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Subrata Saha, PhD
SUNY Downstate Medical Center
450 Clarkson Avenue - Box 30
Brooklyn, New York 11203
Email: Subrata.Saha@downstate.edu

CITIZEN-SCIENTISTS: PURSUING THE GOOD IN AN AGE OF DISCOVERY

Mildred Solomon, EdD
President, The Hastings Center, Garrison, NY

The U.S. is a leader in the preparation of scientists and engineers, and yet there has been insufficient attention to equipping scientists and engineers to fully consider the societal impact of the new knowledge and technologies their discoveries produce. This session will call upon scientists and engineers to better equip themselves -- and the students they train – to anticipate the social and ethical implications of emerging technologies. We will explore the differences between scientific questions and ethical ones, review where science has sometimes gone awry, articulate why ethical reflection should be a critical habit of mind for all scientists and engineers, and offer suggestions for integrating ethics teaching in the professional development of scientists and engineers.

WHY BIOENGINEERS CANNOT SHARPLY DISTINGUISH TECHNICAL QUESTIONS OF FEASIBILITY FROM ETHICAL QUESTIONS OF PERMISSIBILITY

George Khushf, Ph.D.
Director, Center for Bioethics, University of South Carolina

The biomedical engineer requires a teleological frame for optimization, and all design requires optimization with respect to design constraints and ends that frame the engineering task and its solution. The design

constraints and ends are those of humans, and they reflect what humans value and consider worth pursuing. Engineering is a highly disciplined form of action advanced for realizing those ends. What distinguishes biomedical engineering from other forms engineering is the way the activity must interface with the norms and functions of subsystems of the human organism. At some stage, the bioengineer is interfacing with a human organism, and the optimization is of the capacity of some organismic subsystem with physiological norms that reflect how that subsystem is integrated with and attuned to other human subsystems. There are thus natural norms and functions associated with the human subsystem, and technical norms and functions associated with the designed system that interfaces with that subsystem and with the human who is viewed as a whole and as nested in a yet higher communal context. Traditionally, questions about the physiological norms and functions are regarded as "scientific," while questions about the higher scale ends that guide the engineering activity are regarded as "ethical." Technical or engineering questions are then related to techniques and technologies for instrumentally realizing the higher order ethical ends, and for interfacing with the lower order subsystems, both to ascertain their norms and functions and to enhance them in ways that realize the higher order goals. This way of disentangling science, ethics, and engineering may have a heuristic function and work as a first approximation, but it misses deeper similarities between the "natural" norms and functions of subystems and the higher order "ethical" norms and instrumentalities. Engineers must at least implicitly appreciate these similarities. I'll provide a framework that can assist engineers in reflecting more explicitly on how these natural, technical, and ethical aspects of optimization come together and must be jointly addressed in bioengineering.

3 VERSIONS OF ANTICIPATORY ETHICS FOR ISSUES IN BIOMEDICAL ENGINEERING

Richard L. Wilson
Philosophy/School of Engineering
University of Maryland at Baltimore County, Baltimore Maryland, rwilso4@umbc.edu

Anticipatory Ethics has recently emerged as an important new orientation in practical ethics. In general, anticipatory ethics can be said to relate to the development of emerging and innovative technologies. In this discussion anticipatory ethics will be focused on developments in Biomedical Engineering. For the sake of our analysis we shall refer to the development of Biomedical IT technology. In this discussion 3 variant views on emerging IT and anticipatory ethics will be introduced. These views are those of Phillip Brey in "Anticipating ethical issues in emerging IT", the view of Deborah Johnson in "Software Agents, Anticipatory Ethics, and Accountability", and the view of Floridi and Sanders in "On the morality of artificial agents". Each of these views offers important insights for the future development of anticipatory ethics and for the development of anticipatory ethics in the fields related to Biomedical Engineering.

The view taken in this analysis is that a comparison and contrast of these 3 views of emerging IT and anticipatory ethics as it relates to Biomedical engineering and medicine revolves around 3 types of interactions. These interactions are agent to agent interactions, agent to artefact interactions and artefact to artefact interactions. Each of the authors has a unique view of these relationships and the ethical issues related to these relationships. By comparing and contrasting these views the ground is prepared for seeing the strengths and weaknesses of each these views and then developing a view of anticipatory ethics in biomedical engineering and medicine based upon them. Issues that can be briefly addressed employing anticipatory ethics will include BCI's, Prosthetics, and Exoskeletons.

The importance of anticipatory ethics for practical ethics in today's world is critical due to the rapid development and influence of information technology in all its forms on all aspects of contemporary existence. The introduction of 3 contemporary views on anticipatory ethics prepares us to see what is likely to become important in the future for issues arising in biomedical engineering and medicine. Anticipatory ethics allows us to develop strategies for identifying potential ethical problems before they arise.

INCLUDING BIO/MED TECHNOLOGISTS IN ETHICAL DISCUSSIONS CONCERNING INNOVATIVE PRODUCTS- ARE THE AVAILABLE PLATFORMS APPROPRIATE?

Ilana Kepten D.Sc. ORT
Braude Engineering College, Israel

In our quest for improved life, health and living environments, we eagerly await the products and technologies that Biomedical and Biotechnology (Bio/Med) industrial R&D promises to manufacture. Bio/Med technology professionals (aka engineers, industrial R&D developers, industry based scientists etc.) are continuously envisioning, designing and manufacturing those highly anticipated and innovative products. Some of these innovative technologies and products could be conceptually new, thus having the potential to disrupt and eliminate known and established products. As such, and as has been in the past, they may also disturb beliefs and behaviors, question established concepts, and challenge values at the user and the public levels. These probable challenges demand an ethical evaluation and ethical preparedness. Based on past experiences, different platforms have been established to facilitate ethical discussions regarding innovative Bio/Med technologies and products.

This paper aims to explore the inclusion of Bio/Med technologists in, and their contribution to, the discussions regarding the ethical challenges ensuing from the introduction of the innovative technologies that they produce. The established platforms for such a discussion will be analyzed and I will suggest that, unlike the contribution of other partners such as bioethicists, scientists, and regulators, the inclusion of Bio/Med technologists is fairly limited.

