workshop on 'Combating Vaccine Hesitancy' on 17th September, 2021. Twenty-two undergraduate and postgraduate students attended this workshop. Dr Shreeraj Talwadekar, Assistant Professor of Microbiology, Dr Deepika Sadawarte, Assistant Professor of Community Medicine, Dr Shilpa Adarkar, Associate Professor of Psychiatry were the faculty for this workshop.





Awards and Honours

Ms Zoya Khatri participated in International Artistic Poster Competition organized by World Bioethics Day Committee as a part of World Bioethics Day 2020 celebrations and won **Third Prize** in this category

Dr Pratik Debaje, Ms Shruti Tilak, Ms Natasha Mehta, Ms. Sayoni Shah, Mr Jayesh Urkude & Ms Alisha Sayyad participated as a team in International Short Film Competition organized by World Bioethics Day Committee as a part of World Bioethics Day 2020 celebrations and the team won **Third Prize** in this category

Looking Ahead: Training of clinical faculty in Bioethics and AETCOM Modules

GSMC MUHS INTERNATIONAL STEERING COMMITTEE 2021

Sr. No.	Name	Unit Affiliation
1	Dr. Hemant Deshmukh	Chairperson
2	Dr Milind Nadkar	Co-Chairperson
3	Dr Mariya Jiandani	Head Bioethics Unit
4	Dr Padmaja Mavani	Head Steering Committee & Editor
5	Dr Anjali Telang	Secretary
6	Dr Jyotsna Thosar	Treasurer
7	Dr Trupti Ramteke	Website coordinator
8	Dr Praveen B Iyer	Member
9	Dr Deepika Sadawarte	Member
10	Dr Varsha Kulkarni	Member
11	Dr Santosh Salagre	Member
12	Dr Priyanka Prasad	Member
13	Sister Vaishali Chavan	Member
14	Sister Aarya Deshmukh	Member
15	Brother Ravindra Markad	Member
16	Dr Usha Kasar	Member
17	Dr Kanchan Kothari	Member
18	Dr Padmaja Marathe	Member

19	Dr Yashashri Shetty	Member
20	Dr Venkatesh Rathod	Member

GSMC MUHS INTERNATIONAL STEERING COMMITTEE 2021

Dr. Hemant Deshmukh
Dean & Chairman

Dr.Nilind Nadkar
Academic Dean &
Co Chairman

Dr. Mariya Jiandani
Head of Unit
PHYSIOTHERAPY

Dr. Padmaja Samant
Head - Steering Committee & Editor
OBSTERTRICS & GYNECOLOGY

Dr.Anjali Telang
Secretary
ANATOMY

Dr.Jyotsna Thosar
TREASURER
PHYSIOTHERAPY

Dr. Trupti Ramteke
Website Coordinator
BIOCHEMISTRY

Dr.Praveen Iyer
Member
ANATOMY

Dr.Deepika Sadawarte
Member
COMMUNITY MEDICINE

Dr. Varsha Kulkarni
Member
GENERAL SURGERY

Dr. Santosh Salagre
Member
MEDICINE

Dr.Priyanka Prasad
Member
MICROBIOOGY

Sister Vaishali Chavan
Member
NURSING

Sister Arya Deshmukh
Member
NURSING

Brother Ravindra Markad
Member
NURSING

Dr. Usha Kasar
Member
OCCUPATIONAL
THERAPY

Dr. Kanchan Kothari
Member
PATHOLOGY

Dr. Padmaja Marathe
Member
PHARMACOLOGY &
THERAPEUTIC

Dr. Yashashri Shetty
Member
PHARMACOLOGY &
THERAPEUTIC

Dr. Venkatesh Rathod
Member
PHYSIOLOGY

GSMC MUHS International Unit of Bioethics

grieves the loss Faculty member

Dr. Dilip Kadam

STUDENT WING MEMBER 2021

Sr No	Name of the Student	Course
1	Pratik Debaje	MBBS
2	Shruti Tilak	MBBS
3	Piyush Vinchurkar	MBBS
4	Jayesh Urkude	MBBS
5	Paras Arora	MBBS
6	Vaibhavi Tapade	MBBS
7	Vaishnavi Miskin	MBBS
8	Alisha Sayyad	MBBS
9	Himani Nahta	Occupational Therapy
10	Sarah Sarosh	Occupational Therapy
11	Janvi Panchal	Occupational Therapy
12	Mrinmayi Sanap	Occupational Therapy
13	Shreya Shah	Occupational Therapy
14	Tina Parker	Occupational Therapy
15	Sayoni Shah	Physiotherapy
16	Natasha Mehta	Physiotherapy
17	Param Sampat	Physiotherapy
18	Eshita Shah	Physiotherapy
19	Drishti Sheta	Physiotherapy
20	Suraksha Thakur	Nursing

