FERCI

KASTURBA MEDICAL COLLEGE
MANGALORE
(A constituent unit of MAHE, Manipal)

MANIPAL 25 1993-2018

6th National Conference of Forum for Ethics Review Committees in India

FERCICON 2018

30th November - 1st December 2018

Report

THEME :

Dilemmas Challenging Ethics Committees and Their Stakeholders

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Dr. Ramdas M Pai
Padma Bhushan Awardee, Chancellor, MAHE

Patrons:

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Vice Chancellor, MAHE
Dr. V Surendra Shetty
Pro-Vice Chancellor, Mangalore Campus
Dr. Poornima Baliga
Pro-Vice Chancellor, Faculty of Health Sciences, MAHE
Dr. Narayana Sabahit
Registrar, MAHE.

Organizing Chairperson:

Dr. M Venkatraya Prabhu
Dean, Kasturba Medical College, Mangalore
Dr. Anand Venugopal
Medical Superintendent, KMC Hospitals, Mangalore

Advisors:

Dr. Vasantha Muthuswamy
Retd. Senior Deputy Director General, ICMR & President, FERCI.
Dr. Nandini Kumar
Retd. Senior Deputy Director General, ICMR & Vice President, FERCI.
Dr. Roli Mathur
Scientist E, ICMR.
Dr. Urmila Thatte
Professor and Head, Department of Clinical Pharmacology, FERCI.

Organizing Secretary:

Dr. B Unnikrishnan
Associate Dean and Proferssor, Department of Community Medicine, KMC Mangalore.

Joint- Organizing Secretaries:

Dr. Animesh Jain
Professor and Head, Department of Community Medicine, KMC Mangalore.
Dr. Sheetal Ullal
Associate Professor, Department of Pharmacology, KMC Mangalore.

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Organising Secretary
Dr. B Unnikrishnan

Jt. Organising Secretary
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Dr. Sheetal Ullal

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FERCICON 2018

6TH National Conference of the Forum for Ethics Review Committees of India

Organized by Kasturba Medical College (Manipal Academy of Higher Education), Mangalore.

Preconference Workshop: 29th November 2018

Conference: 30th November 2018 and 1st December 2018

Venue: Dr. T.M.A Pai International Convention Centre, Mangalore

Theme: 'Dilemmas Challenging Ethics Committees and their Stakeholders'.

Forum for Ethics Review Committees of India (FERCI) is a registered society set up as the national chapter of FERCAP (Forum for Ethics Review Committees in Asia-Pacific), the latter being an initiative undertaken by WHO TDR established in 2002. FERCI is a forum which fosters improved implementation of ethics review, facilitates opportunities and acts as a coordinator between various stakeholders towards imparting appropriate protections in research. FERCI operates in close collaboration with important institutions like the World Health Organization (WHO), Indian Council of Medical Research (ICMR), Central Drugs Standard Control Organization (CDSCO), FERCAP, SIDCER (Strategic Initiative for Development of Committees for Ethics Review) etc.

FERCI conducts its National Conference annually to unite and provide a platform to all the stakeholders of biomedical research. Biomedical research involves many inter-related disciplines and the various stakeholders include the investigator, the research participant, the sponsors, the pharmaceutical industry, students, regulators and ethics committees, among others. Each stakeholder faces a plethora of dilemmas, both ethical and others, which need to be resolved by contemplation and consensus.

The **6th National Conference of Forum for Ethics Review Committees in India (FERCICON – 2018) held at Kasturba Medical College, Mangalore** brought together the various stakeholders to discuss and brainstorm about the current challenges faced by each of the stakeholders and modalities to overcome them. The conference helped to strengthen skills and knowledge of the roles and responsibilities, procedures and ethical review of proposals, in accordance with good clinical practices and current regulatory requirements in India, thereby making the Ethics Committee accreditation ready.

More than 280 delegates attended FERCICON – 2018 from across India representing not only the Medical field but also the field of Sociology, Philosophy, Law, Ayurveda, and Integrated Medicine as well as the Lay persons.

The theme of the conference was 'Dilemmas Challenging Ethics Committees and their Stakeholders'.

The sub-themes of the conference included:

- **Ethical Issues in Stem Cell Research**
- **Accreditation of Ethics Committees: SIDCER, AAHRPP, NABH**
- **Ethical Issues in In Vitro Fertilization**
- **Ethical Challenges in Early drug development and Clinical Trials**
- **Ethical challenges in Biobank and Bio repositories**
- **Ethical Issues in Qualitative Research**
- **Eternal Values in Ayurveda for Changing Modern Medical World**

The preconference workshops which was held on 29th Nov 2018 included details about the recent **update of the ICMR Ethical guidelines 2017** and approaches and modalities of **Incorporating clinical and research ethics into the medical education curriculum**.

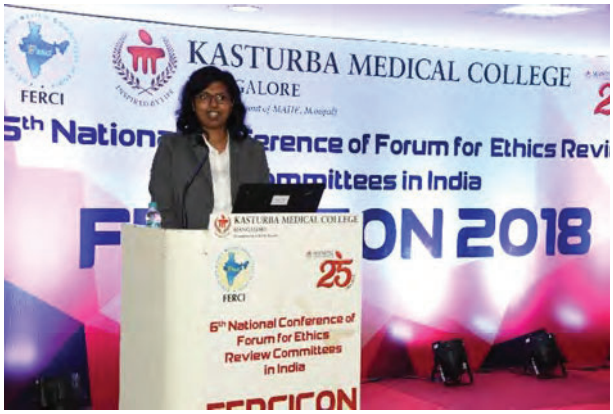
CONFERENCE

Day 1- 30th November 2018

Theme – Dilemmas challenging Ethics committees and their stakeholders

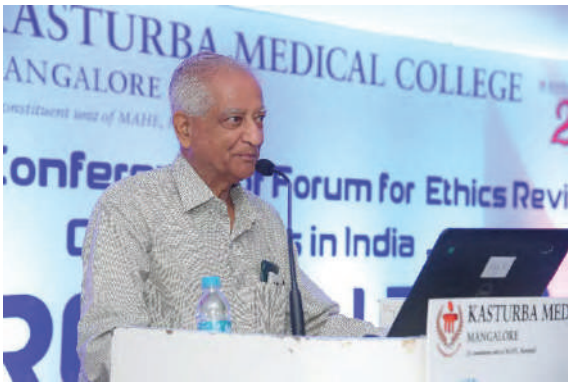
The first day of the conference started with an Opening address by Dr. V. Surendra Shetty (Pro Vice Chancellor, Manipal Academy of Higher Education, Manipal, where he spoke about the status of clinical research and ethics in India. He mentioned that, India is an ideal place for a clinical trial due to the large population and also because Clinical Research is expensive outside India. He reiterated the importance of conferences and workshops and said that conferences and workshops act as a mode for updating of knowledge. Interaction with experts, during the conference also helps in enhancing our knowledge in a particular field.

First Session (9.00-9.30 am)



The first session started with Dr. Vinita Jagannath, Post-Doctoral Researcher, French National Institute of Health and Medical Research, Paris; where she spoke about Ethical Issues in Stem Cell Research. The session was chaired by Dr. Raviraja N.S., Director – Innovation and Business Development, Stempeutics Research Private Limited, Manipal. Dr. Jagannath mentioned that stem cell research is ethical as it is derived from human cells which are about to be discarded. Ethical issues at different phases of stem cell research were also discussed. She also spoke about the guidelines of International Society for Stem Cell Research (ISSCR).

Second session (9.30-10 am) KEY NOTE ADDRESS



MEDICAL ETHICS AND VALUES IN HUMAN LIFE

- Prof. S R Bhatt,
Chairman, Indian Council of Philosophical Research, New Delhi

During this session the key note address was delivered by Prof. S R Bhatt, on the topic, Medical Ethics and Values in Human Life. The Chairpersons for this session were Prof Shrinivasa Varakhedi, Vice Chancellor, Sanskrit University, Ramtek, Nagpur and Dr. G G Laxman Prabhu, Professor and Head, Department of Urology, KMC, Mangalore.

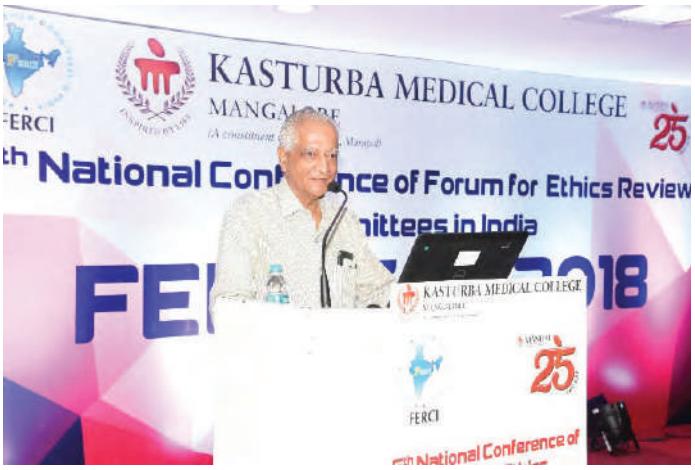
The key note address was an exercise in self-awareness and self- realization by a thoughtful human mind with regard a very problematic but highly significant enigma of human life concerning the antinomy of freedom and determinism experienced in our concrete day to day living and consequent adherence/non-adherence to moral norms and realization of values. In this respect we may derive helpful guidance and redemption from the deep insights and enlightening visions of Indian seers and sages, ancient and modern. In this enterprise the entire wide and variegated reality is to be kept in view with the main focus on human existence. It has to be a holistic reflection from varied perspectives and multiple approaches (*anekanta drsti).* It has to be done with the objective of being benefited by it in shaping the cosmic and human existence for universal well-being. Naturally therefore the individual human existence, human society, natural environment, scientific and technological enterprises and socio-political organizations become crucial points in a purposeful deliberation. Consideration of deeper issues concerning these areas provides it practical orientation in the context of human life planning, social engineering, science policy and environmental stewardship.

Human being as highest emergent

Human being is the highest emergent in the cosmic process so far. Shaped by genetic endowment, ecological interaction and cultural transformation human existence is multi relational, multi-dimensional and multi-layered. It has individual, social and cosmic aspects in a holistic and organic framework. It is intimately related with nature, other human beings and non-human species. Human identity, therefore, cannot be determined by any one of these facets alone in isolation with others; it is constituted by the totality and intricate unity of all of them.

Human being as rational, free and responsible agent

Human being, ideally speaking, is ratiocinative, goal-oriented, free and responsible agent. He /she is a knower (*jnata),* responsible agent *(karta)* and enjoyer of consequences of action (*bhokta)* through innate competence and overt performance. As a self-conscious and reflective person he/she has the capacity to understand one's own self as also others. The term used in Indian culture for such a human being is *purusha.* And his/her planned, purposive and methodical action is termed as *purushartha.* As *jnata* human being is endowed with the capacity



to know, to discriminate and to form judgment. He/she has freedom of will and can make a choice. He/she is also a responsible agent and has to be accountable for his/her actions. The free will is regulated will. All his/her willful actions should therefore be in the form of *purushartha.* He/she has to perform actions with full knowledge, freedom and responsibility. They should be in the form of "*artha"* (conducive and leading to well-being) and *ishta* (desirable) and not "*anartha*" (detrimental) or *anisht*a (harmful land therefore not desirable). Activity is the law of life and every human being must act as *purusha* for survival, sustenance and for enhancement of quality of life. So there is inclusive alternation between freedom and determinism. Rationality as discriminative ability implies freedom to choose but being guided by certain norms. It also implies responsibility for the consequences so inevitably generated by ones actions.

Meaning and significance of human life

Human life is unique and special gift which is rare among all the creatures. It is a prized possession acquired through a good deal of meritorious acts in the previous birth (s).It is valuable and is to be valued. A mechanistic

understanding of human nature is truncated and cannot explain the spontaneity, creativity and goal-orientation inherent in human nature. Only a teleological, holistic and inclusive understanding of human potentialities, capabilities and achievements can do justice to human aspirations. The knowledge and quest for values and planned efforts to realize them constitute the core of ideal human life. All human beings must participate or made to participate in the process of value-realization. This is our universal responsibility.

Constitution of human being

Human being is an intricate psycho-physical complex animated and enlivened by spiritual principle called soul or self. There are varied understandings of human constitution in different cultures and disciplines of knowledge, but the Indian understanding in terms of five sheaths (panchakoshas) is most helpful. Among these five the physical and vital are material, mental and intellectual are quasi-material and they are termed as psychical, and spiritual (adhi+*atma*) is transcending these four which are empirical. It is a very neat and useful classification. But it should be kept in mind that all these five are integrally correlated and cannot be separated. In order to understand human nature our attempt should be to know the nature, functioning and interrelationship of all these five in a holistic framework. The fine and subtle constitution of physical body, the marvelous functioning of mind, and cognitive and conative senses, the wondrous play of vital breaths, the wonderful functioning of senses, the brilliant displays of thoughts, emotions, feelings and volitions are all amazing and astounding. The functioning of human mind is amazing. It is something more than a live computer. But much more significant are beatitudes and bliss of consciousness, the spiritual principle. But we have to know all these. We may at the present juncture of our knowledge and capabilities may have only partial or faltering understanding of all these marvels of human life but we much steadily continue our efforts to enhance our knowledge.

Human being responsible for all ailments

Unfortunately, human mind is prone to perversion and susceptible to wrong-doing and evil. The perversity-prone human mind more often than not indulges in law-violation rather than law-abidance. This leads to ecological and environmental pollutions and consequent suffering at the physical, mental and intellectual levels. The pollution is all-round at the individual level, at the family level, at the community level, at the social organizational level and at the cosmic level. Sometimes this is done out of ignorance, sometimes by force of circumstances but more often by weakness of will or habit of mind. It is not unnatural as its seeds are potentially present in human mind and start fructification before one becomes aware of it or makes an attempt to get rid of it. This is one of the facets of the operation of the law of *karma. This law has attributive, retributive and distributive facets which need to be understood properly.* But it is very difficult to understand this operation and go beyond its labyrinth.

Significance of health and hygiene

Recognition of value of health and hygiene, both individual and social, is a hall mark of civilized society. Health and hygiene are essential for socioeconomic as also for total development. It is a truism to say that only in a healthy body healthy mind resides and when there is psycho-physical health there is spiritual solace. For this apart from cleanliness of body and external surroundings, purity of eatables and drinkables is also necessary

along with considerations of quality, quantity and modality. Health is primarily an individual value, though figuratively we also talk of social and national health, whereas hygiene is both individual and social. Maintenance of both is human responsibility for which purity of thought and conduct are essential prerequisite.

Need for Ethics and Morality

Since all pollution and perversion is human making there is need to regulate human conduct. The discipline of Ethics is primarily concerned with postulation of norms for good human life and regulation of human conduct in accordance with these norms. On the presumption that human being is a *purusha* ethical considerations, ethical theorizing and ethical judgments are undertaken. Rationality as discriminative ability implies freedom to choose but being guided by certain norms. The determination and choice of alternatives requires norm-prescription but human freedom also implies a scope for both norm-adherence and norm-violation. Values to be pursued and disvalues to be shunned are both equally central to moral considerations.

What is Ethics?

Philosophy, of which Ethics is a part, is systematic reflection on our lived experiences with a view to be profited from it and one of our most problematic experiences is human behavior which is indeterminate and unpredictable but concerning which paradoxically constant endeavor is made for determination and regulation. The discipline of Ethics is primarily concerned with postulation of norms for good human life and regulation of human conduct in accordance with these norms. As stated earlier, ideally speaking human being is a rational, free and responsible agent. On these presumptions only ethical considerations, ethical theorizing and ethical judgments are undertaken. It is hoped and believed that human conduct can be regulated and be made norm-abiding. This is the objective of the discipline of Ethics.

Activity is the law of life and every human being has to act for survival, for sustenance and for enhancement of quality of life. So, human conduct has to be teleological and goal-oriented. In the choice of conduct there is freedom as also regulation of freewill. There is inclusive alteration between freedom and determinism. Rationality as discriminative ability implies freedom to choose but being guided by certain norms. It also implies responsibility for the consequences so generated by ones actions. Freedom to choose means availability of alternatives to opt for that which is good, right and conducive to well-being or to opt for that which is bad, wrong and harmful to well-being. A human being can act in either of the two ways, but he has to be responsible for that action. This determination and choice of alternatives requires norm-prescription but human freedom also implies a scope for both norm-adherence and norm-violation. In this context ethical considerations become meaningful since they tell us about the rules and regulations to be adhered to and prohibitions to be avoided. Values to be pursued and disvalues to be shunned are both equally central to moral considerations. In ethical context values are termed as virtues and this relation between values and virtues should be kept in mind.

Ethics and values

Our awareness of values is always prescriptive. It is different from the descriptive awareness concerning facts. A description can be true or false or doubtful but the logic of prescription has another set of values. A prescription can be good or bad or indifferent. It may be conducive to well-being or harmful or of no effect. A description has to be local with the possibility of *universalizability* but a prescription has to be global with the need of being applied to local situations. Accordingly, the mode of knowing prescription cannot be the same as the mode of knowing the description. Of course, both are to be grounded in experience but the nature of experience cannot be the same. The ideals are conceived in and spring from actual situation but their source is not sense experience.