Few suggested models exist that allow for the ongoing inclusion of Bio/Med technologists in a discussion regarding the ethical impact of their innovative endeavors. Analyzing those models shows they promise change if they can be further developed and adapted for current needs.

Taken together, the underrepresentation of Bio/Med professional technologists in the ethical discussions, and the un-availability of an appropriate platform for such a discussion, cast a doubt on the effectiveness of the discussions and their ability to enhance preparedness for the anticipated technologies.

EMPOWERING RESEARCHERS TO SHAPE MEDICAL INNOVATION

Jennifer A. Nichols, PhD, MA
Department of Orthopaedics, University of Utah

When presenting and publishing translational research studies, engineers and scientists are often asked to demonstrate clinical relevance or provide a clinical recommendation. However, it is difficult to determine when making a clinical recommendation based on scientific research is justified. How much data is necessary to justify changing medical practice? And, what is the role of researchers and scientists, who have no formal medical training, in deciding when and how medical practice should change?

The answers to these questions begin with examination of the cultural and historical factors that shape the professional relationship between researchers and physicians. By analyzing the process of medical innovation, I demonstrate that researchers and physicians have unique roles: researchers develop knowledge and share it through publication, while physicians receive a filtered version of that knowledge (e.g., clinical practice guidelines) and utilize only that filtered knowledge to change clinical practice. Although this separation could be perceived as a beneficial division of labor, I argue that limiting the interaction between physicians and researchers is likely to impede medical advances that cross-disciplinary collaboration and disciplinary integration could foster. I conclude that integrating biomedical researchers into clinical culture would empower them to more effectively change medicine. This empowerment of researchers would be beneficial in ensuring the development of needed medical innovations. Researchers would be better equipped to work with physicians, provide meaningful clinical recommendations, and disseminate those recommendations to appropriate medical specialties.

THE ETHICS OF PHARMING: ENGINEERING DESIGN AT THE CELLULAR LEVEL

Abidemi O. Ologunde[1] and Oyinlola O. Adeyanju[2]
[1]Department of Electrical Engineering, University of South Florida, Tampa, FL, USA
[2]College of Pharmacy, University of South Florida, Tampa, FL, USA
aoologunde@mail.usf.edu; oadeyanj@health.usf.edu

"Pharming", is a branch of genetic engineering where plants or animals are genetically *engineered* to produce pharmaceutical proteins. Although pharming has led to better and cheaper drugs, however, questions still remain as regards the choice of plants or animals, environmental and pharmacological safety, the welfare of pharming animals, the legal regulation of pharming, societal concerns, and moral evaluation. In their paper, Ologunde et al (2014) argued that the classification of engineering designs affects the ethical considerations and the amount of social responsibility ascribed to the design engineers. In the same vein, the authors of this paper address the ethical questions surrounding pharming, by regarding it as a form of engineering design albeit at the cellular level. This therefore raises ethical concerns and social responsibility issues for the "engineers" involved in this branch of genetic engineering. Future trends in research are then discussed, with focus on ethical recommendations and appraisals.

USE OF VIRTUAL HUMANS IN DESIGNING VEHICLES FOR OCCUPANT SAFETY

Arunima Deb, Shreya Agarwal
Mandya Institute of Medical Sciences (MIMS), Mandya, Karnataka, India

An important aspect of designing vehicles plying on land, air, etc. is to protect occupants during crashes. This involves not only designing vehicle body structures for absorbing impact energy but also ensuring minimization of risk of severe injury to occupants of vehicles. The occupants of a vehicle become susceptible to bodily injury in a crash due to complex interactions between the occupants and interior surfaces of the vehicle in the form of secondary impacts. As each real-world accident is potentially different from another, standardized laboratory tests have been formulated in various countries (such as the USA) and geographical entities (such as Europe) for assessing the capability of vehicles in protecting their occupants in the event of a mishap. It may be noted that dynamic vehicle response parameters such as deceleration and intrusion provide a broad idea of a vehicle's ability to protect occupants. However, a human interface is needed to obtain a quantitative assessment of injury severity. It is rather obvious that it would not be conscientious or ethical to carry out vehicle crash tests with live human subjects.

An alternative is to use human surrogates or dummies, technically termed as Anthropomorphic Test Devices (ATDs), whose responses should be correlated with human injury. In practice, the correlation has been done against human cadavers which have been subject to impact tests in controlled laboratory environments. Through extensive research, a number of injury parameters such as chest acceleration, rib deflection, femur load, tibia index, head injury criterion (HIC), neck injury criterion, viscous criterion (v*c, for soft tissue damage), thoracic trauma index (TTI), pubic symphysis force, etc. and their safe limits have been formulated. For prediction of these injury parameters, well-known ATDs employed are Hybrid III dummy and recently developed WorldSID for vehicle front and side impact safety assessments respectively. Additionally, countermeasures for vehicle interior head impact safety are evaluated with a free-motion featureless Hybrid III headform in the USA.

The ATDs mentioned are reviewed here. It may be pointed out that though ATDs are re-usable and have contributed substantially to the enhancement of vehicle occupant safety, these human surrogates cannot predict details of injuries such as fractures, damages to brain, soft tissue damage, etc. An approach that is currently gaining popularity is the usage of mathematical replicas (i.e. finite element models) of human beings to which tissue properties are assigned. These virtual humanoids pay due consideration to the anatomy of human body and incorporate vital organs. Vehicle manufacturers such as Toyota, Ford, etc. have taken lead in developing proprietary humanoids for making improved predictions of injury and perhaps making vehicle passive safety

design including seat belts, airbags, etc. as more robust. In conclusion, it may be mentioned that humanoids which have been developed by engineers with the aid of medical professionals are testimonies to modern interdisciplinary research for societal good that do not naturally clash with the well-known principles of ethics.

ALLERGIC TO MODERN TECHNOLOGY: WHAT ARE THE ETHICAL RESPONSIBILITIES OF SOCIETY TO ELECTRICALLY HYPERSENSITIVE INDIVIDUALS?