21	Prachi Agre	Nursing
22	Asmita More	Nursing
23	Samruddhi Samant	Nursing
24	Nitika Sawant	Nursing
25	Sarika Kamble	Nursing
26	Rutuja Bhoir	Nursing
27	Priyanka Bunde	Nursing

Pratik Debaje
MBBS

Shruti Tilak
MBBS

Piyush Vinchurkar
MBBS

Jayesh Urkude
MBBS

Paras Arora
MBBS

Vaibhavi Tapade
MBBS

Vaishnavi Miskin
MBBS

Alisha Sayyad
MBBS

Himani Nahta
OCCUPATIONAL THERAPY

Sarah Sarosh
OCCUPATIONAL THERAPY

Janvi Panchal
OCCUPATIONAL THERAPY

Mrinmayi Sanap
OCCUPATIONAL THERAPY

Shreya Shah
OCCUPATIONAL THERAPY

Sayoni Shah
PHYSIOTHERAPY

Natasha Mehta
PHYSIOTHERAPY

Param Sampat
PHYSIOTHERAPY

Eshita Shah
PHYSIOTHERAPY

Dhrishti Sheta
PHYSIOTHERAPY

Samruddhi Samant
NURSING

Nitika Sawant
NURSING

Surbhi Raghoji
NURSING

Ashwini More
NURSING

Dipti More
NURSING

Sarika Kamble
NURSING

Rutuja Bhoir
NURSING

Priyanka Bunde
NURSING

Winners of WBD 2021 Competition

1. POETRY COMPETITION		
First Prize (English)	Anushka Kantak	Final Year BPTh
First Prize (Marathi)	Aishwarya Admane	I Nursing
2. SHORT FILM COMPETITION		
First Prize	Kingshuk Sarkar Ansh Agrawal Raghav Paranjpe Manali Jagtap Tanmay Gholap	II MBBS II MBBS II MBBS II MBBS II MBBS
Second Prize	Param Sampat Eshita Shah Anushka Kantak Mihika Jasani Mansi Palan Dimple Sachdev Apratim Shambharkar	Final Year BPTh Final Year BPTh Final Year BPTh Final Year BPTh Final Year BPTh Final Year BPTh Final Year MBBS
3. PHOTOGRAPHY COMPETITION		
First Prize	Shreya Shah Mrinmayi Sanap Sunit Malvankar Anjali Sumai	Final Year BOTh Final Year BOTh Final Year BOTh Final Year BOTh
Second Prize	Jaya Wagh	Second year nursing
4. POSTER COMPETITION		
First Prize	Mrunmai Gaikwad	Final Year BPTH
Second Prize	Suyash Kudva	Final Year BPTH
Third Prize	Shivani Parikh	Final Year BPTH
Fourth Prize	Aashna Shah	Final Year BPTH
Fifth Prize	Shivani Shinde	Third year, Nursing

ACKNOWLEDGEMENT

-: Judges Name :-

Poetry Competition

Dr. Rujuta Hadaye, Dr. Anita Agarwal

Poster Making Competition

Dr. Munira Hirkani, Dr. Nayana Ingole

Photography Competition

Dr. Ajay Rana, Dr. Vinita Puri

Ethoscope (Short Film Making Competition)