Another point to be referred to is that norms are posited to be pursued (They are *sadhya* and not *asadhya*). In ideal situation they are to be practiced spontaneously as a matter of habit or by the force of conscience. But in practice it may not be so. That is why importance of moral education is accepted as it helps in cultivation of moral will. But more often than not because of moral infirmity built in human nature there is a need of external

sanctions, social or political. That is why codes and laws are formulated. But this enforcement from outside is always feeble as moral weakness is ingrained in human nature. That is why there is greater need for moral education and constant vigilance. But it should not be overlooked that values are not to be taught but to be imbibed.

There is always a gap between theory and practice and our endeavor should be to bridge it as far as possible. A moral norm may not be adhered to in its totality or fullness but this does not mean that it should be given up as impracticable or utopian. The distinction between *mahavrata* and *anuvrata* in the Jaina tradition is a good guide in this regard. The mark of an ideal being actually perused is harmony between the inner and outer reality of the agent, between inner feelings and outward behavior. But this cannot be a fool-proof criterion. Public vigilance helps in norm –following.

Need for professional ethics and management

Every rational human being has to undertake some profession or the other for survival, for self-fulfillment and for social obligation. It has to be performed for self-expression, self-enhancement and self-realization as an ultimate objective, but its immediate aim is to earn livelihood. In an ideal situation there has to be a balance between the ultimate and the immediate objectives but very often this is overlooked. This calls for professional ethos, regulations and management.

Every profession for its proper and efficacious performance has to depend upon several factors which may be regarded as its guiding principles. There are several criteria on the basis of which the guiding principles can be classified. The most important criterion is the distinction of end-.means-modalities-result *(sadhya-sadhana-itikartavyata-phala*). Every profession is meant to serve some goal, to realize some purpose and to attain some result. It is the basic requirement of every profession to have clarity about the end for which it is to be pursued. An absence of clarity or confusion about the goal very often results in improper or immoral performance. The goal must be good, desirable and conducive to well-being. Contrarily, it should not be detrimental to these. For the realization of the goal appropriate conducive and means are to be thought of and procured. Their availability has to be ensured. After availing them accessibility to them and skillful employment of them are utmost necessity.

Any consideration of professional ethics cannot be piecemeal. It has to take into account all aspects, facets, dimensions and factors. It is not a matter of simple enumeration of do's and don'ts. Human nature is highly complex and human agencies are very much complicated. Only a holistic and integral approach may be helpful. This analysis is only a brief outline to be elaborated further.

Need for multiple profession and management ethics

In the cosmic set up there has to be multiplicity of professions depending upon the needs and aspirations and abilities of the human individual. These professions keep on evolving and dissipating as the societies change. On account of human limitations and large number of wants, there is a need for multiplicity of professions. All professions are equally useful and valuable and therefore they should be treated at par, but it is human selfish nature to prioritize them and to put them in a hierarchy. It is a part of professional ethics to respect all professions and to follow the maxim of "Work is Worship". All professions are meant for universal well-being and we have the universal responsibility of upholding their purity and respectability. Unfortunately we seldom care for this.

Every human individual cannot perform all the actions and fulfill all the wants by himself/herself, and therefore there has to be choice of vocations. This should depend upon ones capacity, ability, interest and need. The Gita calls it as *svadharma.* Everyone has to mind ones *svadharma*. This is professional ethics. Every profession calls for a code of conduct for its proper performance. The code stands for a set of rules and regulations. There rules and regulations are to be both intra-profession and inter-profession. The Gita emphasizes both these types of professional ethics. Generally we tend to side track inter-professional ethics and mind only intra-professional ethics. In modern times most of the professions have become inter-professional. For example, medical

profession has preventive and curative aspects but it is also intimately related with pharmaceutical, engineering, business, dietary, legal, and psychological and many other professions.
There can be as many professional ethics as there are professions. Some professional regulations are common to all professions and cut across all of them in spite of their varied nature, modes of functioning, objectives etc. but they also require some separate or distinct set of norms as per their specific requirements. Every professional ethics is management ethics. It deals with proper and effective management of that profession. This can be realized by proper education. This education need not be formal class room education. It can be imparted in many ways suiting to that profession. But this much is certain that without management there cannot be proper performance and without education there cannot be proper management.

Medical ethics

The medical ethics is guided by the principles of goodness and rightness. The end has to be good and the means have to be right. The goal has to be pure and so should be the means. The goal should determine the means. Any disparity between the two amounts to violation of professional ethics. The relation between means and end is logical and causal whereas the relation between end and means is justifier-justified. One has to know this interrelationship. Modalities consist in proper, efficient and effective employment of means. This is known in Indian tradition as *upayakausala* or *karmakausala*. This involves procurement of the ingredients of modalities, priority and posterity of their employment, their efficient employment and constant vigilance of the consequences of their employment. It may not be necessary to mention the prevalent violations of legal professional ethics in the society and also the ills and evils of medical system on account of ignorance or non-abidance of this quadruple. We are well familiar with the costly, cumbersome, boring and prolonged procedures which are prohibitive, painful and frightful. The role of money-power and muscle-power, the role of police and other supporting agencies and in fact the roles of all the wings of government, viz. legislature, executive and judiciary, are too well known to us to mention. Any consideration of professional ethics cannot be piecemeal. It has to take into account all aspects, facets, dimensions and factors. It is not a matter of simple enumeration of do's and don'ts. Human nature is highly complex and human agencies are very much complicated. Only a holistic and integral approach may be helpful. This analysis is only a brief outline to be elaborated further.
The aim of medical profession is medical-care of public at large for health and hygiene both physical and psychological as body and mind have mutual effects. It has to take into account both the preventive and curative aspects. It has multiple-dimensional as it involves patient-doctor, consumer-provider, state-citizen and such areas of inter-personal relationships. It calls for quality care and general well-being. It demands transparent accountability at all levels, to patients, colleagues, medical councils, state and public at large. Health care has become a team work as for institutionally delivered patient-care service there is team work in hospitals, polyclinics, nursing homes, community health centers, dispensaries, diagnostic centers etc. and team ethics involves ethics for doctors, nurses, para-medical workers, auxiliaries, community workers etc. It has attracted the role of mass media (generally nicknamed as media-trial), and also civil, criminal and consumer protection law courts. We are very well familiar with violations of and deviations from medical ethics. Beginning with pollution in atmosphere, adulterations in eatables and drinkables and use of duplicate and expired medicines, there is rampant commercialization and profiteering. Medical care has become costly and at times unaffordable and prohibitive. Service motto is almost lost. Professional self-restraint is decreasing. There is paucity of effective laws and regulative authorities are becoming weak. There is organ sale and misuse of diagnostic procedures. There is public-private sector divide, with weak public sector and profiteering private sector. There is public subsidy but no public care. Even there are cases of medical graduates joining administrative services. This is another case of either ignorance or non-abidance of the above stated quadruple. The instances can be multiplied.
Material goods are inevitably needed in worldly life. They fulfill our daily requirements. We get them from natural resources, the *panchabhutas*. There are three stages involved in utilization of material goods. They are

production, distribution and consumption. Since material goods being indivisible are normally not shareable as if one utilizes them others are deprived of them, there has to be regulation at all the three stages. Nature has enormous capacity to fulfill our needs and therefore there is sufficient scope for production of material goods. But nature is subject to depletion and there has to be renewing of the capacity of nature. Newer and newer resources are to be generated from within nature itself. So long as newer resources are not generated care should be taken to ensure that our posterity is not deprived of their use. This is the demand of intergenerational justice. Sufficient care is to be taken in judicious utilization of existing natural resources. Production is to be guided by needs and not by consumerism. For distribution equitability is to be ensured so that there is no uneven distribution and everyone gets as per ones requirement. So not only production has to be sustainable consumption has also to be sustainable. Service and not profit has to be the motive in all business transaction. So there are four guiding principles of business ethics, viz., *yoga, kshema, asteya* and *aparigraha* as they are enshrined in Indian culture.

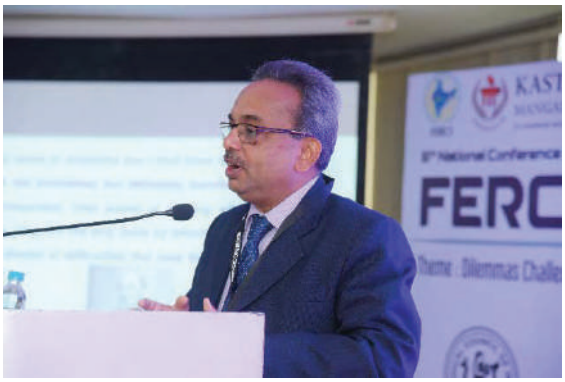
Performance of profession as *yajna*

There is a quadruple principle of knowledge-will-action-result for proper performance a profession. The agent in a profession has to know the knowledge-will-act-result relationship (*jnana-iccha-kriya-phala*). If he/she is knowledgeable of this he/she is a fit and competent person *(adhikari*) to undertake that profession. Then only there can be skillful performance of that profession. Role of knowledge is foundational and pivotal. Lack of knowledge is harmful and detrimental to well-being. In all cultural traditions of India the significance of knowledge is highlighted. But mere knowledge is not enough. It has to generate will and fructify in effort and action. If someone claims to know but does not have a will to act, that knowledge is unripe or incipient or false pretext. Knowledge generates will and this stirs up an agent to act, but his/her power lies only in performance of action and not on the results of action. The human being has control on the performance of action and not on the *accruing* of its results. This is another type of professional management.

The Gita ideal of *anasakta karma* or *karmayoga* is performance of *Brahmayajna*. It provides a blueprint for professional ethics as it comprehends properly both the quadruple principles referred to above. A proper management of these quadruples has been the keynote of the Bhagavadgita which provides a foundation of professional ethics

Performance of any profession has to be in the spirit of *yajna* or universal well-being. This is the meaning of *yajna* in the Gita as well. A yajna is a collective and corporate action for the sake of general well-being (*Brahmarpana*). Brahma stands for totality. Every profession is to be undertaken not for one's selfish end only *(idam na mama*). It is for *vyasti, samasti* and *paramesti* all the three, though apparently it is done for one's own self. So the result of action is to be surrendered to the totality (*svaha*). Every existence is a part of the corporate whole and is integrally related to the whole and its parts. There is fundamental unity of all existences. The basis of *yajna* is in *satya* and *dharma* which are rooted in *rta.* They are at the base of the cosmic process and sustain it. The cosmic process itself is a *yajna*. These are the subtle and sublime ideas not to be taken in their ordinary mundane meaning. They are to be understood in the context of the *adhyatmika* sense. They provide foundation to Indian spirituality which is holistic, integral and unitive approach to reality. These are rich concepts pregnant with profuse meaning for universal well-being. It is unfortunate that in the course of vast temporal span and due to exigencies of history they have lost their original meaning, got distorted and misused. But they need to be re-understood. No culture can survive and thrive if its seminal ideas, key concepts and fundamental doctrines get fossilized and sterilized. Macaulay realized this fact and tried to strike at the very roots of Indian culture and we are witnessing its evil consequences. But it is high time that we become alive to reality.

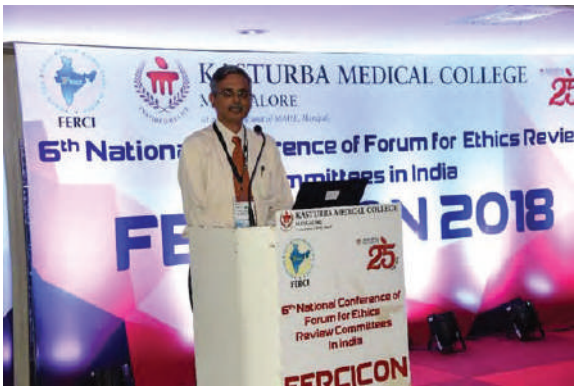
Third Session (10 am to 10.30 am)



The third session on 'Can good statistics enhance the standards of ethics in medical research?' was taken by Dr. N Sreekumaran Nair, Professor and Head, Department of Biostatistics, JIPMER, Puducherry. The chairpersons for this session were: Dr. Avinash Shetty, Medical Superintendent, KMC, Manipal and Dr. Suma Nair, Professor and Head, Department of Community Medicine, KMC, Manipal. Dr. Nair spoke about the role of statistics in medical ethics and whether 'juvenile justice' has a role to play in medical ethics. He mentioned the presence of bias and uncertainty in research and the methods to minimize them. He added that ethics right now focusses on participants and not on a larger audience, who are beneficiaries of the research.

Fourth Session (10.45-11.15 am)

The fourth session on 'Challenges in conduct of pediatric clinical trials' was taken by Dr. Sanjiv Lewin, Chief of Medical Services, St. John's Medical College Hospital, Bangalore. The chairperson for this session was Dr. Kamalakshi Bhat, Professor and Head, Department of Pediatrics, KMC, Mangalore. Dr. Lewin spoke about placebo controlled trials and the ethical concerns related to that in pediatrics. He gave many examples of the historic placebo controlled trials like ACTG076 trial and Zidovudine where placebo was given to the control group due to a lack of ethical concern. He also gave examples of the HPV project in India where 32,000 tribal girls were vaccinated with HPV vaccine. In the Kano Trovafloxacin trial the letter of approval for human trial was falsified. Low dose of ceftriaxone was further reduced for meningitis. He mentioned that it is unacceptable to extrapolate the adult pharma studies for children as they are not small adults. They have different pharmacokinetics, pharmacodynamics and pathophysiology. It should be mandatory for pharma companies to formulate a pediatric formulation for new drugs. In pediatric clinical trials it is always the market that comes to the doctor and creates the need. Dr. Lewin mentioned that the critical issue in pediatric research is the absence of genuine research, clinical equipoise. Reading the consent form to the parents is a big risk. The dilemma in these trials is how much information is conveyed to the parents. He mentioned that problems arise when the treating physician is the Principal Investigator. Commonly those recruited are poor, hence multicenter trials are taken up pharma companies. Written assent of the child in agreeing to take part in the trial is required according to the new guidelines. Also, risk-benefit ratio assessment is very important in pediatric trials.



Dr. Lewin also mentioned that it is very difficult to do clinical trials for neonates as it is difficult to get consent. Long term follow up is required for neonates as they have developing organs. With adolescents, confidentiality becomes important and it is difficult to decide whether to take the consent from parents or directly from adolescents.

In conclusion he mentioned that clinical trials especially in children, adolescents, women, pregnant women and women of reproductive age should be encouraged. ICMR has guidelines for research involving children on ICMR

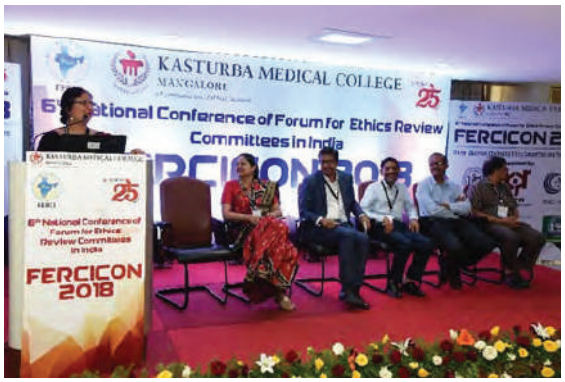
website which specifically suggest that researchers should invite pediatricians during developing project proposal.

Plenary Session I (11:15 AM – 1:00 PM)

Theme: Ethical dilemmas in Biomedical research and strategies to Overcome them

Chairperson: Dr. Girish Menon, Professor and Head, Department of Neurosurgery, KMC, Manipal.

Dr. Urmila Thatte, Professor and Head, Department of Clinical Pharmacology, KEM Hospital, Mumbai.



Dr. Thatte spoke about the foundation and progression of the Institutional Ethical Committee. She mentioned that the IEC came into being in 1975. In 1980 the first policy statement by ICMR stated that protocols should be reviewed by ethics committee. In 1988 it was stated that even in the absence of ethics committee and review the PI and DG Health could review the protocol and start the study. The ICMR ethical guidelines were revised in 2006. She also briefly explained the challenges of an Ethics Committee in India viz. poor administrative support, involved in doing only initial review and approval but not ongoing review of the project and monitoring, absence of SOP. She reiterated that everything that involves human research should go through ethical review (ICMR guidelines). ICMR reported that proper ethics committees are not present in institutions and most of the EC lack legal person in the panel.

Dr. Roli Mathur, Scientist E and Head, ICMR Bioethics Unit, ICMR, Bengaluru.

Dr. Mathur spoke about the role of ICMR in medical ethics. She mentioned that ICMR has collaborated with THSTI for a form on EC and this will be out by 7th December 2018.

Dr. Chakrapani M, Professor of Medicine, KMC, Mangalore.

Dr Chakrapani spoke about the importance of ethical and scientific review. He spoke about the importance of increased number of AYUSH projects. He mentioned that when considering the subject recruitment, if treating doctor is the investigator, it results in biased results.

Dr. B Satheesan, Director and HOD, Department of surgical Oncology, Malabar Cancer Centre, Kerala.

Dr B Satheesan spoke about the imperative perspective where to benefit others, some are put at risk. He also discussed about risk benefit analysis, minimal risk, prevention strategy and unethical manipulations. He stated that a probable solution to this is a well-structured bioethics course.