Kenneth R. Foster
Department of Bioengineering
University of Pennsylvania, Philadelphia PA 19104

The benefits of wireless technology are well known, but the potential harms, either real or perceived need to be considered as well. I will focus on one perceived harm of wireless communications: the perceived sensitivity of many individuals to the radiofrequency fields emitted by devices such as Wi-Fi, cell phones, and wireless enabled utility meters (SmartMeters). Many of these "hypersensitive" individuals are so affected by their perceived sensitivity that they cannot function fully in modern society. "Challenge" tests, in which hypersensitive individuals are exposed under blinded conditions to radiofrequency fields, generally show that these individuals are unable to perceive when they actually are exposed to the fields but only react when they think that they are exposed.

While the etiology of the problem is unknown, two kinds of explanations have been advanced for electrical hypersensitivity (more technically called Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields (IEI-EMF)). The first considers the symptoms in psychological terms, for example as a somatisation disorder or a nocebo effect; many electrically sensitive individuals resist such psychological interpretations of their symptoms.

The second considers the symptoms to be a direct consequence of exposure to radiofrequency radiation. What are the ethical obligations of society towards these individuals? The desire of hypersensitive individuals' to "sanitize" their environments of electromagnetic fields has led to a new industry of consultants and firms that measure and remediate fields in peoples' homes. Is this a constructive approach to solving their problems or does it merely take advantage of vulnerable individuals, and serve to box them in further? Attempts to accommodate requests of hypersensitive individuals to remove sources of electromagnetic fields from their surroundings may have consequences to the rest of society, for example in reducing the availability of technologies such as mobile communications and Wi-Fi that society at large finds to be useful. To what extent, if any, are such accommodations ethically required?

LONGER LIVING THROUGH TECHNOLOGY: IN FAVOR OF LIFE-PROLONGING BIOMEDICAL TECHNOLOGY FOR OLD PEOPLE

Felicia Nimue Ackerman
Professor of Philosophy, Brown University

Many prominent bioethicists, such as Daniel Callahan, oppose the use of biomedical technology to prolong the lives of old people. This paper will criticize their views and will argue that a top priority of a humane society should be to promote research on life-prolonging technology and to make the fruits of this research available to old people.

PERVASIVE TECHNOLOGIES: PRINCIPLES TO CONSIDER

Christine Perakslis, EdD[1], Jeremy Pitt, PhD[2], and Katina Michael PhD[3]
[1]Johnson & Wales University, [2]Imperial College, [3]University of Wollongong

The purpose of this paper was to explore the ethics perspective when contemplating such pervasive technologies as those utilizing biological data and thereby likely to create susceptibilities for users. The authors considered the intensification of opt-in, self-monitoring data collection through such technologies as wearables and bearables, as well as the Internet of Things (IoT) which is burgeoning through the increase of devices, systems, and services that continue to be developed and linked to the infrastructure aggregating vast data. With researchers estimating up to 30 billion devices wirelessly connected to the IoT by 2020, time is of the essence to address ethical considerations. A review of the literature included an overview of the state of such technologies as well as salient issues. The authors then considered the trajectory of such technologies against the backdrop of the principles incorporated in the European Union and international treaties as well as the laws of EU member states which are: the precautionary principle, purpose specification principle, data minimization principle, proportionality principle, and the principle of integrity and inviolability of the body, and dignity. The authors utilized a philosophical research approach with intellectual analyses to support value judgments.

NANO TECHNOLOGY– SOCIAL ETHICS INTEGRATION: A PROGNOSIS!

M. K. Banerjee
Chair Professor, Malaviya National Institute of Technology, Jaipur, India

The present paper encompasses the critical analyses of twenty first century's ethical issues in relation to the development and implementation of nanotechnology for advancement of human civilization. It is to be noted that the discussions on ethical front as narrated in the current paper are principally related to what is called to be the 'social ethics' without much emphasize on 'morality', a term, supposed to be much less clear in the present day technological society. By social ethics it is meant herein that all the humane activities for sustainable existence of Homo sapiens on earth must concern with the basic needs of life, which are food, shelter and clothes. The major apprehension lies in the fallacious balance between the socio political will of a society to bear the responsibility of keeping the inhabitants on earth alive and the equanimity – a typical biologically derived trait of animals and which the human being is not free of.

It is known that nano science and technology insures fascinating benefits in attaining food security, clothing, health care and wealth creation for improvement of quality of lives. Historically the practicing science and technology of a definite era at a specific locality has set the culture and values of the people of the concerned society and therefore the current century is poised to move through a cultural transition typified by the practice of nano technology for the sake of accruing the benefits of nanotechnology aided health care , food security ,faster communicability, secured clothing and many other amenities as token of the demand of comforts in the lives of advanced technological society. Therefore there will be a paradigm shift in the understanding of the meaning of life, material and even the ongoing economic activities.

Knowing that the inevitable threats of nano technology due the reasons of reactivity and toxicity of nano materials, new generation industrial activities including its unknown impacts on ecology have posed additional concerns to the sustainability of human civilization, the paper advocates that the integration of major issues of social ethics with the research and practice of nanotechnology must not be postponed to any later date.

The increasing ethical challenge ahead of nanotechnology in its present state of development has been discussed in the perspective of the potential accessibility of nano technology to common people, the chances of further redistribution of wealth along with the concern for increased cost of healthcare. Further, the need for disclosure of risk in nanotechnology to the user and researchers, need to evolve appropriate environment protection protocol against nano pollution and measures against the effect of bioaccumulation of nano particles of varying size, shape and quality on the possible health hazards are also focused in the thematic discussion on nanotechnology- social ethics integration. Finally the paper opens the debate 'if disregarding the 'social ethics – nanotechnology integration' may bring in a new challenge affront the advancing human civilization which is to mitigate the suspected incoming nanodivide across the global society in the midst of long persisting economic divide ' and ipso facto, what remains to be the roadmap for sustenance of advancement in human civilization.

STICKY ETHICAL ISSUES IN HEALTHCARE AND RESEARCH: HOW WE GOT HERE, WHERE WE ARE GOING

Gregory L. Eastwood, MD
Interim President
Past President (1993-2006), SUNY Upstate Medical University

This is a general topic that will (1) trace the development of current bioethical principles from ancient times but also show how contemporary events have influenced bioethics, (2) show how their development and application to healthcare and research have been synergistic, (3) identify some current ethical dilemmas, and (4) predict future issues that have important ethical dimensions, such as relates to stem cell biology and genetic engineering.

This talk is intended to be both general and specific, to include some of the issues that attendees might be facing.