Dr. Monty Khajanchi, Dr. Ashwini Kolhe

Special Thanks for Providing Online support to

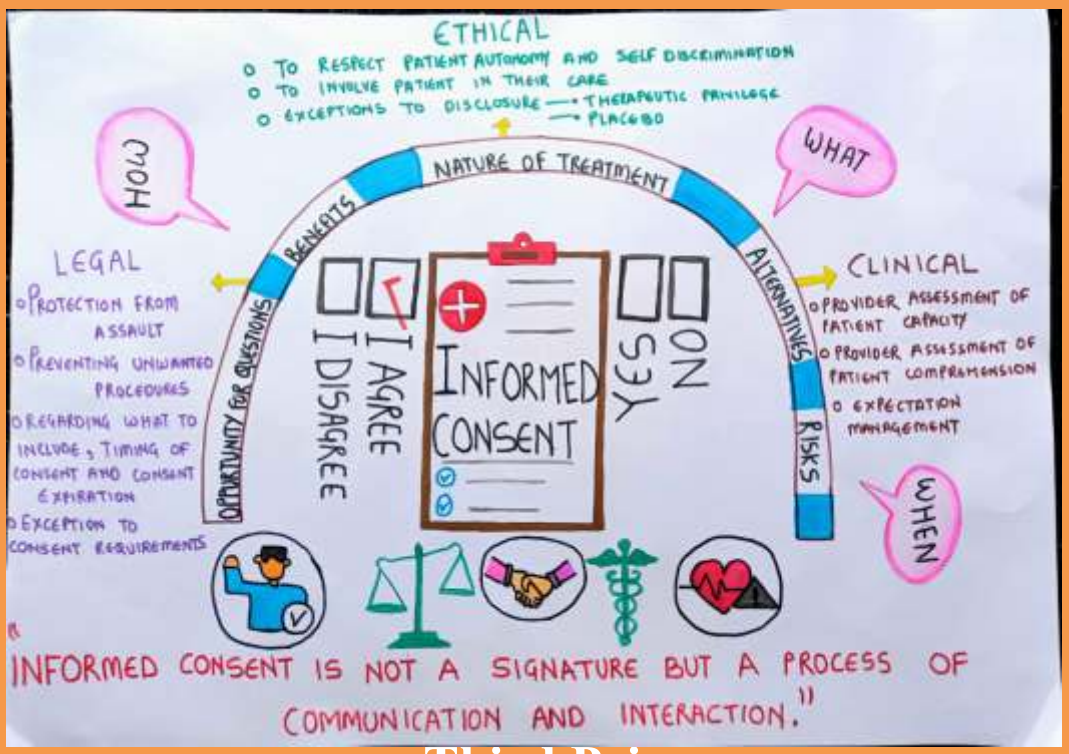
Dr. Gita Nataraj
Mr. Tushar Kotwal
Mr. Badal Patil

GSMC Faculty and Student Wing

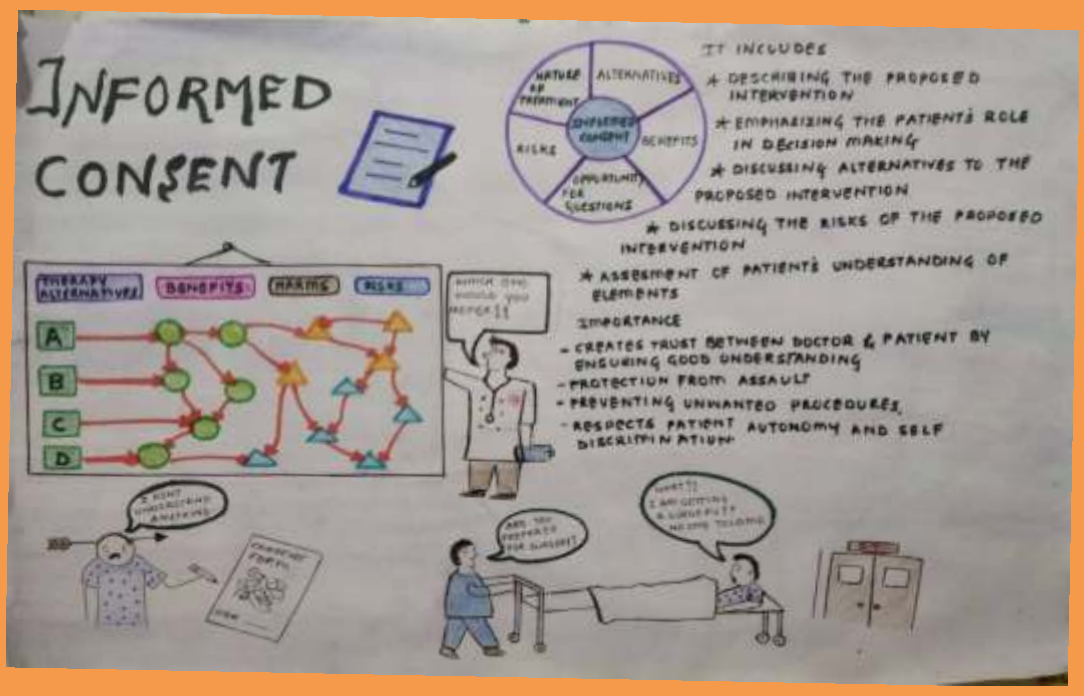
GSMC - MUHS International Chair Bioethics Unit
Poster Competition on