Dr. Joseph Thomas, Head, Centre for Bioethics and Professor of Urology, KMC, Manipal

Dr. Thomas spoke about the ethics in educational research. He stated that the Post graduates and the Under-graduates are the most vulnerable groups. He mentioned the importance

of the need of ethics as part of training. He also stated that RCT is impossible in clinical practice. Also, principles of institutional arrangement, research related harm, responsibility of host institution, ancillary care, continuing review, site monitoring, and requirement of research office were discussed.

Dr. Bhavesh Acharya, COO, Cytespace Research Pvt. Ltd.

Dr Bhavesh Acharya discussed the Industry perspectives on medical ethics. He stated that Ethics Committee is a bridge between a Doctor and organization, and the EC has always looked into giving opinions. Most of EC are not ready to take the responsibility given by DCGI.

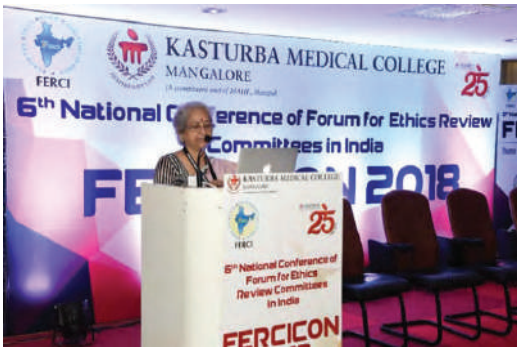
Every 3 years EC should be revised. Many EC do not include placebo controlled studies or do not take phase 3 studies. Less than 5% of EC go to the investigator for follow up and monitor the investigator activities in a project. The only way to resolve the problems is to do mandatory accreditation of the EC, utilize the DCGI inspections as part of learning.

Plenary Session II (2-3.30 pm)

Theme- Incorporating Ethics in Medical Education

Chairpersons: Dr. Sanjiv Lewin, Chief of Medical Services, St. John's Medical College Hospital, Bangalore and Dr. Ciraj AM, Director, MAHE-FAIMER, MMMC, Manipal.

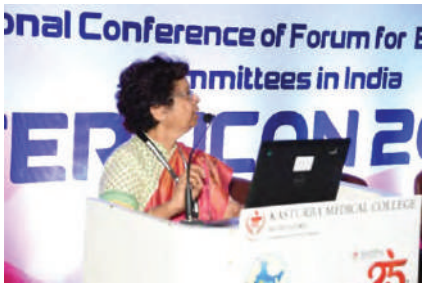
Prof. Brijendra Singh, Dean CSR and HOD of Anatomy, AIIMS, Rishikesh, explained ethics and morals. Ethics is a system of moral principles. Morals refers to individuals own principles regarding right or wrong. He discussed about the need of ethics in medicine, challenges and the contents of clinical ethics. He suggested that medical ethics should be taught during the course.



Dr. Medha Joshi, HOD, Department of Allied Health Sciences, Ramaiah University of Allied Health Sciences, Bangalore., spoke about Interprofessional teaching of ethics learning modules. She stated that WHO module on ethics gives guidelines that help in the formation of teaching learning methods. The challenges faced were also discussed.

Dr. Medha R., Member Secretary, IEC, JIPMER, spoke about ethics in research. She explained that there is no curriculum on research for students in India, therefore she aimed to develop a workbook with a storytelling approach to make a curriculum for students on ethics.

Dr. Nandini Kumar, Retd. Deputy Director General, Sr. Grade, ICMR., spoke about the need for ethics in practice and research. Ethics in Indian systems of medicine, challenges for bioethics education, Goals of Bioethics education were discussed. She also mentioned the types of Bioethics viz. Prescriptive bioethics, Descriptive bioethics and Interactive bioethics.



Panel Discussion

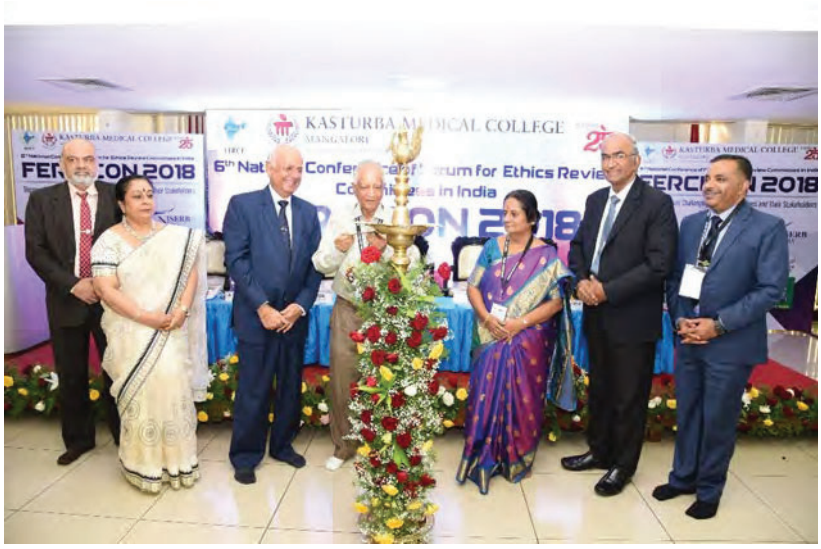
During the panel discussion it was discussed that faculty training programs on medical ethics should be encouraged and Ethics should be an integrated in the MBBS course and not as a separate subject.

Inauguration Ceremony

The chief guest of the conference was Prof S R Bhatt. The conference was presided by Dr. H S Ballal, Pro Chancellor, MAHE The Guest of honors were Dr. V Surendra Shetty, Pro Vice Chancellor, MAHE, Manipal, Dr. Poornima Baliga Pro-Vice Chancellor – Health Sciences, MAHE, Manipal and Dr. Vasantha Muthuswamy, President FERCI. Dr. M Venkatraya Prabhu, Dean, Kasturba Medical College, Mangalore delivered the welcome address.

Lighting of the lamp was done by all the dignitaries.

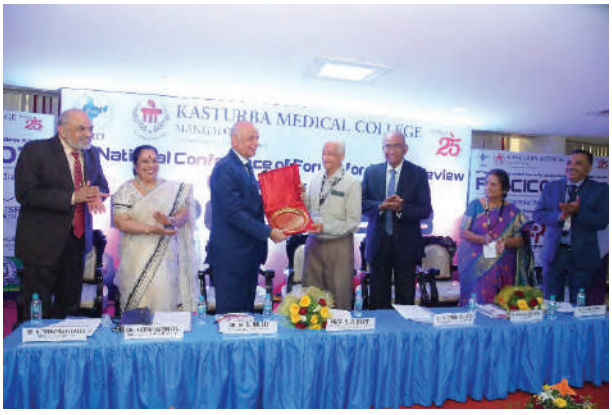
Dr Vasantha Muthuswamy, president of FERCI, spoke about the history of FERCI. The 1st conference was held in 2011. The forum is open to everyone although main focus is on Ethics Committee members. Around 370 people registered in the 1st conference. The 2nd conference was held in Coimbatore, 3rd in Lucknow, 4th in Calcutta and 5th in New Delhi.



The Chief Guest discussed about the importance of medical ethics with respect to medical education, medical research and medical practice. He also stated that Indian perspective with respect to research methodology should also be brought in.

Dr. H S Ballal spoke about the 'Institute of Eminence' conferred to MAHE and 25 years silver jubilee celebrations of MAHE. He informed about the foundation program on Ethics, communication and attitude to be started for MBBS students at the beginning of the course for 2 months. Dr. Surendra Shetty & Dr. Poornima Baliga released the e-abstract book.

The inauguration was concluded by a Vote of thanks address by Dr. Unnikrishnan B.



DAY 2- 1ST DECEMBER 2018

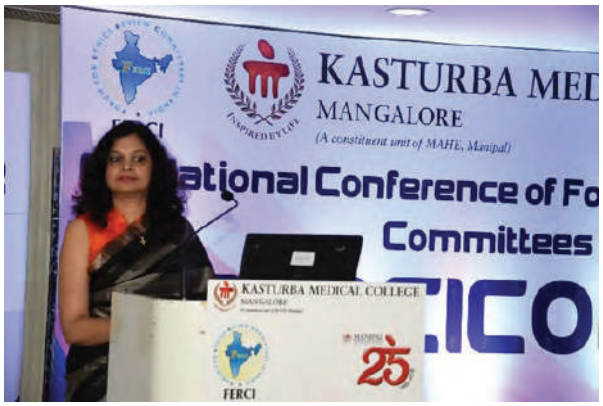
First Session (9.30 am to 10.00 am)

The second day commenced with the continuation of the presentations and the first speaker of the day was **Dr. Kamala Rai**, Global Program Head, Global Health Development Unit, Novartis Healthcare Pvt Ltd.

Dr. Usharani Pingali Prof and head, Department of Clinical Pharmacology and Therapeutics Nizam's Institute of Medical Sciences, Hyderabad chaired the session.

Dr. Kamala Rai gave a brief talk on the topic 'Ethical Challenges in Early drug Development and Clinical Trials'. She spoke about the ethical requirements like collaborative partnership, social value, scientific validity, fair subject selection, Risk – benefit ratio, Independent review and informed consent.

Patient attitudes towards clinical trials were represented with the help of a pie chart. Healthcare spending trends were highlighted and the related studies conducted on similar topics were discussed. Prescription sales and performance of drug launches from the year 1990- 2007 with commercial successful rates and commercial disappointment rates were also discussed. Rising concern for animal studies especially before undertaking clinical trials was highlighted. The tendency of publishers to develop negative attitude towards the studies having insignificant results leading to publication bias was the major challenging issue discussed.

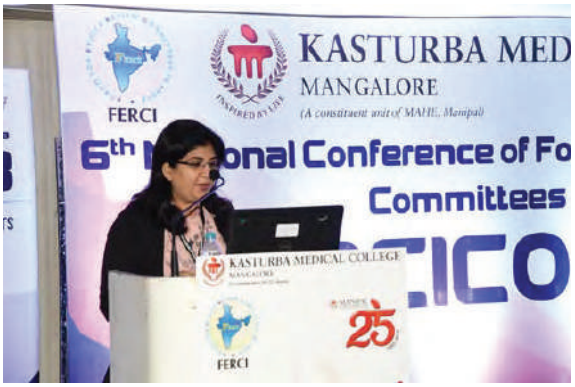


The topic was then concluded by the speaker with the suggestions for the need to innovate advanced knowledge of technology, culture and in investing capacity building, and to focus on ethics committee registration prior to conducting any study, this was deemed to be of utmost importance.

Dr. Usharani Pingali added to the talk saying that the Digital Trials and Digital Medicine are the emerging branches in healthcare with increasing need for patient care along with technology integration.

Second Session (10.00 to 10.30 am)

The second session of the day was on the topic 'Ethical Challenges in Biobank and Bio Repositories' delivered by **Dr. Juhi Tayal**, Consultant Scientist (Pathology) and Coordinator Bio repository, Rajiv Gandhi Cancer Institute and Research Centre, New Delhi. The chairperson for this session was **Dr. Sharada Rai**, Prof and Head, Department of Pathology, Kasturba Medical College, Mangalore.



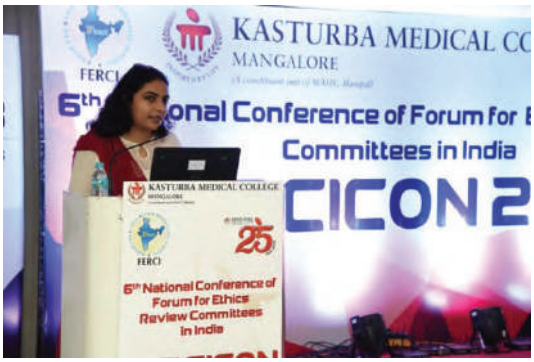
Dr. Tayal outlined the challenges faced at Human Banking and gave an idea on functioning of biobanks. She also elaborated on the location of Biobanks globally and the process of research in these settings.

Dr. Tayal also spoke about the ISBER guidelines that they follow in their organization and how the whole frame work works and the 14 guidelines that the biobanks need to use. Challenges faced were addressed, the foremost

being the Consent forms, Re-consenting Process, Unidentified data, Return of Research Results, the ICMR commercial values in benefit sharing, timing of consent and anonymization in registries.

Third session (10.45am to 11.15am)

The third speaker of the day was **Prof. Anumita Shukla**, Asst. Professor of Philosophy, Ramanujan College, University of Delhi, Delhi. The chairperson for the session was **Dr. Satish Rao**, Prof and Head, Department of Medicine, Kasturba Medical College, Mangalore. Prof Anumita spoke on the significance of care ethics for medical Ethics. She introduced everyone to the topic and also to the laws that corresponds to care ethics. Dr. Anumita also addressed problems for care ethics vis - a- vis Medical Ethics and resolving those problems by adequate analysis of care, systematic approach towards patients. She also spoke on motive accounts of care and its components that included



- Ethics of evaluation of action
- Care ethics that also evaluates motives for action
- Acting out of care leads one to attempt to meet the needs of one cared for

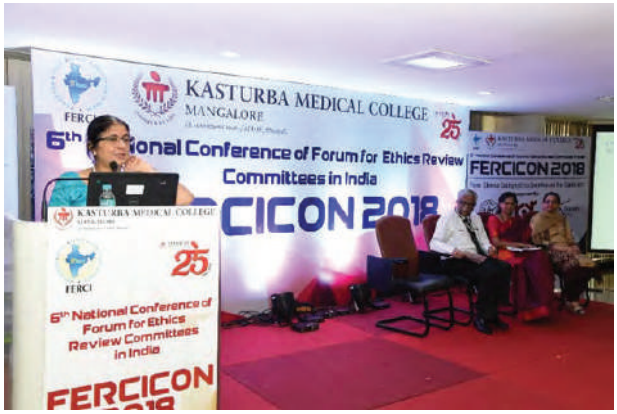
Dr. Shukla also discussed the problems of care ethics i.e. it lacks the normative and descriptive content and it is difficult to analyze care.

Plenary session III (11.15 am to 1.00 pm)

Theme: Accreditation of Ethics Committees: SIDCER, AHAARP, NABH

Speakers

- Dr Urmila Thatte, Prof and Head, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai (SIDCER)
- Dr MK Sudarshan, Chairman, IEC, Fortis Hospital and IIPH, PHFI, Bangalore (NABH):
- Ms. Annam Visala, Deputy Drugs Controller, CDSCO, Hyderabad (CDSCO)
- Dr Seema Pai, Director, India Cluster, Clinical Development and Operations, Pfizer (AAHRPP)



The session was chaired by Mr. Prashant Paschal, Assistant Director, NABH and Dr. Vardraj Shenoy, Professor of Pediatrics, Father Muller Medical College, Mangalore.

Dr. Urmila Thatte Prof and Head, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai (SIDCER):

OIG report: Institutional review boards; time for reform (June 1998)

Dr. Thatte spoke about the importance of accreditation and registration. She mentioned that it is mandatory for any research sponsored by USA to be registered under OHR. She discussed the DCGI registration process and pointed out that just registration of the Ethics committee is not enough but re-registration is also very important.

Dr. Thatte also spoke about the accreditation process and explained that accreditation is a self-assessment & external peer assessment process used to accurately assess lack of performance in relation to established standards and to implement ways of continuously doing it. She also mentioned that accreditation is needed to take a comprehensive look at their process, identify weaknesses and build up strength.

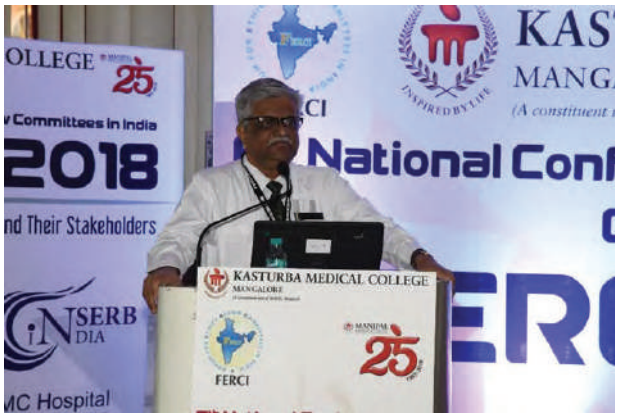
Who benefits from accreditation? 1) Research Organization 2) Participants 3) Whole research enterprise

She mentioned that accreditation assures a high ethical & professional standard and a comprehensive way of protecting the research participants.

She also mentioned that there is a huge deal of variability in working of Ethics Committees around the country. Therefore, we need to have universal standards which can be done by accreditation.

Dr Thatte also spoke about SIDCER accreditation which is a strategic initiative for developing capacity in ethical review.

Dr. MK Sudarshan, Chairman, IEC, Fortis Hospital and IIPH, PHFI, Bangalore (NABH):



NABH accreditation of Ethics Committee

NABH is a constituent body of quality council of India setup to establish and operate accreditation programme for healthcare organizations. The applicant for the accreditation process is an Ethics Committee.

Accreditation is an incentive to improve quality & capacity of the Ethics Committee to carry out ethical research.