BULLETPROOF HUMANS: AN ANTICIPATORY ETHICAL ANALYSIS OF BULLETPROOF SKIN

Richard L. Wilson
Philosophy/School of Engineering, University of Maryland at Baltimore County, Baltimore Maryland

In this discussion anticipatory ethics will be focused on a specific development in Biomedical Engineering, and medicine, the development of bulletproof skin. Project 2.6 grams at 329 m/s is working towards one day giving normal humans a degree of invulnerability by developing bullet proof skin. This paper will view the current emerging technology of bulletproof skin. The analysis will include an examination of the technology as it exists today, what is preventing it from further development, and the groups being affected by it. The people who are affected directly are known as primary stakeholders. These groups of people include the engineers developing bulletproof skin, the military, law enforcement officers, and animals. Groups that can be involved in the development and use of bulletproof skin in the future will referred to as secondary stakeholders. For the development of bulletproof skin, these groups will include political personnel, hospital surgeons, and the general public.

After looking at these stakeholders, an ethical analysis of bulletproof skin will be conducted from the perspective of the primary stakeholder's. In order to do so, ethical principles and the Code of Ethics for Engineers will be employed. These ethical principles will be employed to identify and address ethical issues with the technology itself, the use of it by humans, and the issue of animal's rights. After analyzing these issues, solutions will be proposed about the development and use of bullet proof skin from the standpoint of anticipatory ethics. The recommendations proposed will include future changes that will be based upon an anticipatory ethical analysis since if they are not considered the consequences could potentially be negative. If bulletproof skin is fully developed and precautions are not taken ahead of time, then consequences, positive or negative, are simply unforeseeable.

Current Technology: The project was named 2.6 grams at 329 m/s because that is the qualification for any other type one bulletproof material. These dimensions are the maximum weight and velocity of a .22 caliber long riffle which is used to test type one materials (Chan, 2011). Current type one bulletproof material is the commonly known bulletproof vest. These vests cover the major internal organs. Not only do the vests not cover everything, but they are also hot, expensive, uncomfortable, and limit movement. The goal of bulletproof skin is to protect the body's largest organ, the skin. Other added benefits for this breakthrough technology combat the issues of current vests: lightweight, flexibility, no added heat, and no replacement cost.

In order to make this so called 'super-skin', goats have been genetically modified to contain spider-silk proteins. This protein is "stronger than steel, and it's the toughest natural protein fiber" (Chan, 2011). Since the protein is stronger than steel, it is then determined to be four times stronger than kevlar, the current material for bulletproof vests. Once these goats are milked, scientists can extract the silk proteins from the milk. Afterwards, the silk is used to spin a bulletproof fiber. Once the material is ready, human skin cells can actually grow around the material on both sides, creating skin that is impenetrable to bullets. Not just impenetrable, but four times more impenetrable than what is currently being used.

"WE WON'T KNOW WHAT'S GOING ON INSIDE": TISSUE ENGINEERING HIDDEN MUSCULOSKELETAL TISSUES

Nancy Pleshko, PhD[1] and Richard G. Spencer, MD, PhD[2]
[1]Dept. of Bioengineering, Temple University, Philadelphia, PA
[2]Magnetic Resonance & Spectroscopy Section, National Institute on Aging, NIH, Baltimore, MD

Musculoskeletal pathology of the knee commonly occurs with aging and as a result of injury. As but one important example, osteoarthritis (OA) is a potentially severely debilitating disease characterized at least in part by degeneration of articular cartilage As cartilage has very limited capability for self-repair due to low cellular metabolism and lack of vascularization, once initiated, progressive and inexorable further degeneration of cartilage is the norm. However, there are no currently accepted non-surgical options for treatment of OA. Therefore, tissue engineering approaches to replace damaged cartilage are a topic of intense research activity, with the goal of engineering and implanting a tissue that can recapitulate the normal function of cartilage.

Typically, porous polymer scaffolds, such as polyglycolic acid or polycaprolactone, are widely used in the research setting for *in vitro* cultivation of cartilaginous tissues. Scaffold degradation rate can be modulated so that initial mechanical support for cultured chondrocytes can be provided to ensure production of extracellular matrix, but with eventual resorption of the scaffold. Further development of viable cartilage tissue may then be established following *in vivo* implantation into the sites of cartilage defects.

While a logical approach to eventual OA therapeutics, the potential effectiveness of this procedure is greatly limited by the inability to assess the quality of the nascent repair tissue. Clinically, arthroscopic evaluation is the gold standard for the assessment of intra-articular tissues, but provides only qualitative evaluation of surface characteristics. More quantitative outcome measures are under development, including advanced non-invasive magnetic resonance imaging (MRI) analyses. However, the MRI approach suffers from significant limitations, most prominently lack of molecular sensitivity and specificity, but also limited spatial resolution, which does not even approach the histologic scale that would be optimal for evaluation of tissue engineered structures. Other possible methods, such as Fourier transform infrared spectroscopy, suffer from other limitations, such as partial invasiveness at the present stage of development, and complexities in data interpretation. Thus, the detection of specific compositional changes in engineered tissues after implantation into the joint present ongoing challenges.

Ethical considerations abound in the early stages of any new therapeutic development, often in the context of the tradeoff between potential benefit and potential risk. In the case under consideration, we raise the ethical dilemma presented by one of the chief challenges of the tissue engineering approach to musculoskeletal disease: *Should engineered constructs for repair of musculoskeletal tissues such as cartilage be approved for clinical use prior to the development of definitive imaging modalities for ongoing evaluation?* Is it ethical to offer this therapy, given that the only currently available means of determining the etiology of complications such as post-implant pain or restriction of motion may be arthroscopy, with its attendant risks, such as infection, discomfort, and possible further structural damage? These considerations are of special concern given the emerging power of noninvasive imaging techniques, and the faith placed in them by patients who may be unaware of acute limitations in existing imaging modalities.

BRAIN-COMPUTER INTERFACES: EXTENDING EMBODIMENT, REDUCING STIGMA?