World Bioethics Day
Informed Consent

'Informed Consent'

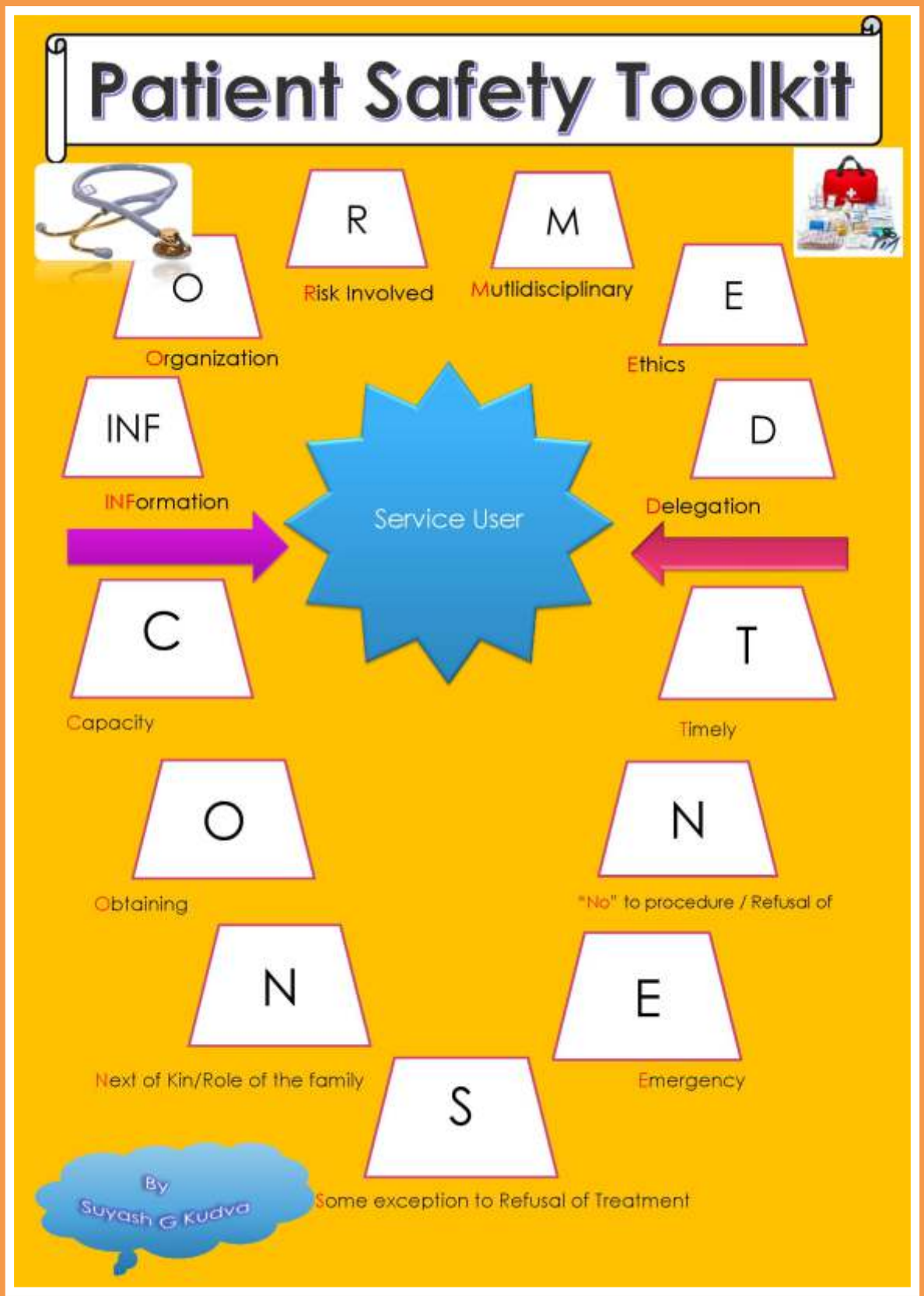


Third Prize
Shivani Paraikh



Fourth Prize
Aashna Shah

GSMC - MUHS International Chair Bioethics Unit



Second Prize
Suyash Kudva