Assessment is done using 10 standards and 49 elements

NABH: CT (EC) Assessment process

1. Panel of trained assessors
2. A team of 2 assessors (PA &A)- Allotment of the city/hospital by NABH

At the hospital:

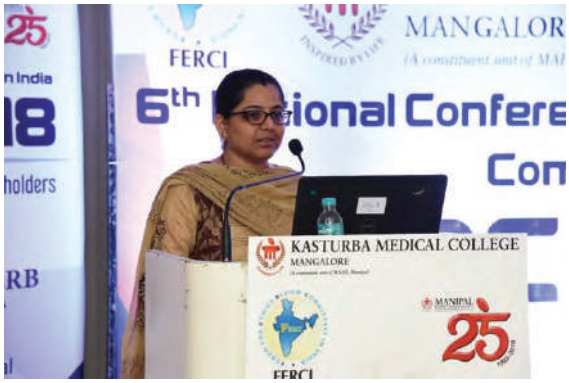
- Opening meeting- introductions, presentations etc.
- Assessment formats: 3 FORMATS + Score sheet
- Review of documents ad records of EC
- Interviews(EC measures and staff , head of institute, PI's, research staff and others)
- Clinical facility rounds EC: office, record, archival etc.
- Closing meetings: Debriefing, providing a copy of assessment report to EC.
- Uploading the report
- Emailing the filled score sheet
- Accreditation certificate is valid for 3 years.

Dr Seema Pai, Director, India Cluster, Clinical Development and Operations, Pfizer (AAHRPP):

Dr. Pai spoke about the AAHRPP program i.e. the association for the Accreditation of human research protection program. It was founded in 2001 (by funding members, public-private, US universities and many others.). It is the sole accrediting body in the USA and offers accreditation worldwide. AAHRPP looks after the respect of the participants in a project and to protect them from any harm.

She mentioned the values practiced by AAHRPP i.e.:

- Accountability
- Shares knowledge and provides encouragement
- Operates under high ethical standards
- Constantly improves the accreditation process so that it remains independent.



Goals of AAHRPP Accreditation:

- To improve systems and protecting the rights of participants.
- Ultimate goal to protect human research participants.

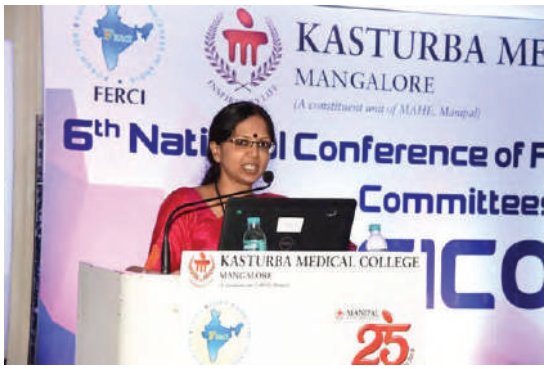
To promote goals, AAHRPP has adopted 9 overarching goals.

Benefits of AHARPP accreditation:

1. Clear, understandable pathway
2. Process is educational involving collegial discussion
3. Responsive to changes

Dr. Pai also explained the expectations of AAHRPP from the organizations i.e. 1) Protecting the rights & welfare of research 2) Protecting research participants 3) Continuously seeks for newer safe guards

Ms. Annam Visala, Deputy Drugs Controller, CDSCO, Hyderabad (CDSCO)



Ms. Visala spoke about her experiences as a regulator. She mentioned that responsibilities of the regulator should be shifted to the ethics committee as EC are also semi-regulators.

She reiterated the importance of having India specific guidelines for Ethical Committees and having more guidelines for review of protocol, review of serious events & compensation and documentation. This will help to bring more uniformity.

She also discussed the new guidelines for an RCT where most of the responsibilities of the regulatory body has been shifted to Ethics Committee and explained that this is the time for Ethics Committee to build up their systems & strategically build guidelines for reviewing protocol & adverse events/compensation and taking decision. The most important person in this process is lay person. Role of EC is immense and cannot be ignored/undermined.

Plenary Session (Panel discussion)

During the panel discussion it was reiterated by all the plenary speakers that self-assessment is the backbone of both SIDCER & NABH.

Also, for Accreditation the team support and secretariat support is mandatory. And some other important points that were mentioned are 1) Training the members who are a little weak. 2) Importance of self-assessment forms. 3) Common guidelines for all the assessors of accreditation assessment process is being framed (NABH).

Fourth Session (2-2.30 pm)

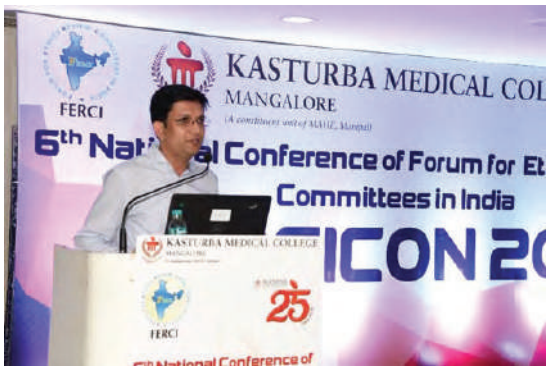
Ethical Issues in Qualitative research: Challenges and options

Dr Anmol Dongre, Dean (Research), Professor and Head, Community Medicine, Sri Manakula Vinayagar Medical College and Hospital, Puducherry.

This session was chaired by **Dr. DS Aswath Narayan,** Professor and Head, Department of Community Medicine, KIMS Bangalore

Dr. Dongre spoke about the six myths associated with qualitative research, mentioned below:

1. Qualitative Research is not a science.
2. There are many ethical issues in qualitative research.
3. There are no ethical issues in qualitative research.
4. I have never used a Qualitative Research before.
5. It's not everybody's cup of tea.
6. It's a matter of community medicine.



Dr. Dongre then explained the different methodological movements which are 1) Post positivist 2) Constructivist 3) Participatory & Advocacy 4) Pragmatism (where mixed methods research is used. He also spoke about the frameworks used in qualitative research and mentioned that all decisions in Qualitative Research are influenced by frameworks.

Types of framework used in QR are 1) Principle approach 2) Consequentialist approach 3) Virtue ethics

He also spoke about the risks involved in QR like risk to participants, risk to researchers and risk to institutions. Dr. Dongre mentioned that since QR involves sensitive topics, this leads to ethical concerns. Some examples of this are deceptions due to covert observations, emotional disturbance due to interviews, stigma due to repertory traditional and cultural practices.

Some of the common concerns with respect to ethical issues in a QR are ensuring confidentiality, selection of study tool for sensitive topic, designing a consent form, wrong questioning or probing, storage and retrieval of data.

He also reiterated the Ethical issues e.g. topics, methods, consent form, confidentiality and Privacy, respondents, researchers, gatekeepers (both formal and informal), publications.

At the end Dr. Dongre highlighted the important points to remember for ethical considerations in qualitative research like rapport and trust building, selection of study tools, consent form with sample open ended question and probes, freedom to refuse to answer some questions, ongoing consent. He also mentioned that "access protocol"-should be clearly mentioned in the proposal.

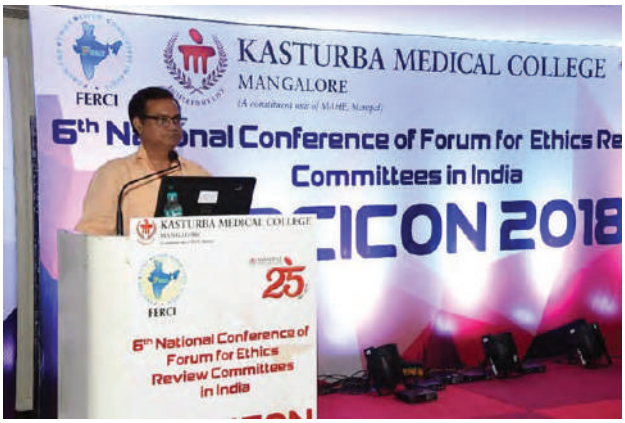
Where are we now?

- ICMR guidelines have offered guidance in this matter.
- Use of online platforms for the collection of qualitative data.

Fifth Session (2:30- 2:50PM)

Dr. Rajiv Bhatt

Medical Ethics: Tenets from Ayurveda and Buddhism



Dr Rajiv Bhatt spoke about the importance of AYUSH and its importance in medical ethics. He mentioned some of the important points in the history and concepts of AYUSH, as mentioned below:

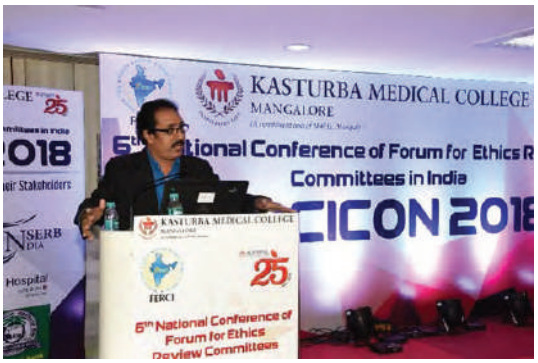
- National Ayurveda Day was started from 2016 by the Government of India
- Four stakeholders as per AYURVEDA
  - Vaidya/Physician- a medical teacher/practitioner
  - Paricharak (Paramedical staff)
  - Rogi (Patient & Caregiver)
  - Aushadhi (medicines include its handler, consumers and manufacturers)

Dr. Rajiv Bhatt, also elaborated on the important features of the Charak Samhita, i.e. duties of teachers/Doctors, duties of students and relationship between doctors, relationship between doctors and para medical staff.

Sixth Session (2:50-3:10PM)

Dr. Jayachandran, Ayurvedic Physician, Ahmedabad

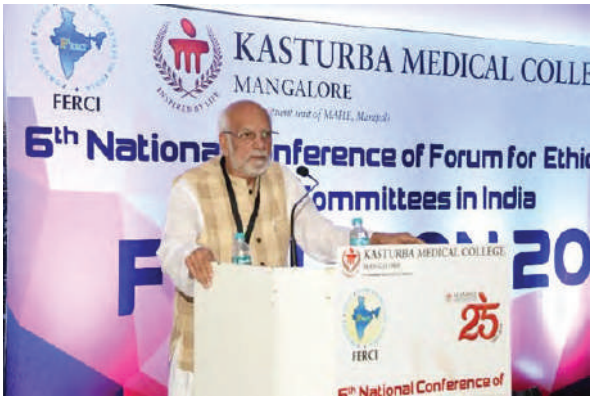
Eternal Values in Ayurveda for changing Modern Medical World



Dr. Jayachandran discussed the importance of the interrelation of Ayurveda and ethics. He mentioned that Ayurveda and ethics are not separate from each other. He reiterated that according to Ayurveda, doctor is the most important link.

Seventh Session (3:10-3:30PM)

Prof. LP Singh, Retired Professor of Philosophy, Magadha University, Bihar



Impact of biotechnology in Medical Ethics

Prof. Singh spoke about the importance of biotechnology in medical ethics and biotechnology in general. He mentioned that there are three types of Biotechnology i.e. Red Biotechnology, Green Biotechnology, and White Biotechnology. He also mentioned that medical ethics should be taken in a wider perspective that deals with scientific and technological advancement.

Valedictory Ceremony

The two-day conference concluded with the Valedictory ceremony that was presided by **Dr. B. Unnikrishnan, Dr. Rajiv Bhatt** and **Dr. Vasantha Muthuswamy.**

Dr. Vasantha Muthuswamy delivered her concluding remarks where she spoke about Ethics being a part of life and the importance of Philosophy in ethics. She mentioned that every year in a FERCI Conference new concepts come up. Therefore, attending conferences is necessary to keep on updating our knowledge. Dr. Muthuswamy also declared that the next year conference will be held in the month of November in Pune.

During the valedictory ceremony best student oral and poster presentations were awarded and encouraged.

At the end, Dr. Unnikrishnan B delivered the vote of thanks, where he thanked all the eminent speakers, delegates, sponsors and members of the organizing committee for their valuable contribution towards making the conference into a great success.

Abstracts

Retrospective analysis of protocol deviation and violation reports submitted to Institutional Ethics Committee of Cancer Research Centre in Navi Mumbai.

Parikh P*, Bandekar B, Awatagiri K, Kannan S, Murthy V, Mokal S, Sawant N
*Associate Professor, General Medicine, Tata Memorial Centre, ACTREC.

Background: Any accidental or unintentional changes to or noncompliance with the IRB approved protocol results into Protocol Deviation (PD) and Protocol Violation (PV) depending on its significant effect on subject's right, safety or welfare; and/or on the integrity of data. There is need of frequent training to PI on site specific SOPs for PD/PV and GCP to avoid occurrence of deviation/violation in the study. This study was undertaken to evaluate the rate of reporting PD/PV and the action taken by Institutional Ethics committee (IEC) on PD/PV reported by the Principal Investigators in the Cancer Research Centre in Navi Mumbai.

Methodology: This was a retrospective audit of 88 protocol deviation/violation reports (PD/PV) received between April 2013- March 2017 which were retrieved from the electronic database maintained by IEC. The CRF was designed to collect the information on each PD/PV reports submitted to IEC. This study was undertaken after seeking the approval from the IEC of Tata Memorial Centre ACTREC, Navi Mumbai. The PD/PV details and IEC responses were anonymized by coding and identification numbers.

Results: The majority of the **PD/PV** reports (75%) were noted by the IEC, followed by 17% of the **PD/PV reports** were noted by IEC and requested PI not to perform deviation/violation in future and IEC sent query for 8% of the reports. Out of total 88 PD/PV's reported the highest number of PD/PV were found in a Phase I Pharma sponsored study was 23 (26.1%) as compared to IIT and Thesis. The most common types of lapse were found in consenting in IIT study and laboratory assessment in Pharma Sponsored trial and enrolment and eligibility in thesis.

Conclusion: This study further emphasis the need for frequent GCP training of all study team members to strictly follow the protocol and avoid the occurrence of deviations in the future.

Keywords: Retrospective, Protocol deviation/violation, IEC

Integrated ethics: Incorporating ethics in to clinical research and innovation

Dr (Hon) P. Sundarraj*

*MSW., M.Phil., Head – R&D, Member, IEC – MMHRC: DSMC, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai – 625107.

Integrated ethics was developed by National Centre for Ethics in Health Care – USA, (Public sector innovation 2011), and receiving national and international attention.

The term ethics is vary depending upon its usage government side, education side legal side. Ethics in health care organizations presently facing issues like a) isolated service, b) lacking in clarity of defined purpose, c) lack in quality standards and accountability, d) outdated, technique to bridging the gap, integrated ethics model is addressing the issues implementing through ethics consultation, preventive ethics, and ethical leadership structure.

Establish and ICT ethics observatory, provide regulatory framework in order to support ethical impact assessment for ICTs, establish a forum for stakeholder involvement and incorporate

ethics in to ICT research and development framing integrated ethics councils are the some of the steps will addressing the innovative approaches in the ethical sectors.

The benefits expected while implementing integrated ethics as follows, improved shared decision making, ethical practices from beginning of life to end of life care, ensure patient privacy and confidentiality, professionalism in patient care, resource allocation, research, management, and everyday workplace.

The researcher wanted to present novel ethical model to health care industry that who practice clinical research, education and treatment on its own.

Keywords: Integrated Ethics, Ethic Model, ICT, Health Care, Service Innovation

Awareness and Uptake of Maternal and Child Health benefit schemes among the women attending a District Hospital in coastal South India.

Sequeira RM *, Rao K, Alfam K M, Kamath S, Unnikrishnan B, Rathi P.
*MBBS Student, Kasturba Medical College, MAHE, Mangalore.

Introduction: Maternal and Child Health (MCH) benefit schemes were introduced to increase institutional deliveries, to reduce out of pocket expenditure, to provide quality care and nutrition to mother and baby and thereby reduce Maternal Mortality Rate and Infant Mortality Rate.

Objective- To assess the awareness and estimate the uptake of benefits regarding various MCH benefit schemes among study participants.

Methodology-A cross sectional study was conducted at district hospital, Mangaluru, Karnataka, India, among 250 Antenatal women and Postnatal mothers. They were interviewed using a semi-structured validated questionnaire. Data was analysed using SPSS version 11.5.

Result-Awareness for scheme varied, ranging from 94% for ICDS and 0.8%for RBSK. Major source of information being ASHA (40.41%). Most of the study participants had a favourable opinion regarding the benefits of MCH schemes. Maximum uptake was seen for JSSK (100%) however, none of them availed Prasoothi Araike.

Conclusion-Our study showed that the awareness and uptake for different MCH related Schemes varied. Most of the study participants had a favourable opinion about the benefits of MCH Schemes. Since awareness for some schemes were low, efforts should be made to increase awareness regarding all schemes by displaying the information. Uptake can be increased by proper channelizing the resources.

Key words - JSY, JSSK, Madilu Kit, ICDS, Nagu Magu. Prasoothi Araike, Thai Card.

Introduction of online submission in Ethics Committee Functioning: Boon or Bane

Shetty YC*, Marathe PA, Lad M, Auti P, Katkar J.

*Associate Professor, Department of Pharmacology & Therapeutics, Seth GS Medical College & KEM Hospital, Mumbai

Background: Software technology has come into existence in every field of research including ethics functioning, but the stakeholder's perception is not known.

Objectives were to assess the perception of different stakeholders (investigators, IEC members, chairperson, Member secretary, Administrative staff) regarding the e- software usage in IEC submission, to find out the challenges faced by them while using it and to enquire for recommendations. Along with that to find out from other IECs who are using the same e-software regarding the administrative challenges faced by them.