Sean Aas, David Wasserman
Department of Clinical Bioethics, National Institutes of Health

Brain-Computer Interfaces (BCIs) now enable an individual without limb function to "move" a detached mechanical arm to, e.g., feed herself. The computer recognizes patterns of neural activity associated with her "willing" the movements involved and directs the arm accordingly. It is difficult to learn to operate these interfaces now, but the process will be streamlined in the near future, requiring less practice and no physical connection between the individual and a robotic effector. It may eventually offer almost everyone a simple way to move objects at

a distance, by exercising cognitive control of a mechanical device. At that point, BCIs may be seen less as an assistive technology for disabled people, and more as a technology like the internet, which can benefit all users.

This presentation will outline two sets of conceptual and ethical of issues raised by this new technology:

1) How will the widespread and routine use of these BCIs affect our understanding of embodiment and bodily rights? Are BCIs mere tools, or, rather, can these devices come to be seen as "neural prostheses" that extend the body itself therefore the objects over which the individual has special rights? Will such an extension be precluded or qualified by the fact that many of these devices will have multiple users?

Will people with disabilities benefit by increased inclusion and reduced stigma as BCI and other technologies, like robotics, replace, supersede, or reduce the importance of species-typical functions?

ENVIRONMENTAL GOODS AND HEALTH GOODS: ETHICAL ISSUES OF FAIR DISTRIBUTION

Michael Lindquist, BS
Philosophy MA Candidate at Western Michigan University

Natural environments and natural objects (e.g., parks, tree cover, etc.) within cities are shown to have beneficial environmental effects on the surrounding area, making these natural environments and objects into environmental goods. The same natural environments and objects are also shown to have positive effects on the mental health of those who are around them. This allows for the potential of having these environmental goods fulfill a dual role as health goods. These dual goods occupy a place in public space; however, the current assessment of the distribution of these dual public goods (environmental and health) reveals a striking inequality, as those who are typically at greater risk for various mental pathologies often have less access to these goods. Furthermore, the distribution of environmental and health risk creators (e.g., landfills, power plants, etc.) increase the likelihood of various mental pathologies. These dual public harms also tend to target, intentionally or not, those who lack the access to the dual public goods.

The unequal distribution of these dual public goods may have an impact on the mental wellbeing of people, and thereby impact mental health services as well. The impacts of this unequal distribution will be considered, concluding that mental health professionals and the public ought to be aware of such issues and advocate accordingly within their respective professions, as well as in the public sphere, for better, fair distribution of these dual public goods. Issues concerning potential barriers to policy changes will also be touched on and dealt with.

ETHICAL AND THERAPEUTIC CHALLENGES WITH THE USE OF INDUCED PLURIPOTENT STEM CELLS (IPSCS).

Glenn Monastersky, Ph.D
Center for Biotechnology and Interdisciplinary Studies
Rensselaer Polytechnic Institute, 110 8th Street - Troy, NY 12180-3590, monasg@rpi.edu

The use of human embryonic stem cells for research and therapeutic purposes is subject to several ethical and biosafety concerns. The moral status of the early human embryo is the basis for the primary ethical conflict. Specifically, a large proportion of the public believes that the human zygote and subsequent embryonic stages, including the stem cell-containing blastocyst, represent actual human lives with full human rights. Therefore, proponents of this concept believe that the derivation of stem cells from these embryos or the use of previously generated stem cell lines is unethical. Such utilitarian use of human embryonic stem cells to benefit mankind has been compared to the use of the medical use of non-consensual prisoner data.

During the past decade, a promising compromise to this intractable conflict has been developed in which genetically pluripotent cells are derived from the *in vitro* dedifferentiation of adult human differentiated cells. The resultant Induced Pluripotent Stem Cells (IPSCs) appear to exhibit the developmental and therapeutic potential of *de novo* embryonic cells but are produced without the manipulation of human embryos. IPSCs, especially from patients with specific diseases, already are being used in innovative, high-throughput drug discovery platforms.

As human clinical trials begin with IPSCs, critical ethical, biosafety and regulatory concerns with the therapeutic application of these biologic products must be assessed. Preliminary studies in animals have shown that transplanted IPSC derivatives can form teratomas and other neoplastic pathologies in recipients. Once transplanted, these cells are irretrievable and their future genetic stability is unpredictable. The use of autologous IPSC derivatives in patients would diminish the prospects for immune rejection but the genetic "memory" of the cells might create unforeseen challenges, especially in patients being treated for certain genetic and metabolic disease states. A thoughtful compromise between precautionary research studies and comprehensive clinical trials must be developed to guide the assessment of the safety and efficacy of IPSC therapies.

GENOMIC PRIVACY

Mark Gerstein
Gerstein Lab, New Haven, CT, mark@gersteinlab.org

With every new exciting development in genomics come the often underappreciated ethical legal and social concerns. Particularly with regard to issues of privacy, there are ultimate tradeoffs as the technology continues to develop and the real-life applications of genomics become more of a reality. Numerous technical solutions have been proposed, but every technical safeguard is accompanied by increased complications with analyzing and manipulating datasets. Moreover, technical solutions invite both white-hat and black-hat efforts of circumvention, making them less useful in the long-run. Rather we propose a multi-prong approach to dealing with privacy issues in genomics that includes technical, regulatory and social advances that will create an environment that both safeguards privacy, prevents harms associated with a lack of privacy and promotes innovation in the fields of genomics and medicine.

THE ETHICS OF GENE EDITING TECHNOLOGIES IN HUMAN STEM CELLS

Michael W. Nestor, Ph.D., mnestor@hussmanautism.org, Richard L. Wilson

Over the past decade, advances in DNA sequencing and gene expression analysis have yielded technologies that have become less expensive. Consequently, scientists have significantly increased their understanding of the human genome and helped discover new ways to modify genes while working within living cells. In parallel, the use of human stem cells in research, particularly related to topics in regenerative medicine, has significantly increased. One goal for such research is the ability to correct any genetic aberrations in host stem cells by specifically editing out mutations in those cells. By doing so, researchers hope to uncover possible phenotypes related to genotype. Currently research is being persued using this gene correction approach in diseases that have a monogenetic and highly penetrant origin.