Methodology: After Ethics committee permission, various questionnaire for each stakeholder were validated and used. The study was conducted in Ethics department and Department of Pharmacology of KEM Hospital, Mumbai. All the stakeholders (investigators – 40, IEC members -30, Chairperson-2, Member secretary- 2, Administrative staff- 3) of Seth GSMC &KEM Hospital of Mumbai were enrolled after consenting. The Administrative staff of all respective IECs from different parts of India (12) who are using this software were included. Strict confidentiality was maintained. The data was analysed using descriptive statistics.

Results: A total of 54 stakeholders were interviewed. Majority of the respondents were females (30/54). Twenty responded in a positive tone that they were happy with the e submission process which saved lot of their time, but they had problem with software malfunctioning, autosaving of documents. Investigators (25/54) commented on software training before implementation. Members (18/54) and member Secretary (4/54) commented that assessment form is a must in the software. The administrative staff all over India (5/54) had issues with software which were resolved timely.

Conclusion: e-technology has made life comfortable of all stakeholders with few modifications and should be made part of ethics committee functioning

Keywords: ethics, software technology, perception, stakeholder

Knowledge about eye donation among college students in Mangalore, Karnataka

Ushasti Sinha*, Dr. Rekha Thapar
*3rd MBBS student, Kasturba Medical College Mangalore

Background: Eye donation is a charitable act of donating one's eyes after death and is purely voluntary and for the benefit of the society. Of late, corneal diseases are one of the major contributing factors for visual impairment worldwide, especially among the developing countries like India.

Objective: To assess knowledge about eye donation among college students in Mangalore.

Materials and Methods: In this cross-sectional study, 862 college students in Mangalore were assessed about their knowledge regarding eye donation. The participants were briefed about the nature and purpose of the study and written informed consent was obtained from those willing to participate and the self-administered semi-structured questionnaire was distributed.

Institutional Ethics Committee approval was taken. Data was entered and analysis using Statistical Package for Social Sciences version 16.0.

Results: The mean age of the participants was 19.85 years. Of the total study participants 93.5% were aware about eye donation. Medical students are more aware (97.2%) than the non-medical students (89.7%) about eye donation.

Conclusions: Students of Mangalore were relatively aware of the concept of Eye donation. However, medical students were found to be more aware than the non-medical students. There were gaps in knowledge amongst both groups of students especially about legal aspects related to eye donation.

Key words: Eye donation, College student

Ethical dilemmas in Orthodontics

Dr. Supriya Nambiar*, Dr. Asavri Desai
*Associate Professor, Department of Orthodontics, MCODS, Mangalore.

Does our governing body Indian Orthodontics society have a "Principle of Ethics and Code of Professional Conduct "underlined in their constitution like the one of American Association of Orthodontists. The answer is a big "No" in matters related to patients. As per AAO's Principles of Ethics and Professional Code of Conduct, Section VI, it states, "Members may exercise discretion in selecting a patient into their practice, provided they shall not refuse to accept patients based on their race, gender, origin, medical status etc." Every individual should be provided with equality in treatment. Ethical problems are encountered by orthodontists during treatment procedures which may preclude to some important human values at stake like prevention of pain, rehabilitation and restoration of oral function and improving the patient's physical appearance. Another matter of concern is treatment for children, wherein important ethical issues may arise relating to the best interests of the child and decision making for minors. Ethical dilemmas usually arise due to the conscionable conflict between the orthodontist's line of duty to the child and the greater need to respect parental autonomy. This is not addressed to clearly in orthodontic speciality as most clinical setups do not have an Assent form in addition to a parental consent form and ethical problems usually occurs because of this moral uncertainty. Declaration of Helsinki is very much valid for orthodontics as with other specialities. Keeping the five basic ethical principles as laid down by the declaration, in mind, it is not enough that we just give simple moral justification to our duty, but also follow these ethical principles, to ensure that not only will it protect us legally as a professional but also will help us to provide overall health to our community in the best possible way.

Patient's Understanding and Perceptions Towards Legal Nature of Informed Consent

Abhishek Singh*, Rajesh DR, Venkteshan M.

*Department of Community Medicine, SHKM Govt. Medical College, Mewat, Haryana

Background- Autonomy of patients is an important issue in the health service area. It is a fact that patient's awareness of legal and ethical issues related to the consent process is often limited.

Objectives- To define patient's awareness of legal issues, attitude towards consent and to determine what patients want to know and to find out whether or not the patients actually understand what has been explained to them.

Methods- In this observational study a structured interview schedule was developed and handed out to 500 patients in the Surgery department of a tertiary care hospital who have just undergone surgery after pilot testing in 10 patients.

Results- Great deal of misconceptions regarding the legal status of consent were seen. 87.9% of participants believed that they had no right to change their mind after signing the consent. Regarding understanding of the legal standing of written consent, 41% did not mind what happened to them provided they were made better; 54% trusted their doctor to do the right thing and did not think detailed explanation was important; still most patients felt that consent forms were necessary. Level of understanding was satisfactory in 32% of patients.

Conclusions- The study concludes that there exists a vast discrepancy between the informed consent that perceived by patients. Current consent procedures seem inadequate as a means for the expression of autonomous choice and their ethical standing can be called into question.

An observational study to assess completion reports for compliance of research proposals to the institutional ethics committee approved protocol.

Shweta Surve*

*Executive Assistant, Institutional Ethics Committee, Seth G.S. Medical College and KEM Hospital, Mumbai, Maharashtra.

Background - The protocol is a document that describes the objective(s), design, methodology, statistical considerations, and aspects of conduct of study. The protocols are approved by the institutional ethics committee. The research team must follow the protocol thoroughly. However, compliance has been a delicate issue during the conduct of research projects. Poor compliance may lead to unreliable, misleading, conflicting and invalid results. In clinical trials, it may reduce the benefit to the research participants or increase the risk of treatment failure.

Thus, with this background the study is planned with the objective to assess the compliance of the research projects to the approved protocol/ amendment document submitted to institutional ethics committee.

Methods - The study is retrospective observational. All the projects submitted with study completion reports between the duration Jan 2017–Dec 2017 will be reviewed. The investigator will examine the completion reports and will compare with the approved protocol version submitted before the initiation of the study. To make the comparison we have designed a checklist. Checklist has been developed using the Standard operating procedure of Seth GSMC and KEM Hospital, Code of Federal regulations –Protection of human subjects, Declaration of Helsinki 2013 and ICMR guidelines 2017.The checklist is prevalidated and has 20 items. The responses include "Yes", "No", 'Insufficient information' or 'Not applicable'.

Results - There are total of 193 studies who have submitted study completion report in the year 2017.13(6.7%) modified selection criteria,6(3.1%) modified data collection tool and 13(6.7%) modified data analysis tool. A substantial 25% proposals have taken either less or more sample

size than was estimated for the study and 40% proposals did not complete the study in stipulated time.

Conclusion–The protocol was adhered for certain aspects. However, the adherence to protocol was poor for sample size and study duration.

Keywords-Protocol, completion report, noncompliance

Assessment of Knowledge, Attitude and Practices Regarding Blood Donation Among Students of Health Sciences in Mangaluru

Avinash Kumar[1], Akash Bhardwaj, Navjot Singh Dhillon, Rinu Peter, Nihad Navas
*Associate Professor, Department of Community Medicine, KMC Mangalore

Introduction Nearly 1% of the population is needed to meet the country's most basic requirements for blood, it is an irony that despite being a nation with a population of more than one billion and an annual requirement of 12 million units of blood, India is able to collect only 6.4 million units. The present study was conducted to assess the knowledge, attitude and practice regarding blood donation among undergraduate students of medical, dental and allied health science streams.

Materials and Methods: A Cross Sectional Study was conducted in Kasturba Medical College (KMC), Mangaluru and Manipal College of Dental Sciences (MCODS), Mangaluru among the 2nd year MBBS, BDS & AHS students of medical, dental and allied health Sciences College. The sample size calculated was 260. All consenting students were given a semi-structured questionnaire and the data was analysed using SPSS version 17.

Results The amount of blood to be drawn for each donation is 350 ml was answered by 69 MBBS students (46%), 33 BDS students (54%), AHS students (36.7%). The age group of the people who can donate blood is 18-60 years was answered by 64 MBBS students (42.7%), 29 BDS students (47.5%), 15 AHS students (30.6%). Allergies are not a condition which prevents a person from donating blood, 46 MBBS students (30.7%), 13 BDS students (21.3%), 15 AHS students (30.6%) knew the answer. Measles is a condition which is not screened before a donation, 38 MBBS students (25.3%), 15 BDS students (24.6%), 18 AHS students (36.7%) and a total of 71 students (27.3%) knew the answer.

Conclusion: Knowledge among the students about blood donation needs to be improved and updated.

Ethical Perspectives of Advertising among Dental Health Providers and Health Consumers

Dr. Priya Thomas*, Dr. R. Sujatha

*Reader, Department of Oral Pathology & Microbiology, Annoor Dental College & Hospital, Muvattupuzha, Kerala.

Background: Ban on advertisements by dental professionals in India can be traced back to the1950's with the implementation of the Dentist Act. As the practice of dentistry is mounting towards complexities, an ethical dilemma persists as to whether dentists should advertise their services. Most of the developed countries have partly relaxed their restrictions on advertising. Considering the fact that the health consumer has the right to know as a principle of autonomy and the right to access the latest technologies available, this study was set to evaluate the ethical perspectives of advertising by dental health care professionals and health consumers

Methodology: A questionnaire-based survey was conducted among the dental healthcare providers and health consumers with a sample size of 799, after obtaining ethical clearance. Data was collected by means of a validated closed ended questionnaire format. Two questionnaires were formatted in English and local language, for each study group evaluated by three subject experts. The questionnaire was distributed as a print form or through SurveyMonkey.com.

Results: 26.8% of the health providers considered advertising by dentists unethical, 52.4% disagreed on the fact that advertising can benefit their dental practice. 32.5% of the consumers disagreed to the fact that advertising can help them select the right dentist for their dental needs. Majority (43.3%) perceived that there is no requirement for the dentists to advertise their services.

Conclusion: Our survey indicated that healthcare providers still adhered to the code of ethics and worked towards the maintaining the integrity of the profession. This survey also projected that the consumers do not depend on the advertisements to select their dentists. A doctor patient relation is built on many other virtues of ethics like compassion, communication skills, trust etc. Unethical advertising is not cherished by the neither the public nor the providers.

Keywords: Advertising, Dental healthcare provider, health consumers

Study of ethical issues encountered by the researchers of a tertiary care hospital

Vimal.M*, Nishanthi. A, Amol. R. Dongre, Kavner. N

*Associate Professor of Pathology, Sri Manakula Vinayagar Medical College and Hospital, Puducherry.

Background: An effective and meaningful research should embrace the ethical principles. During the research process, researchers are often encountered with various ethical issues which should be properly addressed.

Objectives: To study the possible ethical issues and suggested solutions identified by the researchers in their research proposal documents submitted to the IEC of a tertiary care hospital.

Methods: A retrospective cross-sectional study where the possible ethical issues and plans to address them, as stated by the Principal investigators and suggestions proposed by the IEC in the research proposals submitted to IEC from July 2016 to December 2017 was reviewed.

Results: Out of 161 proposals, 134 (83.2%) mentioned about autonomy, 102 (63.4%) about beneficence and non-maleficence, 52 (32.3%) about justice and equality, 110 (68.3%) about privacy, 112 (69.6%) about confidentiality and 104 (84.55 %) proposals about therapeutic

misconception as possible ethical issues in their proposals. 36(22.4%) proposals involved research on vulnerable population, 30 (18.63%) proposals required mandatory CTRI registration**,** 145 (90.06%) proposals required consent forms, 18 (11.18%) proposals required the inclusion of assent forms, 16 (9.94%) proposals required consent waiver, 5 (3.11%) proposals required consent from LAR and 10 (6.21%) proposals posed the risk of diminished autonomy for its research participants. Some solutions to the possible ethical issues were identified by the researchers which were complemented by the IEC members during the review meetings.

Conclusion: Through this study, common circumstances where the researchers face challenges of ethical issues were identified. The researchers can be sensitized about ethical challenges and their solutions in the research by conducting Mock sessions, Hands on training and Case scenario-based training. Effective capacity building exercises for IEC members, researchers and policy makers will ensure the protection and wellbeing of the research participants who play the key role in any biomedical research.

Keywords: Autonomy, Beneficence and non-maleficence, Justice and equality, Privacy and confidentiality, Therapeutic misconception

A study to assess the completeness of Informed Consent Documents for Biomedical research on human participants submitted to the Institutional Ethics Committee (IEC) of a tertiary care hospital

Nishanthi. A*, Vimal.M, Amol. R. Dongre, Kavner. N

*Assistant Professor of Pharmacology, Sri Manakula Vinayagar Medical College and Hospital, Puducherry.

Background: Informed consent is an essential pre-requisite for research on human participants. However, many studies have shown that informed consent forms are incomplete and lack many of the essential elements.

Aim: To assess the completeness of informed consent documents submitted to Institutional Ethics Committee in compliance with the standard guidelines like ICMR ethical guidelines, and Drugs and Cosmetics Rules, 1945 Schedule Y.

Methods: This is a retrospective cross-sectional study. The informed consent documents submitted to the Institutional Human Ethics committee during the period from January 2015 to December 2017 were reviewed. The completeness of these informed consent documents was assessed with the help of a checklist based on the standard guidelines for informed consent document preparation in accordance with ICMR ethical guidelines for biomedical research on human participants 2006, and Drugs and Cosmetics Rules, 1945 Schedule Y.

Results: The total number of proposals submitted were 247, out of which consent waiver was granted for 26 proposals and informed consent document was missing in 9 proposals. Thus, a total of 212 informed consent documents were reviewed. More than 50% of the informed consent documents have explained many of the essential elements of an informed consent document like nature and purpose of the study, voluntary participation, procedures, investigations, risks and benefits, alternative treatments, maintaining confidentiality, no loss of benefits on withdrawal from the study, contact details of PI and participant's responsibilities.

However, some consent forms do lack certain essential elements like statement that it is research, duration of participation, number of participants, probability of random assignment, treatment of study related injury and storage period of biological samples.

Conclusion: This study has shown that although majority of the informed consent documents submitted for review by the Institutional Ethics Committee have mentioned many of the essential elements, some of them do lack certain elements.

Keywords: Informed consent, ICMR ethical guidelines, Drugs and Cosmetics Rules, 1945 Schedule Y, Institutional Ethics Committee

Assessment of Knowledge of the Revised Ethical Guidelines put forward by Indian Council of Medical Research among health care professionals in a medical college, Mangalore

Gupta R*, Rathi P.

*2nd year MBBS Student, Kasturba Medical College, Mangalore

Background: Research is an invaluable and integral part of the medical profession. Without it, new discoveries for treatment of diseases previously thought incurable would never have been found. It is important to put the needs and health of the participant above all and to see that no malpractice is being done in such setting. The self-administered questionnaire serves the purpose to assess the knowledge of health care professionals regarding the same.

Methodology: The cross-sectional study was done at hospitals affiliated with Kasturba Medical College, Mangalore. A self-administered questionnaire was given to a total of 80 clinical, pre-clinical and para-clinical departments after taking informed consent from them.

Result: The response rate was 87.5% with 28.4% from clinical, 45.9% from para-clinical and 25.7% from pre-clinical departments. The median age of the responders was 37 years with 56.8% being females. Highest qualification of 68.9% was MD. 94.6% of the responders had conducted research and 77.1% had experience in research of more than 5 years. 62.96% of the responders were aware of the general ethical guideline, 52.72% were aware of the responsible conduct of research. 94.32% responders were aware about the Informed Consent taking process. Only 39.2% of the responders were aware about the vulnerable groups. Responders aware of the guidelines to be followed during clinical trial of drugs and other interventions are 47.3%. 42.94% responders were aware of research guidelines to be followed during humanitarian emergencies and disasters.

Conclusion: In conclusions, more than 50% of the clinicians, pre-clinicians and para-clinicians of Kasturba Medical College, Mangalore are aware about the Ethical Guidelines put forward by the Indian Council of Medical Research.

Keywords: Ethics, Research, ICMR Guidelines, Awareness

Factors influencing the number and type of deviations in clinical trials; Audit from a tertiary care cancer centre

Uthara H Iyer, * Dr. Girish Chinnaswamy

*IRB Administrator, Tata Memorial Hospital, Mumbai

Background: The IEC plays a major role in regulating the conduct of clinical studies. The IEC has the responsibility to closely monitor studies to ensure ethical and scientific conduct of studies and pin-point key areas that need improvement. Review of deviations reported can throw light on key areas of trial management that need better understanding.

Aim: To analyse the nature of deviations reported to IEC and correlate with various factors related to investigator, study team and nature of the clinical trial.

Methodology: This audit was carried out after obtaining review exemption approval from the IEC. Data between 2007 and 2015 was analysed. All deviations were analysed to see the nature of deviation. Correlation was also done with various factors such as number of studies handled by investigators, the sample size of the studies and status of the study at the time of reporting the deviations. Based on the impact of the deviations on patient safety and quality of data, the deviations were classified as major and minor. A panel of IEC members with varying expertise reviewed the deviations to identify if the deviations were avoidable or unavoidable. The deviations were also classified into two- deviations to the protocol that occurred due to study management issues and deviations that occurred due to patient non-compliance issues. Correlation and regression analysis each were done to understand if there was a relation between the number of participants enrolled in the study and the number of deviations reported per study.

Resource: Hard copy and soft copies of IEC records were reviewed and relevant data was captured on excel.

Results:

A total of 2231 deviations filed with the IEC from 2007-2015 from 128 studies were analysed.

Major Deviations	556 (24%)
Minor Deviations	1675 (75%)

Avoidable	1659 (74%)
Unavoidable	572 (26%)

Study Team Errors	1621 (73%)
Patient Non-Compliance	610 (27%)

The analysis also showed that there is a weak association (r= - 0.0091) between the number of participants enrolled/ study and deviations reported per study. Regression analysis yielded a p value of 0.91 indicating that the data is not statistically significant.

Conclusion: These results indicate that the key to significantly lower deviations, thus ensuring fool proof conduct of the study is a well informed and coordinated study team and rigorous patient as well as relative counselling on the importance of protocol adherence.

Attitude of researchers towards Ethics Committee at a Medical Research Institute in Coimbatore

Dr. Subhashini Ganesan*, Dr. Sujatha R, Dr. Kavitha S, Ms. Jayagowri K

*Assistant Professor, Department of Community Medicine, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu.

Background: The roles and responsibilities of Ethics Committees have been well defined in International guidelines such as the Declaration of Helsinki and National Ethical guidelines on Biomedical and Health Research on Human participants 2017 by ICMR. Though we have guidelines, many researchers regard ethical review as a road block and slowing the progress of science. Studies have also shown that researchers lack understanding about the process and functioning of institutional review committees and some papers also argue about the paternalistic attitude of the ethics committees. Therefore, understanding researchers' attitude becomes imperative and it would also help in organizing workshops and sessions clarifying the role of the committee and for improvisation of the work done by the committee. Hence this study aims at assessing the attitude of the researchers towards the ethics committee.

Methodology: A cross sectional study was conducted among researchers which includes both faculty and undergraduate students at a Medical Research Institute. Ethics committee approval was obtained. The study was done among 100 participants chosen by convenience sampling. Informed consent was obtained. Questionnaire assessing attitude of the researchers were used to collect data and anonymity was maintained. Demographical variables were also collected.

Results: Research is in progress. After completion of data collection, the results will be described in percentage of researchers who thought (i) ethics committee should review only ethical issues (ii) ethics committee role is purely advisory (iii) only accomplished researchers should be in the committee (iv) non-medical members have a significant role in a committee (v) review as a hindrance to research projects (vi) time consuming (vii) delays research projects (viii) additional burden for minimal risk projects (ix) documentation is extensive (xii) annoyed by committees' queries and closure reports. These findings would be associated with gender, years of experience in research, number of publications, designation and prior ethics training.

Keywords: Ethics committee, attitude, research personnel, academics and institutes.

Challenges faced by researchers conducting clinical trials at a tertiary cancer centre

Desai V A*, Raganathan P, Manhantshetty U, Patil P, Hawaldar R

*Administrator, Institutional Review Board, Tata Memorial Hospital, Parel, Mumbai. Contact number- 09833348059, e-mail- avdesai06@gmail.com.

Background: Tata Memorial Centre is a tertiary centre for the prevention, diagnosis, treatment, education and research in cancer. The researchers are involved in investigator-initiated institutional/collaborative as well as pharmaceutical industry sponsored clinical trials/studies related to oncology. Researchers are likely to encounter with various challenges related to study designing, approval, conduct and reporting during the conduct of these trials/studies. Our survey aims to identify these various challenges faced by the researchers.

Methodology: A questionnaire was developed and validated by Delphi method. After obtaining written informed consent, the questionnaire was then served to the investigators maintaining strict anonymity of the respondents. The responses were analysed using descriptive statistics.

Results: Twenty-five investigators responded to the survey. 80% investigators expressed challenges and more so in investigator-initiated studies. 79% reported having difficulty in protocol writing. 83% found writing informed consent forms or getting translations in lay language to be challenging. 79% found IRB review process cumbersome and time consuming.

While 58% thought that preparing clinical trial, agreement was complicated. Inadequate infrastructure, manpower (95%) and time (96%) were the big constraints for conducting research. 75% expressed the opinion that recruitment in clinical trials was laborious. Common problems faced were with consenting (75%), IP management (20%), source data documentation (71%) and serious adverse event reporting (54%). Archival and disposal was a major burden according to 71% of respondents. 88% investigators had problems in getting the data analysed. 79% reported difficulty in publishing the research.

Conclusion: Our survey reports that majority of researchers encounter major challenges in research. The survey identifies and classifies the challenges and is in process of coming with working solutions in consultation with the Tata Memorial Centre Research Administrative Council. Our survey emphasizes the need to bridge the gaps towards a better, effective and meaningful research.

Keywords: challenges, researchers

Attitude towards research among undergraduate medical students

Dr Kavitha S*, Ms. Sudharshini S, Dr. Sujatha R.

*Associate Professor, PSG Institute of Medical Sciences and Research, Melamed, Coimbatore, Tamil Nadu, India Affiliated to The Tamil Nadu Dr MGR Medical University

Background: Research is a part of any doctor's career. Internal motivation is necessary for being a good researcher. Lack of internal motivation may be due to attitudinal issues or lack of knowledge. Knowledge improvement about research during under graduation plays a major role in improving research skills as well as attitude later during their practice. Recently there is increase in awareness about research and its advantages among students and the need for the same among faculty. This can be indicated by an increase in number of conferences, workshops for students, etc. Hence this study is designed to analyse attitude among undergraduate medical students towards research.

Methodology: This is a cross sectional questionnaire-based study. After obtaining institutional ethics committee approval, informed written consent was obtained from all the willing participants. Pre-validated Attitude Towards Research Questionnaire developed by Papanastasiou was given to the participants. It consists of 32 items on research usefulness, research anxiety, positive attitudes, relevance to life and difficulty of research. Other additional demographic details including age, gender, year of study, involvement in research and publications were also collected from the participants.

Results: Out of 112 participants, 59% were females and 41% males with average age of 19 ± 0.7 years. 14 participants are already involved in research with two in more than one. Mean score of attitudes was 147 [max 214]. Factor analysis showed mean score of 45 [max 63] for research usefulness, 27 [max 49] for research anxiety, 44 [max 63] for positive attitudes on research, 18 [max 28] for relevance to life and 12 [max 21] for difficulty of research. Considering 160 as cut-off [75% of max score], 36 participants had good attitude towards research.

Conclusions: We conclude that attitude towards research among undergraduates is generally low and requires necessary actions to improve their attitude.

Keywords: Attitude, research, medical students, undergraduate

Ayurveda trials: Is *apathaya ethical* in dermatology patients?

Sruthi Mol.V*

*Dietitian (Institute of Applied Dermatology), Joint secretary IEC, IAD

Introduction: Clinicians are increasingly challenged by their patients, to recommend diet which will complement their medical therapy and improve their disease. Ayurveda doctors routinely assess such parameters as patients' appetite, bowel habits, and constitutions. This paper looks at ethical issues of diet recommendations (pathya and apathya) given by Ayurveda in dermatology patients.

Methods: The group studied 50 dermatology patients who attended the Institute of Applied Dermatology (IAD), South India. Each patient was assessed by an expert from allopathy and Ayurveda, dietitian assessed patient's nutritional status based on the 24 hrs diet recall. Pathya and apathya suggested by Ayurveda doctor s was incorporated into the treatment regimen.

Repeated 24 hrs diet recall and nutrient calculation was done by dietitian during follow up. Nutrition intake was compared for baseline and follow up

Results: After the *Pathya & apathya* was followed during the treatment recommended by Ayurveda doctor, it was noted that intake is less than baseline & RDA (Recommended Dietary Allowance). *(Changing the staple food & stress of shifting from favourite diet)*, it showed evidence of nutritional deficiency.

Recommendation: When diet recommendations are essential for ayurvedic point view and if empowered patients adhere to recommendations complete diet evaluation are mandatory. When necessary food substitution to the patients should be recommended to maintain the nutrition level.

Key words: Pathya, Apathya, Dermatology

Ethical issues related to Cancer Registries

Dr Rajib Kishore Hazam*, Mr. Stephen S.

*Research Associate, National Centre for Disease Informatics and Research (Indian Council of Medical Research), Bangalore.

Background: Cancer registries play a vital role in surveillance and serve as a foundation for cancer research and are used for planning, designing, monitoring and evaluation of cancer control activities. Cancer registries involve collection of data; storage and management of data; retrieval and disbursement to researchers.

Ethical Issues: - Informed consent for caner registries poses specific ethical issues as the aims of study are not defined clearly at the time of collection and there is a time lag between collection of data and its use in research. The issues involve multiple stages at which consent needs to be administered – storage, use of data, incidental findings, return of results to the participant, sharing of the data with researchers/national or international institutions and potential commercialization. These raise issues of access and benefit sharing. Data privacy, data accuracy, data security and possibility of legal liability should be ensured when the data is outsourced or sold. No identifying or sensitive data related to patients should be shared with third party. Data related to dead persons should be protected as data on living persons. Databases of cancer registries maintained in electronic/digital formats, linked by internet, using cloud computing technologies and associated with big data initiatives, may pose additional risks to privacy and confidentiality. It is very important to ensure physical safety and security of the involved devices and servers. Security measures such as password protection, controlled access to data elements, data encryption etc should be taken.

Implications: Research proposals, which require cancer registry services and available data sets should be reviewed by the EC, either an institutional or that of the registry. Registries must have an established governance structure and should have its own technical authorization committee which should function in tandem with the EC.

Keywords: - Cancer Registries, Registries, ethical issues, data sharing

A cross sectional study to assess the awareness of good clinical practice among health care providers: Does this enough for initiate clinical Research?

Maya Padmanabhan*, Dr. B Satheesan

*Lecturer in Biostatistics,Clinical Research & Biostatistics Division, Malabar Cancer Centre, Thalassery

Background & Objective: Good clinical practice (GCP) guidelines are used for designing, conducting, recording, and reporting clinical trials that involve participations of human beings. To improve the credibility of data and to ensure the safety and well-being of the patients GCP guidelines play an important role. In India, these guidelines have evolved with consideration of the WHO, USFDA, and European GCP guidelines as well as the ethical guidelines for biomedical research on human subjects issued by the ICMR. The aim behind this cross-sectional study was to explore the awareness of Indian GCP among the health care providers in a tertiary hospital setup.

Methods: A cross sectional study was conducted at Malabar Cancer Centre, Kerala among health care providers by using the questionnaire method before and after the GCP training. The questionnaire was contained 15 questions and each carried one marks. Total 58 (medical and non-medical) participants attend the training.

Result: Out of 58 participants, 34(58.6%) were Oncologist and 24 (41.4%) were non-medicals. Out of which 32 Oncologist returned their feedback form and from the non-medical received it back of 22. The pre- post analysis showed that there is a statistical significance difference in the GCP training (Mean difference 2.5$\pm$2.0, 95 % CI: 1.9 to 3.0, P=0.001). By comparing the medical versus to non-medical the same difference was noted, p=0.021. In the medical professional the score was changed from 10.0$\pm$2.6 to 11.9$\pm$1.7. The non-medical category the score increased from 8.5$\pm$1.9 to 11.7$\pm$1.5. The impact of the GCP training was uniformly distributed in medical and non-medical category.

Conclusion: The study provides the positive impact of GCP training among health care providers. The pre-post evaluation showed that they had adequate knowledge about the GCP and this knowledge would help them remove misconceptions and motivate them to undertake clinical research.

Evaluation of recruitment and retention of participants in clinical studies at a tertiary referral centre

Bose D*, K Harshad, S Shruti, Saxena U. Thatte UM, Gogtay NJ

*2nd year DM Resident, Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai

Background: Screen failure and dropouts impacts both the scientific validity and financial viability of any study. Hence, recruitment and retention of participants are considered as one of the critical steps for any study. The present study was planned to audit the recruitment and retention of participants in clinical studies conducted over the last five years at our centre.

Methodology: Studies completed between 2013 and 2017 in our department were included in the audit. Screening ledgers and study trackers were hand searched. The studies were then stratified as per risk classification of ICMR 2017 guideline. The Studies were analysed for their a) Nature b) Design c) Laboratory testing at screening d) Nature of participants. The screen failure and dropout rates were further assessed. Descriptive statistics and inferential statistics with crude odds ratio [cOR] were used at 5% significance level using STATA version 14.2.

Results: A total of n=19 completed studies were audited. Among these, 09 [47%] were pharmaceutical industry funded and 10 [53%] were investigator initiated. A total of 14 [74%] studies were interventional and 05 [26%] were observational. Among these, 07 [37%] had laboratory testing at screening. As per risk stratification, 11 [68%] had more than minimal risk, 05 [26%] had low risk and 03 [06%] had minimal risk. A total of 07 [37%] studies recruited healthy participants, whereas 12 [63%] studies recruited patients. A total of 07 [37%] studies had screen failure with median screen failure rate of 26% [0-65%] A total of 09 [47%] studies had dropouts with median dropout rate of 13% [0-24%]. The odds of screen failure were 11 times higher with the studies that included laboratory testing at screening [cOR 11, 95% CI - 1.13,106.4].

Conclusion: Studies with laboratory testing at screening had significantly higher screen failure rate. Since reference interval used in these tests, are usually of central labs, this may contribute to screen failure, if the population is different.

Key words: Screen failure, Dropout, Investigator initiated studies

Challenges leading to delay in approval of Academic Research proposals: An Institutional experience

Vinita Agrawal*, Omkar Prasad Asthana

*Chairman, Institutional Ethics Committee, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareilly Road, Lucknow (U.P), India—226014.

Background: The Institute Review boards (IRB)/ Institutional Ethics Committees (IECs) are required to provide timely approvals of research projects submitted for ethical clearance. However, this is often a challenge primarily related to the issues in the submitted protocol. This pilot study evaluated the issues during primary review related to the delay in approval of academic research proposals (academic non-intervention studies and investigator-initiated non-regulatory clinical trials) with an aim to identify avoidable concerns.

Methodology: Categorization of issues related to academic studies and investigator-initiated non-regulatory clinical trials was done for studies reviewed in the full board IEC meetings over a period of one year. The issues were categorized as scientific, ethical, legal, informed consent documents and others including administrative issues.

Results: Over a period of one year, eight full board IEC meetings were held including six scheduled and two unscheduled due to high number of submissions. 183 new projects were reviewed in these meetings including 167 academic studies and non-regulatory clinical trials. 12% (20/167) were approved in the first primary review while 1.8% were rejected. Minor modification (140/167; 84%) formed the predominant decision leading to delay in approval

followed by major modifications (2.4%). The reasons for minor modification were primarily related to issues in participant information documents (PIDs) which constituted 96% (135/140) followed by scientific (69%), ethical (20.7%) and legal (7.8%) issues. Other reasons for delay included non-submission of clearance from other EC of collaborating centres, clearance of other committees like animal, stem cell research, HMSC, material transfer agreement, etc.

Conclusion: The study shows that most of the delays in academic studies and non-regulatory clinical trials are avoidable. If the project submission forms are filled meticulously, most of the delay can be avoided. The measures our IEC has taken to avoid these delays include training session on framing of PID, specimen copies of PIDs made available to researchers, interaction with researchers at the time of project receipt and development of a software for project submissions.

Key words: Institute Ethics Committees (IEC); academic research; non-regulatory clinical trials; scientific issues; ethical issues; participant information document.

Health Literacy among adolescents in Mangaluru: A school based cross-sectional study.

Disha Kalra*, Dr. Nithin Kumar

*Final MBBS Student, Kasturba Medical College, Mangalore

Background: Health Literacy among adolescents is important in any society as it is a crucial determinant of health and of quality of life in future and is also necessary for a country's economy and development.

Objective: The study aims to assess the level of literacy regarding health amongst adolescents in Mangaluru.

Methodology: It's a school based cross sectional analytical study with the sample size of 610 adolescents studying in 9^{th} and 10^{th} standard in various schools in the city who were assessed using a Pre-tested semi-structured questionnaire. Data were computed using SPSS (version17). Descriptive statistics like mean (SD), median (IQR), and proportions were used for expressing the results.

Results: Of the 610 participants assessed, 71.6% were less than 15 years old and 67.7% were boys. It was found that majority obtained information regarding health from doctors followed by internet (55.9%) and cell phones rating doctors as the most reliable source. 33.4% participants looked up for health information every few months and majority of them did so on experiencing new symptoms. Using HELMA, health literacy was found to be inadequate in the domains of reading, appraisal, use and numeracy; problematic in the domain of access and sufficient in the domains of self-efficacy, understanding and communication.

Conclusion: After conducting the study it was found that adolescents have sufficient personal judgement of how well they can execute a task to deal with a situation, comprehend given information and exchange the same information with others but face problems in accessing or obtaining information regarding health which can be because of inadequate availability of resources, limited access to them or inequitable distribution. They have insufficient skills when it comes to reading, assessment and use of the given information.

Keywords: Health literacy, adolescents

Common forms for Ethics Committee review

Dr.B.S. Manoranjitha*, Dr. Rajib Kishore Hazam

*Program Officer, National Centre for Disease Informatics and Research (Indian Council of Medical Research), II Floor of Nirmal Bhawan, ICMR Complex.

Background: Currently, in India different formats are being followed by various Ethics Committees (EC) for the review of proposals submitted. This is causing difficulties when research studies are to be conducted using common protocols. To address the felt need, an initiative was taken to harmonize various formats being used in the country and prepare common forms for use by EC and researchers.