Most gene editing approaches (zinc finger nucleases, transcription activator-like effector nucleases) have little appeal beyond basic research because this type of gene correction confers many off-target effects for the cell, and when used *in vivo* might result in unintended harm and/or consequences for the organism. The advent of clustered regularly interspaced short palindromic repeat (CRISPR) technology has largely removed the possibility of off-target effects after gene manipulation. Thus, CRISPR genome editing allows researchers to easily and precisely change the DNA sequence at specific areas on the chromosome in stem cells and *in vivo* with minimal harm. CRISPR makes gene therapies more widely available and will provide treatments for simple genetic disorders such as sickle-cell anemia. It could eventually also lead to cures for more complex diseases.

CRISPR genome editing has already reinvented the direction of genetic and stem cell research. For more complex diseases it allows scientists to simultaneously create multiple genetic changes to a single cell. Technologies for correcting multiple mutations in an *in vivo* system are already in development. On the surface, the advent and use of gene editing technologies is a powerful tool to reduce human suffering by eradicating complex disease that has a genetic etiology. In this paper, we critically analyze this hypothesis from an ethical perspective by developing an anticipatory ethical analysis of potential issues related to the intersection between gene editing technology and human stem cell research. We pay particular attention to the concept that gene editing strategies may reduce human genetic diversity as they serve to reduce suffering.

THE RELEVANCE OF GENETIC RESOURCES GOVERNANCE TO SYNTHETIC BIOLOGY

Catherine Rhodes

In discussions of how to address synthetic biology within the Convention on Biological Diversity, concerns have been expressed that synthetic biology is currently unregulated and that proceeding with work in the area is unethical unless a strict precautionary approach is applied to it: "scientists aren't just mapping genomes and manipulating genes, they're building life from scratch – and they're doing it in the absence of societal debate and regulatory oversight."

International governance of genetic resources is extensive, and because most of the inputs into and outputs from synthetic biology can be classified as genetic resources (fitting the international definition of "genetic material of actual or potential value"), it is clear that this is not an unregulated field. Existing rules may, however, need adaptation or guidance on their interpretation in this context, and some additional rules and guidance may be needed. This paper therefore examines the extent to which existing rules cover concerns associated with synthetic biology as an emerging technology, identifying any gaps and problematic areas. It will focus particularly on two areas: deliberate or unintentional release of synthetic genetic resources into the environment (including coverage of potential misuse); and ownership, access and benefit-sharing. It will argue that in areas that are well-covered by existing regulations, proceeding with work in synthetic biology is not unethical, but that there are areas which need further consideration by the international community in relation to both synthetic biology and other novel and/or converging technologies.

ETHICAL IMPLICATIONS ON 'CREATING LIFE': THE FIRST SYNTHETIC CELL

Dr. Beena Jose, Dr. Binoy Jacob Pichalakkatt
Jesuit School of Theology of Santa Clara University, 1756 Le Roy Avenue, Berkeley, CA 94709, *USA*
Email:drbeenajose@gmail.com
Jesuit School of Theology of Santa Clara University, 1756 Le Roy Avenue, Berkeley, CA 94709, *USA*
Email:binoysj@gmail.com

The emergent new science of synthetic biology is challenging especially entrenched distinctions between life and non-life, the natural and the artificial, the evolved and the designed, and even the material and the immaterial. This paper aims at exploring the ethical concerns over 'creating life' with special emphasize to Crag Venter's synthetic cell with a view to ensure hope and security in the context of the scientific predictions and mounting apprehensions. It underscores the worries that synthetic cells are inherently bad because they are unnatural or that their creators are 'playing God.' The analysis of the prospect of creation of synthetic cell by Crag Venter and team suggests that it could be considered morally justified and the project is typically be prompted by laudable motives. We conclude that the creation of synthetic cell seems hospitable when it is in accord with God's good and loving purposes rather than serving chaos and destruction. The study illustrates that making decisions about synthetic cells requires prudent vigilance and responsible environmental stewardship about accepting uncertain risks when warranted by the potential gains.

THE AVAILABILITY AND COMPREHENSIVENESS OF PATIENT EDUCATION TO COUNTER THE PREMATURE MARKETING OF UNPROVEN STEM CELL INTERVENTIONS ("STEM CELL TOURISM")

Zubin Master, PhD[1, 2], Kelsey Robertson, BA, JD[2], Daniel G. Frederick, BS, MPH[3], Christen Rachul, BA, MA[4] and Timothy Caulfield, LLM, FRSC, FCAHS[2]
[1]Alden March Bioethics Institute, Albany Medical College, Albany, NY, zubin@zubsplace.com, [2]Health Law Institute, University of Alberta, Edmonton, AB, [3]School of Public Health, University at Albany, State University of New York, Albany, NY, [4]School of Linguistics and Language Studies, Carleton University, Ottawa, ON

Stem cell tourism refers to the direct-to-consumer advertised industry where patients undertake unproven stem cell-based interventions (SCBIs). One proposal to curtailing this market is to educate patients, physicians, and the public about the dangers of receiving unproven SCBIs. Several groups have invested significantly into public education including the International Society for Stem Cell Research, Stem Cells Australia, the UK MS Societies, and we have also created a Canadian patient booklet (http://bit.ly/scnpatientbooklet). Despite these efforts, no assessment of the accessibility or comprehensiveness of publically available educational content has been made – an examination necessary to begin determining the effectiveness of public education on unproven SCBIs. We examined online education offered by 175 scientific organizations (n=50) and patient advocacy groups (n=125) of five diseases/injuries (MS, cerebral palsy, spinal cord injury, Parkinson's disease, and ALS). Organizations' websites were analyzed for educational content on stem cell science, ethics and policy, and unproven SCBIs. Overall, scientific organizations had significantly more content on stem cell science (51%) than patient advocacy groups (21%). Even though there was at least some information on stem cell science, both scientific organizations (16%) and patient advocacy groups (12%) had very little information on stem cell treatments, tourism and clinical translation. These results indicate that there is little web-based information on unproven SCBIs and clinical translation that is comprehensive in nature. We need to be realistic about the degree to which education could deter patients from seeking unproven SCBIs. Educational tools can help patients make informed healthcare choices and add to a more informed public debate. Thus, efforts to educate patients/public should continue.