Methodology: Draft forms were prepared through a consultative process and piloted to evaluate the structural and functional ease in translating a research protocol into EC review format. The responses were recorded and structural modifications such as removing information submitted in the protocol to reduce the length of the form, increasing space to answer, colour coding various sections and annexures, identification of skip questions and uniformly placing check boxes were done. Functional modifications such as providing instructions and abbreviation as footnotes, removing repetitions, separating sections relevant to clinical trials, genetics and socio-behavioural research as annexures, were done. The revised forms were reviewed by experts and it was suggested to focus more on biomedical research, logically group the questions, add additional options and definitions wherever required and make the form comprehensive.

Results: The draft forms were revised and the finalised forms included a main initial review form consisting of five sections; basic information, research related, participant related information, other issues, declarations and checklists. 12 annexures for other types of reviews and formats were also included.

Conclusion: The finalised forms would be useful for the ethics committees and researchers across India as they facilitate and improve ethics committees functioning in an efficient and uniform manner.

Keywords: EC review formats, common forms, harmonized forms

Ethical aspects of blood transfusion: Where do we stand?

Dhivya Kandasamy*, Shamee Shastry, Prethika

*Department of Immunohematology & Blood Transfusion, Kasturba Medical College, Manipal Academy of Higher Education, Manipal.

Background: Ethics in blood transfusion is considered as a key element in blood safety where both the blood donors and recipient are given equal importance. In 1980, International society of blood transfusion endorsed first code about the ethics of blood transfusion. This code was adopted by WHO which was later modified in 2000.This study was carried out to observe the

ethical issues related to patient in blood transfusion service and identify the gaps if present to improve the quality of blood transfusion service at our centre.

Methods: It was a retrospective study carried out to observe the ethical aspects of blood transfusions in multiply transfused and critically ill patients at our centre from January 2018 to September 2018. The data required for the study are taken from the hospital records. The following details like total number of patients, age, gender, diagnosis, mental health status, ability to give consent were noted. Also, we observed whether ethical principles (autonomy, non-maleficence, beneficence and justice) pertaining to patient care were in compliance with ISBT (International Society of Blood Transfusion) ethics code standard.

Results: A total of 63 multiply transfused patients and 75 critically ill patients were studied of which 87.4% were males and 12.6% were females. The age group ranged from 6 to 69 yrs. Out of 89 patients, 38% were able to give consent and 42% patients, guardian has given the consent. The remaining 20 % of patients received blood transfusion without consent on emergency basis weighing the benefit Vs risk to the patient. The ethical aspects pertaining to blood transfusion in patient care were observed to be 100% compliance with international standard.

Conclusion: This study facilitates us to further improve the transfusion ethics and quality of patient care in our centre.

Keywords: Transfusion Ethics, Emergency, informed consent

Ethical Issues In Investigator Initiated Physiotherapy Trials

Safa*, Dr. Abraham M Joshua, Gargi Kundaliya.

*2nd year Postgraduate student, Department of Physiotherapy, KMC Mangalore

Ambiguity and lack of clarity regarding clinical trials in the field of physiotherapy. Though ICMR guidelines are available specifically for clinical drug trial, the guidelines/ instructions regarding exercise trial are not available.Exercises are a non-invasive and inoxious form of therapeutic approach. Are exercises potential threat to the population? Standardised therapeutic techniques in physiotherapy have proven to be beneficial and safe.For such standardized approach why insurance coverage is required? If compulsory, who will bear the coverage-

- Student?
- Supervising staff?
- Institution?

In many research studies (e.g.: SCOPUS, PubMed etc.), the details of the authors if inspected reveals that fair number of investigators are postgraduate students/ residents.

Why RCT cannot be carried out by postgraduate students that too for safe, beneficial, and non-invasive therapeutic exercises. Many therapeutic interventions do not require added expenditure as they are regular over ground exercises (use of plinth, weight cuff, chair, TheraBand).

Why such studies require funding when not needed?

Drugs vs exercises clinical trials

DRUG TRIALS

- Has side effects
- Approval for clinical trial not required
- It requires animal trials and clinical trials prior to general population administration for usage.

EXERCISES CLINICAL TRIALS

- No side effects
- Approval for clinical trial required

Why disparity in regulatory approval?

As per ICMR guidelines**,** “registration of research in CTRI ensures that more complete, authenticated, readily available data in research is available publically. This improves transparency, accountability & accessibility.”

If therapeutic exercise clinical trials are not been given permission to be registered, then publishing such interventions in leading journals will be curtailed and will affect the level of evidence.

A Study on Judicial Ethics Towards the Medical Experts

Mr. Koushik*, Mrs Deepa Salian

Medical profession is one of the oldest professions of the world and is the most humanitarian one. There is no better service than to serve the suffering, wounded and the sick. Vedas embodied the rule that, Vidyonarayanoharihi (which means doctors are equivalent to Lord Vishnu). Since long the medical profession is highly respected, but today a decline in the standard of the medical profession can be attributed to increasing number of litigations-against doctors for being negligent narrowing down to "medical negligence”.

The Hon'ble Supreme Court in the case of Dr. Laxman Balakrishna v. Dr. Triambak, has held that" all medical negligence cases are scrutinized on various questions of fact involved, when we say burden of proving negligence lies on the Complainant, it means he has the task of convincing the court that his version of the facts is the correct one". In the case of Indian Medical Association v. Santha, the Apex Court has decided that the skill of a medical practitioner differs from doctor to doctor and it is incumbent upon the complainant to prove that a doctor was negligent in the line of treatment that resulted in the loss of life of the patient. Therefore, a judge can find a doctor guilty only when it is proven that he has fallen short of the standard of reasonable medical care.

The burden of proof is correspondingly greater on the person who alleges negligence against a doctor. It is a known fact that even when a doctor with the best skills is involved, things sometimes go wrong during medical treatment or in a surgery. A doctor is not to be held negligent simply because something went wrong. Simply because the patient's eyesight was not restored satisfactorily, this alone cannot be grounds for holding the doctors guilty of negligence and deficient in his duty. When incidents like this occurs, judiciary play vital role in protecting the interest of the medical experts – this Article broadly speaks how a judiciary follows ethics to uphold the honor and dignity of Medical experts.

Law will not make a community virtuous nor will cannons of professional ethics make dishonourable men honourable. Nevertheless, in a democratic country good laws help to raise and strengthen the standard of social virtue, and cannons of professional ethics similarly tend to raise and strengthen the standard of professional honour.

Key Words: Litigation, Medical Negligence, Profession, Reasonable Care

Awareness of Profession Ethics Among the Mortuary Professionals

Dr. B Suresh Kumar Shetty*

*Professor and Head, Department of Forensic Medicine, KMC, Mangalore, MAHE, Manipal.

Autopsies are an integral part of the of the health and justice systems that has been less understood by the medical professionals other than forensics and society in general. Hence the ethical aspects towards the workers (autopsy surgeons and mortuary technical staffs) are less understood by everyone in general. This is unfortunately a gloomy state of affairs in a developing country. In developed countries across the world, there seems to be a set guideline regarding the facilities and operation of hospital and forensic mortuaries and they address the ethical issues faced by the mortuary workers. This includes Professional and ethical conduct and response of the bereaved relatives. Mortuary workers face various perils in the course of carrying out their responsibilities. Unfortunately, these ethics issues are the least addressed by the firms and the personnel in their professional areas. Hence it is imperative to introspect and put efforts to identify and address these issues in order to make a conducive atmosphere at the work place. This would further help to overcome the stressful situations and in turn avoid the risks leading to accidents and even death at the work place. There is a requirement to increase the awareness and attitude among the general public and medical professionals towards dilemmas faced by the mortuary staff on daily basis.

Key words: Ethics, Mortuary workers, Guidelines.

Ethical Issues in Physiotherapy in Private Practice Settings

Dipika Yadav*, Shweta Mistry, Tanvi Shah

*Intern, Department of Physiotherapy, KMC, Mangalore.

Background: The for-profit nature of private physiotherapy makes physiotherapy in private setting different from that in a public setting. This itself brings with it a bunch of ethical issues. Both, private and public setting practices have common ethical issues but some issues are more specifically pertaining to private practices. (e.g., self-referral, product sale) and that could go against the interests of the patient losing the parternalism.

Purpose: The aims of this study are:

1. Acknowledge the ethical issues confronted by physiotherapist in private practice settings and
2. Acknowledge potential answers and endorsement to address these ethical issues.

Discussion: Private practice, as a whole, has a lot of impact on the ethics and that these impacts are primarily based on an individual's understanding or on deontological

understanding. The ethical issues that physiotherapists face is based on a simple perception of situation or facts. Issues arise when physiotherapists strive to act in the best interest of the patient but are hesitant above how to without harming, offending, or violating the rights of the patients.

Keywords: Ethical issues, private practice, physiotherapy

Law V/S Ethics

Suma Suresh Kogilgeri

Assistant Professor, S D M Law College.

Every person has to follow certain standard in his professional work. Code of ethics vary by profession and discipline. Medical profession is not an exception to this. Medical profession has set of rules to be followed in practising their profession. But today one of the controversial subjects is the relationship between Law and Ethics. As far as these two disciplines i.e. law and ethics go hand in hand there is no issues. However, the real controversy arises when there is a conflict between the two. Hence the object of this paper is to analyse the relationship between Law and Ethics with regard to section to Section 53 of Criminal Procedure Code and Medical Ethics.

Key Words: Ethics, Medical profession, Law, Criminal Procedure Code.

Common Ethics Review of Multicentre Research

Dr Rajib Kishore Hazam*, Dr. Kalyani Thakur, Dr. Manoranjitha B S**.**

***Research Associate, National Centre for Disease Informatics and Research (Indian Council of Medical Research), II Floor of Nirmal Bhawan, ICMR Complex.

Background: In India a large number of multicentre research studies are carried out and as per procedures followed currently, each site is responsible for ethical review. Since, common ethical review is not done, there is a lack of coordination between centres, duplication of efforts, loss of time and delays in ethical review processes which affect timely completion of research.

Aims and Objective: The ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 have created the provision for common review of multicentre research and efforts are being made to develop a new detailed national guidance to address the issues related to common ethics review.

Methodology: The requirements for common review are being worked out, such as, identification of common designated ethics committee (EC), role of coordinating sites and local site EC's, common proforma for multicentre research, SOP's for common review etc. In addition, requirement for monitoring and oversight committee, reportable events, issues related to conflict of interest (COI), payment of compensation, benefit sharing, publication, etc.

A new guidance is being developed in this regard by ICMR which is the apex body for biomedical and health research in India.

Implications: Guidance on common review of multicentre research will improve the conduct of research by saving time, preventing duplication, streamlining and improving the ethics review process. It will also improve communication and networking between the EC's.

Qualitative analysis of ethical decision making in clinical care among final year medical students

Shweta Samantha*, Sahana D Acharya, Sheetal Ullal, B Unnikrishnan

*Final year MBBS Student, Kasturba Medical College, Mangalore, MAHE

Background: The field of global health is rapidly expanding in many medical centres. As a result, medical students have increasing opportunities to incorporate global health experiences (GHEs) into their medical education. Ethics is a critical component of global health curricula. Ethics has become a common topic of discussion within the medical community. Ethical sensitivity enables the professionals to respond morally to the suffering and vulnerable individuals in need of professional care and services. As per the literature the four theories are important for ethical decision-making in-patient care. The contextual factors underlying ethical aspects of clinical care fall into four essential domains that correspond to the principal systems of guidance for clinicians: moral/personal values, professional codes of conduct, ethical principles and the law. The Beauchamp and Childress' ethical principles commonly used in health care ethics autonomy, beneficence, non-maleficence and justice provide a foundation in making ethical decision.

Objectives: To analyse the ability of final year medical student's in identifying and solving ethical issues in clinical scenarios.

Research question: What is the final year medical student's ability in identifying and solving ethical issues in clinical scenarios**?**

Concepts: Moral/personal value, Professional codes of conduct, Ethical principles, The law

Methodology: In depth interviews to be conducted with individual students of final year MBBS to analyse their ethical decision-making capacity in clinical care to a given case scenario.

Implications: The study findings will help us to develop a curriculum in medical ethics for MBBS students.

Key words: qualitative study; ethics; clinical care; ethical principles

Perception of PUC College and degree college students on the necessity of incorporating sex education in the academic curriculum

Dr Gabriela, Dr Rekha Thapar

Field of research: Community Medicine

Introduction: Sex education is the lifelong process of acquiring information and forming attitudes, beliefs, and values about identity, relationships. It encompasses sexual development, reproductive health, interpersonal relationships, body image, and gender roles.

Young individuals receive information from a myriad of unreliable sources. School curriculum-based sex education helps in providing health information.

Materials and Methods:

Study Design: A Cross-Sectional Study

Study Population: Degree college and PUC college students in Mangalore

Study Period: March 9^{the} to March 17^{the}, 2017(9 days)

Sample Size: With an expected proportion of awareness of sex education as being 36%, 5% absolute precision and 95% confidence interval and taking 10% as non-response error, the sample size was calculated to be **389** students.

Study Instrument: A questionnaire was circulated among the students and their responses were noted for the assessment.

Results:

In the study conducted, 88% of the students were aware of the term sex education out of which 50.3% of the students mentioned that sex education is a part of their curriculum. Majority (37.9%) acquired this information from friends. 93.2% thinks it's very important to include sex education in the school curriculum. 40.3% thinks sex education can reduce sexual abuse while 48.3% is neutral.

87.5% of the students are aware of the term of birth control.

88.6% of the students were aware of the HIV/AIDS while 76.3% were aware of STDs.

Conclusion:

Most of the students (93.2%) felt that it was very important to include sex education as a part of curriculum to overcome the ethical social stigma and ambiguous conceptions and to avoid the consequences of ignorance. Most of students were aware of the term sex education (87.5%) about birth control measures and basics of pregnancy.

Key words: Sex education, birth control, sexual abuse, reproductive health

Attitude and practices regarding eye donation among college students of Mangalore

Rekha T*, Nithin Kumar, Prasanna Mithra

***Associate Professor, Department of Community Medicine, Kasturba Medical College, Mangalore**

Background: The best line of treatment for corneal diseases is corneal transplantation. The patients in need of corneal transplantation outnumber the rate at which eye donations that take place every year in a developing country like India.

Objectives: To assess attitude and practice regarding eye donation among college students of Mangalore.

Materials and Methods: In this cross-sectional study, 862 college students in Mangalore were assessed about their attitude and practice regarding eye donation. Institutional Ethics Committee approval was taken before the commencement of the study. Data was entered and analysis using Statistical Package for Social Sciences version 16.0.

Results: The mean age of the population was 19.85 years. Of the total participants, 53.6% (N=455) students were willing to donate eyes, of whom 59.7% (N=254), were medical students, while 48.4% (N=206) were non-medical. A total of 71% were willing to motivate others regarding eye donation. Of the total participants 20% pledged to donate their eyes.

Conclusion: Positive attitude regarding eye donation was found among both medical and non-medical students. There were gaps in the practices towards eye donation in both medical and non-medical group of students.

Keywords: Attitude, Practices, Eye donation, Medical students, Mangalore.

Contribution of Social Scientist serving Institutional Ethics committee in the State of Maharashtra

Dr. Uma Jadhav*, Dr. Yashashri Shetty, Ms. Jhanavi Katkar and Dr. Vishal Singh
***Dept. of Medical Social Service, GSMC & KEMH**

Introduction: In the era of global clinical trials, the role of the social scientists, that are part of ethics committees, plays an important role for protection of rights of research participants, distributive justice and health equity. In India mandatory inclusion of non-technical members like social scientist (SSst) on Institutional Ethics Committee (IEC) is stipulated under Schedule Y of Drugs & Cosmetic Act of 1940.

Objective: The objective of the present research is to study the contribution of SSst while serving CDSCO registered IEC in the state of Maharashtra, India.

Methodology: This was prospective cross-sectional web based online survey where SSst of IEC of 6 zones in the State of Maharashtra contacted through emails from the period of July 2016 to July 2017 after approval from IEC of GSMC & KEM hospital. A validated questionnaire administered comprising questions on SSst profile, role, perception, bioethical knowledge and their contribution while serving IEC in the State.

Result: Overall, 18 SSst from 12 districts across various zones [Vidarbha =1, Marathwada = 4, Nagpur =1, Pune =4, Mumbai = 8] responded. 72% (n= 13) respondent reported that they did not received formal training before joining IEC & as a result 11.1% (n=2) participants are able to follow scientific and bioethical part of research projects and 55% felt intimidated in IEC meetings. Only 11.1% (n=2) of SSst were actively engaged in serious adverse events committee discussion which oversee the infringements of participants rights and accord due compensation to them. Ambiguity in terms of their role in IEC was noted, as 61% of SSst did not answer to questions posed. Qualitative exploration of SSst views on functioning of IEC underlines imperativeness of training in bioethical aspects to achieve benchmark in reviewing biomedical protocols

Conclusion: The research findings show heterogeneity of profile, role and perception of SSst while serving IEC which warrants need to design training module

Ethical perspectives in use of personal data from Medical Records for Health Research

Dr.Vijaya Hegde

Introduction: Health care registers have been defined as organized systems with uniform data aimed at comprehensive coverage of a target population with a particular disease, condition or exposure. Register based health research is based on databases, some of which are originally not created for research use. This can provide important and valuable contributions to Public health research. However these data are sensitive and private for many people. Respect for privacy is a basic human right and maintaining confidentiality is important for a trusting Doctor-patient relationship. But the primary ethical problem is that it requires the “sacrifice” of a few, for the benefit of many. There is little evidence on how people view the use of their confidential information. Hence the study aims to assess the common views regarding the use of personal data from medical records for the purpose of research.

Research Question: To describe the attitude of the study participants about ethical issues in using their health care information from medical records for research purpose.

Methodology:

- **Study Design**: Cross-sectional study
- **Study setting:** Outpatient waiting areas of a Tertiary care hospital, Mangalore, India.
- **Research Ethics:**
  - ✓ Study was approved by the Institutional Ethical Committee.
  - ✓ Informed Consent was obtained from the study participants.
  - ✓ Transcripts were anonymized.

- **Study Participants**: A total of 348 participants above the age of 18 years of age.

- **Study Period:** Data was collected for a period of two months.
- **Sampling Method**: Convenience Sampling
- **Exclusion Criteria:**
  - ✓ Participants who did not provide the consent.
  - ✓ Participants who could not follow English.
- **Data Collection tool:**
  - ✓ A questionnaire was developed based on a previous study, which was modified according to Indian context.[1]
  - ✓ Closed ended questionnaire was used which consisted of 12 items
  - ✓ The questionnaire covered demographic information such as Age, Gender and the ethical perspectives in use of their personal data from Medical records for research purpose.

Results:

- Males-45.1%, Females-54.9%
- 52% of the participants felt that their health information is safe and secure.
- 71.8% of the participants are concerned about invasion of their personal information.
- Majority of the participants felt that people who have authorized access to computer and also those who do not have, are the biggest threat to privacy and confidentiality of personal medical records.
- 49.2% of the participants would like to be informed if their information would be used for research purpose.
- 7.5% of the participants responded that their information was used without their consent.
- 58% of the participants responded that there is no need to be informed if the research is of public health importance.
- 64.7% of the participants did not know the existence of any laws in India which prevent medical data being used without consent.
- 73.3% of the participants felt that only the doctor and the concerned patient should have access to medical records.

Conclusions: Register based research provides valuable benefits for public health, in terms of knowing the disease aetiology, risk factors and in disease surveillance. But the key issue is finding the balance between the public health benefits and respect for autonomy with privacy protection.

The study results conclude that the participants were willing to share their data without consent if it was of public health importance.

An ethical analysis of a case of disruptive and difficult patient in dialysis with respect to Indian context and setting

Bryal Dsouza,
Assistant Professor, PhD Scholar, PSPH, MAHE

Ethical Question: Is Withdrawal and withholding dialysis acceptable on a clinically futile patient and having lack of decision-making capacity??

82-year-old man with end-stage renal disease requiring three-times-weekly outpatient in-center HD. He had a solitary kidney owing to an earlier nephrectomy and did well until he developed glomerulonephritis at the age of 74 years, which ultimately progressed to end-stage. After much discussion he elected to pursue HD and he did well for several years, living independently in his own home. His past medical history was notable for well-controlled hypertension, gout, and remote situational anxiety/depression. Ischemic cardiomyopathy developed after the initiation of HD, and there was question of small vessel ischemic brain injury.

Patient has a complex social situation—having been divorced for two decades and having lived alone in his childhood home. He had a daughter and a son, neither of whom lived nearby and were settled abroad. He had a history of alcoholism but had been sober for 25 years and currently did not smoke. He was a retired mechanic described by his children as fiercely independent and, at times, stubborn, coupled with a life-long maladaptive approach to conflict in aggressive, manipulative, or avoidant ways.

Around the age of 79 years, DS was increasingly hospitalized for hyperkalemia thought to be due to medication and dietary noncompliance. He experienced multiple falls with injury. His family raised numerous questions about his cognitive status; however, clinical bedside cognitive testing indicated only mild impairment, and he was assessed not to have dementia. Both the family and outside sources raised concerns about patient safety because of a series of incidents and capacity evaluation by psychiatry determined that he lacked decision-making capacity. Family remained involved in his care involved in his care distantly and appointed a care taker, however patient believed that the guardian's appointment was financially motivated. And that his family recused themselves from serving him began to display behavioral disruption during HD. Initially, constant nurse presence could calm him. Eventually, his behavior progressed to physical combativeness and demands to stop dialysis immediately. He attempted to remove his dialysis needles risking exsanguination, needle injury to staff, and blood exposure to staff and surrounding patients. He required physical restraint, often by multiple personnel, during episodes to prevent injury to himself or others. When asked why he insisted on being taken off HD during a treatment, he was repeatedly unable to verbalize why. When discussed with him outside of HD, he indicated a strong desire to continue HD, although he remained unable to describe the ramifications of continued HD. He did not recognize the discordance of his behaviors and his expressed wishes. Antipsychotics were used, but even low doses markedly sedated the patient, raising ethical concerns about sedating a patient to provide a life-sustaining treatment (potentially against his will).

Interpersonal Communication in Health Care: An effective approach to Human Values

Dr.Nandini Lakshmikantha
Professor, School of Communication, Manipal Academy of Higher Education, MAHE.

Networking with the public is basis of success, in this era of technological advancements. Many methods have been adopted by people and organization heads to stay connected with their public instantaneously. With every industry explicitly using various methods of communication particularly digital and web-based communication, health care is not excluded. It has to be noticed here that though newer technologies have helped medical professionals to achieve wonders, what remains in the mind of patient, how he was treated by the staff of a hospital. Along with the increase in number of hospitals offering super specialty treatment there appears an increase in unpleasant situations between patient or their relatives with that of hospital administration. Probably this is the right time to analyze the influence of interpersonal communication skills among the health care professionals, keeping Human Values as the centrifugal force. This paper will explore how techniques of interpersonal skills will help in building a good human relation with the patients. The papers derives its observations from the secondary research.

Ethical Dilemmas and Electronic Health Records(HER)-The patient as a stakeholder

Dr B.Reshmi
Associate Professor, Health Information Management
School of Allied Health Sciences, Manipal Academy of Higher Education

The health care industry is witnessing a transformation in which Electronic Health Records (EHR) are playing a crucial role in providing the best quality care to the patient . EHRs have demonstrated value in features such as legible information, accurate prescriptions, remote access to information, and prevention reminders. Although these systems promised to improve the quality of patient care, increase efficiency, and reduce costs, health care providers are finding that current EHRs instead require time-consuming data entry, can interfere with patient interactions, and cause medical errors. EHRs should facilitate patient care and, as an essential component of that care, support the patient–physician relationship. Ethical dilemmas, as regards use of electronic health records which for the benefit of the patient will require consultations with ethics experts. The debates should involve the patient who is the key stakeholder and how best can technology be used without compromising on human values and ethical principles.

Key words-Electronic Health Records, Ethics, Challenges, Dilemmas.

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6th National Conference of Forum for Ethics Review Committees in India

FERCICON 2018

Pre-Conference Workshop Schedule

Date : 29th November 2018 ; Time : 2:00 PM - 5:00 PM

Venue : Medical Education Unit Hall, Kasturba Medical College,
LightHouse Hill Road, Mangalore.

Parallel Workshops		Resource Persons
1. 2:00 – 5:00 PM	Incorporating Ethics in Medical Education	**Dr. Sanjiv Lewin,** Chief of Medical Services, St. John's Medical College Hospital, Professor of Pediatrics, Medical Education and Clinical Ethics, St John's Medical College, Bengaluru. **Dr. Animesh Jain,** Professor and Head, Dept. of Community Medicine, Kasturba Medical College, Mangalore.
2. 2:00 – 5:00 PM	Update on ICMR Ethical Guidelines 2017	**Dr. Vasantha Muthuswamy,** Retd. Senior Deputy Director General, Indian Council of Medical Research. **Dr. Nandini Kumar,** Retd. Deputy Director General, Sr. Grade Indian Council of Medical Research. **Dr. Urmila Thatte,** Professor and Head, Dept of Clinical Pharmacology, Seth G S Medical College and KEM Hospital, Mumbai. **Dr. Roli Mathur,** Scientist E and Head, ICMR Bioethics Unit, NCDIR, ICMR, Bengaluru.

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FERCICON 2018
Conference Schedule

Date : 30th November 2018
Venue : Dr. TMA Pai International Convention Centre, MG Road, Mangalore.
HALL B

Time	Topic	Speaker(s)
8:30 – 9:00 AM	Registration and Breakfast	
9:00 – 9:30 AM	**Ethical Issues in Stem Cell Research**	**Dr. Vinita Jagannath** Post-Doctoral Researcher, French National Institute of Health and Medical Research, Paris **Chairperson:** **Dr Vasudev Shenoy** Head, Project Management and Regulatory, Bioequivalence Studies, ECRON ACUNOVA, Manipal
9:30 – 10:00 AM	**Key Note Address:** **Medical Ethics and Values in Human Life**	**Prof S R Bhatt,** Chairman, Indian Council of Philosophical Research, New Delhi **Chairpersons:** **Prof Shrinivasa Varakhedi,** Vice Chancellor, Sanskrit University, Ramtek, Nagpur. **Dr. G G Laxman Prabhu,** Professor and Head, Department of Urology, Kasturba Medical College, Mangalore.
10:00 – 10:30 AM	**Can good statistics enhance the standards of ethics in medical research?**	**Dr. N Sreekumaran Nair,** Professor and Head, Department of Medical Biometrics and Informatics (Biostatistics), JIPMER, Puducherry. **Chairpersons:** **Dr Avinash Shetty**, Medical Superintendent, Kasturba Hospital, Manipal **Dr Suma Nair,** Prof & Head, Department of Community Medicine, Kasturba Medical College, Manipal.
10:30 – 10:45 AM	Tea Break	
10:45 – 11:15 AM	**Challenges in Conduct of Pediatric Clinical Trials**	**Dr. Sanjiv Lewin,** Chief of Medical Services, St. John's Medical College Hospital, Professor of Pediatrics, Medical Education and Clinical Ethics, St John's Medical College, Bangalore. **Chairperson:** **Dr Kamalakshi Bhat** Prof & Head, Department of Paediatrics, Kasturba Medical College, Mangalore

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11:15 AM – 1:00 PM	**Plenary Session I:** **Ethical dilemmas in Biomedical Research and Strategies to Overcome them** **Chairperson:** **Dr. Girish Menon,** *Professor and Head, Department of Neurosurgery, Kasturba Medical College, Manipal.*	**Speaker 1: Dr. Urmila Thatte** Professor and Head, Dept. of Clinical Pharmacology, Seth G S Medical College KEM Hospital, Mumbai. *(Expert in Research Ethics)* **Speaker 2: Ms. Annam Visala,** Deputy Drugs Controller, CDSCO, Hyderabad. *(Regulatory Affairs)* **Speaker 3: Dr. Roli Mathur,** Scientist E and Head, ICMR Bioethics Unit, NCDIR, ICMR, Bengaluru. *(Policy maker and Funding agency)* **Speaker 4: Dr. Chakrapani M** Professor of Medicine, Kasturba Medical College, Mangalore. *(Ethics Committee member)* **Speaker 5: Dr. B Satheesan** Director and HOD, Dept of Surgical Oncology, Malabar Cancer Centre, Kerala *(Investigator)* **Speaker 6: Dr Joseph Thomas** Head, Centre for Bioethics and Professor of Urology, Kasturba Medical College, Manipal *(Ethics Committee)* **Speaker 7: Dr. Bhavesh Acharya,** COO, Cytespace Research Pvt. Ltd. *(CRO)*
1:00 – 2:00 PM	**Lunch Break**	
2:00 – 3:30 PM	**Plenary Session II:** **Incorporating Ethics in Medical Education.** **Chairpersons:** **Dr. Sanjiv Lewin** *Professor of Pediatrics, Medical Education and Clinical Ethics, St John's Medical College, Bangalore* **Dr. Ciraj A M** *Director, MAHE-FAIMER International Institute* *Prof., Dept of Microbiology, MMMC, Manipal*	**Speaker 1: Dr. S R Bhat** Chairman, Indian Council of Philosophical Research, New Delhi **Speaker 2: Dr. Nandini Kumar** Retd. Deputy Director General, Sr Grade, Indian Council of Medical Research. **Speaker 3: Prof. Brijendra Singh** Dean CSR and HOD of Anatomy, AIIMS, Rishikesh **Speaker 4: Dr. Medha Joshi** HOD, Dept of Allied Health Sciences, Ramaiah University of Allied Health Sceinces, Bangalore.
3:30 – 3:45 PM	**Tea Break**	
4:00 – 4:40 PM	**Inauguration**	
5:00 – 6:00 PM	**FERCI General Body Meeting**	
7:00 PM onwards	**Banquet: Mangalore Club**	

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FERCICON 2018
Conference Schedule

Date : 30th November 2018
Venue : Dr. TMA Pai International Convention Centre, MG Road, Mangalore.

HALL A

Time	Topic	Speaker
2:05 – 2:20 PM	**Medical Ethics in Ancient India and its Relevance Today**	**Dr. Jyotindra Dave** Director, Swaminarayan Research Institute, New Delhi.
2:20 – 2:40 PM	**Passive Euthanasia: To Be or Not to Be**	**Prof. Sonia Mehta** Sr. Asst. Professor of Philosophy Daulat Ram College, Delhi
2:40- 3:00 PM	**Ethical Issues in Research in Integrated Medicine**	**Dr. Pradeep Kumar,** Member Secretary IEC, Institute of Applied Dermatology.
3:00 – 3:30 PM	**Ethical Issues in In Vitro Fertilization**	**Dr. Kavita Agarwal** IVF Specialist, Allahabad.
3:30 – 3:45 PM	**Tea Break**	

Date : 1st December 2018
Venue : Dr. TMA Pai International Convention Centre, MG Road, Mangalore.

Time	Topic
10:00 – 11:15 PM	**ORAL PRESENTATION**
2:30 – 3:30 PM	**POSTER PRESENTATION**

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FERCICON 2018
Conference Schedule

Date : 1st December 2018
Venue : Dr. TMA Pai International Convention Centre, MG Road, Mangalore.
HALL B

Time	Topic	Speaker
9:00 – 9:30 AM		**Breakfast**
9:30 – 10:00 AM	**Ethical Challenges in Early drug development and Clinical Trials**	**Dr. Kamala Rai** Global Program Head, Global Health Development Unit, Novartis Healthcare Pvt Ltd. **Chairperson:** **Dr Usharani Pingali,** *Prof & Head, Department of Clinical Pharmacology and Therapeutics* *Nizam's Institute of Medical Sciences, Hyderabad*
10:00 – 10:30 AM	**Ethical challenges in Biobank and Biorepositories**	**Dr. Juhi Tayal** Consultant Scientist (Pathology) and Coordinator Biorepository, Rajiv Gandhi Cancer Institute and Research Centre, New Delhi. **Chairperson:** **Dr. Sharada Rai,** *Prof & Head, Department of Pathology,* *Kasturba Medical College, Mangalore*
10:30 – 10:45 AM		**Tea Break**
10:45 – 11:15 AM	**The Significance of Care Ethics for Medical Ethics**	**Prof. Anumita Shukla** Asst. Professor of Philosophy Ramanujan College, University of Delhi, Delhi **Chairperson:** **Dr John Ramapuram,** Prof & Head, Department of Medicine, Kasturba Medical College, Mangalore.

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11:15 AM - 1:00 PM	**Plenary Session III:** **Accreditation of Ethics Committees: SIDCER, AHAARP, NABH** **Chairpersons:** **Mr. Prashant Paschal,** *Assistant Director, NABH* **Dr Varadraj Shenoy,** *Professor of Pediatrics, Father Muller Medical College, Mangalore.*	**Speaker 1: Dr. Urmila Thatte** Professor and Head, Dept. of Clinical Pharmacology, Seth G S Medical College and KEM Hospital, Mumbai. *(SIDCER).* **Speaker 2: Dr. M K Sudarshan,** Chairman, IEC, Fortis Hospital and IIPH, PHFI, Bangalore. *(NABH).* **Speaker 3: Ms. Annam Visala,** Deputy Drugs Controller, CDSCO, Hyderabad. *(CDSCO).* **Speaker 4: Dr. Seema Pai,** Director, India Cluster, Clinical Development and Operations, Pfizer *(AHAARP)*
1:00 – 2:00 PM	Lunch Break	
2:00 – 2:30 PM	**Ethical Issues in Qualitative Research**	**Dr. Amol Dongre,** Dean (Research), Professor and Head, Community Medicine, Sri Manakula Vinayagar Medical College and Hospital, Puducherry. **Chairperson:** **Dr. D S Aswath Narayan,** Professor and Head, Department of Community Medicine, KIMS, Bangalore
2:30 – 2:50 PM	**Medical Ethics: Tenets From Ayurveda And Buddhism**	**Dr. Rajiv Bhatt** New Delhi
2:50- 3:10 PM	**Eternal Values in Ayurveda for Changing Modern Medical World**	**Dr. Jayachandran,** Ayurvedic Physician, Ahmedabad
3:10 – 3:30 PM	**Impact of Biotechnology in Medical Ethics**	**Prof. L P Singh** Retired Professor of Philosophy, Magadh University, Bihar.
3:30 – 3:45 PM	Tea Break	
4:00 – 5:00 PM	VALEDICTORY	

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