ETHICAL PROBLEMS IN EXOME SEQUENCING IN RESEARCH AND CLINICAL SETTINGS

Elaine E. Englehardt[1], Michael S. Pritchard[2]
[1]Utah Valley University, [2]Western Michigan University

A new generation of DNA sequencing tools has made it possible to determine the complete sequence of a human genome for costs of thousands of dollars rather than the millions of only a few years ago. The cost of determining the exome, or protein-coding, sequences within the genome is even significantly less costly than the genome. Our presentation focuses on the ethical implications of how information gained from this should be used, both in research and in clinical settings. Some of the ethical concerns include: 1) potential conflicts of interest of physicians who use their patients as participants in research; and 2) communication challenges for clinicians who have to determine whether and how to inform patients of findings, especially when patients (and perhaps even the patients' primary care physicians) do not know how best to interpret the practical significance of the results.

In exploring these questions, we will draw from our recent advisory role in a project proposed by a University of Iowa team of medical researchers [1]. These researchers specialize in the area of severe visual impairment and are proposing to use exome findings from their patients in their research as well as in providing them with clinical advice.

The use of the exome requires that a large fraction of each patient's genomic sequence be obtained and analyzed. However, in addition to uncovering information relevant to what they were originally looking for regarding their patients' visual disorders, researchers can expect to uncover many incidental findings—findings that are apparently unrelated to those original questions. Such incidental findings will include variants of both known and unknown significance, information about carrier status, and information about risk for late-onset disorders. In the case of an incidental finding, there are numerous ethical considerations regarding when (and how) a result should be presented to a research subject or a patient. A common view is that individual sequence variation results should be provided to participants only in circumstances where this can be expected to have actual utility for them. For example, the results may suggest a preventive or therapeutic intervention, or the information could be used for reproductive decision-making or general life planning.

In light of uncertainties about how to proceed in this rapidly developing area, NIH urges that there is a pressing need to develop rational, ethically acceptable, and workable criteria to help guide decision-making about what types of information can, should, or should not be offered to patients in clinical contexts. Another vital concern is how this information should be conveyed, especially since many physicians and clinicians are not yet well prepared to communicate with patients about the possible significance of exomic findings.

In our presentation we will discuss how patients in various clinical contexts might understand (or misunderstand),

react to, and make use of individual exomic results they are offered. Additionally, we will discuss difficulties in discerning patients' wishes and expectations regarding the return of results during the informed consent process. Finally, we will discuss problems that genetic counselors and geneticists face in protecting patients emotionally and physically, as well as in ensuring their confidentiality and privacy.

[1] "Exome Sequencing for Clinical Care of Vision Disorders," proposed to NIH by Edwin M. Stone, M.D./PhD.; Val Sheffield, M.D./PhD.

THE GOODS OF HEALTH CARE

Wade L. Robison
Ezra A. Hale Professor in Applied Ethics
Rochester Institute of Technology, wade.robison@gmail.com

Abstract: Our health-care system is a natural social artifact, something we have created, that is, because of natural features that make us subject to illness and bodily faults. It is like language in the sense that its current structure is the result of many different decisions by many different individuals. Like language, it is not fixed, but evolves, and it evolves as a result of many different individuals with differing interests and different ends making different decisions that affect our health.

It is no wonder that our current health-care system is a hodgepodge, with its inefficiencies and significant failures to provide even the basic minimal health-care services to so many. It is a tragedy that preventable medical mistakes are the third leading cause of death in the United States, after cancer and heart disease, with over 400,000 deaths a year, but it also a telling mark of a system that fails in what ought to be its basic goals.

Our health-care system ought to be organized to achieve a set of basic goods — that birth and infancy occur in such a way and in such circumstances that we have the highest chance of continuing to live without harm, that those of us who live have the best preventive care so that we will be least prone to disease and bodily faults, that those of us subject to disease and bodily faults are well taken care of, that when we are elderly, we receive adequate care, that we have each and all of these without significantly harming such other interests as our financial well-being, and that every one of us has reasonable and assured access to these minimally adequate basic goods.

Every complex human enterprise has ends it achieves. Some it is designed to obtain. Some arise because of a lack of coherent design. Some are effects of its design and some of its incoherence, and of those, some are natural concomitants of the ends the enterprise is designed to achieve and others are unintended and unwanted. The 400,000 deaths a year from preventable medical mistakes are unintended, unwanted and unwarranted in a system that ought to be designed to achieve the basic goods of any health-care system.

THE ETHICAL CONUNDRUM OF HPV-ASSOCIATED HEAD AND NECK CANCER

Andrew G. Shuman, MD[1,2]
[1]Division of Head and Neck Oncology, Department of Otolaryngology - Head & Neck Surgery; University of Michigan Health System, Ann Arbor, MI
[2]Center for Bioethics and Social Sciences in Medicine (CBSSM); University of Michigan Medical School, Ann Arbor, MI, Email: shumana@umich.edu

There is a growing epidemic of head and neck cancer associated with human papillomavirus (HPV). In general, patients presenting with these malignancies do not feature traditional risk factors such as tobacco and alcohol abuse, and the demographic at risk is thus distinctly different. There remains considerable uncertainty regarding the clinical significance and implications of HPV status in this patient population. This uncertainty begets ethical quandaries regarding how to disclose and discuss the impact of HPV in the context of a cancer diagnosis, as well as how to educate and inform the general public.

How should HPV be broached when a patient is newly-diagnosed with head and neck cancer? How should patients be counseled regarding potential communicability and the implications for their family and partners? How can the stigma of a sexually transmitted disease be mitigated among these patients? What is the role of HPV vaccination in this setting? How should HPV awareness and education be integrated into prevention and screening strategies?

Clinicians including physicians and dentists will frequently need to manage expectations and fears related to this emerging clinical entity. This presentation is designed as a primer introducing the ethical issues that are implicated by the emerging epidemic of HPV-associated head and neck cancer.

IS IT WRONG TO LIVE TO A 100?

Gregory E. Pence
Chair, Department of Philosophy, University of Alabama at Birmingham

The allocation of expensive medical resources at the end of life, and the issues of intergenerational justice, are two of the most important of our times. Daniel Callahan and Leon Kass have argued that it's wrong for medicine to help humans live beyond natural limits. In this presentation, I argue that they may be correct, but for different reasons. I discuss Judith Jarvis Thomson's famous essay on abortion, beginning with the conclusion that a woman is not a bad person who, after experiencing an unconsented-to pregnancy, decides against letting an embryo use her body for 9 months to become a baby. Next, I use John Hardwig's equally famous essay, "Is there a Duty to Die?" to suggest that a 55--old daughter also is not a bad person if she does not give up the next 25 years of her life so that her 75=year-old mother can live to a 100. From these two cases, I ask whether a whole generation of 75-year-olds, can claim of younger people, as their right, support and resources that would enable them to live to a 100. I argue that it would be nice and supererogatory if younger people sacrificed so that millions of 75-year-olds could live to a hundred, but that they are not morally obligated to do so. In other words, they are not bad people if they let the 75-year-olds die.

Why? Because the young never had a say in creating any putative obligations to care for 75-year-olds. Any sacrifices of the elderly for the young were voluntary, not contingent upon a reciprocal sacrifice.

So, "is it wrong to live to a 100?" My answer is, "Maybe. Depending on how much sacrifice is required of healthy young people to get you there.

EBOLA VIRUS DISEASE (EVD): A CASE FOR SHARED NATIONAL AND GLOBAL RESPONSIBILITIES IN GLOBAL HEALTH CRISIS

Evaristus Chiedu Obi, MA, MSW, MPA, PHD
Duquesne University, Center for Healthcare Ethics

The current outbreak of EVD which has resulted in more cases and deaths has devastated West Africa especially Liberia, Guinea, and Sierra Leone. The pandemic nature of EVD in those countries engenders global health crisis which establishes the urgent need for shared national and global responsibilities for dealing with the health crisis. With a broader issue of global health inequalities in health care resources and capacities, these countries in West Africa ravaged by the current EVD outbreak are not equipped to deal with the crisis. They significantly lack infrastructure, equipment, trained health care workers and strong primary health systems.

International human rights law is argued as providing a theoretical framework for national and global responsibilities for realizing the core obligation that stem from socio-economic rights and for effectively addressing EVD outbreak in West Africa. The obligation to provide international assistance in realizing the minimum essential level of the right to health which includes treating EVD patients and consequently effectively controlling the outbreak in West Africa is argued as imperative.

A Global Health Fund, rather than the current ad hoc solution of sporadic assistance from some rich countries is proposed as critical in providing infrastructure, equipment, training health care workers and strengthening primary health systems of those poor countries in West Africa. An effective Global Health Fund rooted in the concept of financial sustainability would significantly enhance the realization of the right to health in general and in effectively controlling EVD outbreak in West Africa in particular.

THE ETHICS OF TRANSGENDER INCLUSION IN THE INHABITABLE MEDICAL SPACE

Ronica Mukerjee DNP(c), MSN, MsA
Assistant Professor, Nursing, Saint Francis College
182 Remsen St, Brooklyn, NY 11201

As research around transgender medicine progresses, there is still slow development in creating comfortable, safe spaces for transgender patients. Some of this lack of progress stems from the assumptions that transgender status is a mental health issue, that transgender status is a societal aberrance, or that transgender medicine is unsafe or harmful to patients. This presentation will explore the ethical reasons that clinicians should provide relevant, humane care to transgender patients including care that respects their gender status alongside treatment of their pertinent medical issues. The speaker will also showcase significant research discussing the changes in mental health that occur with inclusion or exclusion of hormonal or other appropriate medical management.

ETHICAL DILEMMAS IN ORTHODONTICS IN A DENTAL SCHOOL ENVIRONMENT

Arun Urala, MDS,
Professor and Head, Department of Orthodontics,
Manipal College of Dental Sciences, Manipal University, India 576104.
arunurala@gmail.com

Orthodontics is a branch of dentistry which combines science with art. Hence it is a commonly accepted fact that no two orthodontists can ever agree on a treatment regimen for any defined problem. These situations are further complicated in a dental school environment where following the evidence based approach to treatment is the norm. Dental schools are the favorite places where patients usually go for a second or third opinion prior to or during treatment. Cases where the clinical specialist in a dental school finds the treatment being given by an outside orthodontist unacceptable are common. The ethical dilemmas arise when the patient after coming to the dental school requests the teaching/clinical faculty to continue his or her orthodontic treatment.

A 15 year old girl with her mother came to the Department of Orthodontics and Dentofacial Orthopedics seeking a second opinion with regards to the treatment with fixed appliance therapy, which was initiated elsewhere by a specialist. She presented with a bilateral Angles class II molar relation and had undergone extraction of teeth in the maxillary arch. She was not sure as to which teeth were extracted (retained deciduous lateral incisor or permanent lateral incisor). The patient with her mother had come to seek a second opinion as she was advised additional extraction of premolars by the treating specialist. The patient was not in possession of the pretreatment records and on further examination she did have a mild mandibular retrusion with fixed orthodontic appliance in place. In addition she presented with bilateral mesially tipped canines with gingival recession, and with elastomeric chains attached from canine to canine in the maxillary arch. The possibilities and options of correcting the prevailing malocclusion were discussed in depth with the patient and the accompanying parent. The patient along with her mother later on a subsequent consultation came back and requested the treatment to be continued in the department, as she was convinced of the options provided in the dental school. The specialist who had initiated the treatment was upset with the patient seeking the second opinion did not wish to have any discussions on the observations made during second opinion, sought in the dental school. It is here it becomes difficult to the clinician to decide to take up a case which was begun elsewhere, with no pretreatment records, periodontally compromised maxillary canines and to treat the case with no further extractions.

The faculty is in a quandary as taking up the case will mean undercutting a fellow specialist. There is a clash between the patient's welfare and respecting a fellow colleague's clinical judgment. Resolving such ethical dilemmas will go a long way in keeping our conscience clear when it comes to advising patients about the best course of action.

DENTAL EDUCATION DISPARITIES IN CHILE: ETHICAL CHALLENGES FOR ACADEMIC PROGRESS IN CHILEAN DENTAL STUDENTS

Martin Pendola[1], Guido Jaramillo[2], Esteban Vargas[3], Gonzalo Antiqueo[4], Mario Flores[3], Subrata Saha[1].
[1]SUNY Downstate Medical Center, Brooklyn, New York. [2]Universidad de Talca, Talca,Chile. [3]Universidad San Sebastian, Puerto Montt, Chile. [4]Universidad de la Frontera, Temuco, Chile.
martinpendola@yahoo.com

Dental School is a challenging academic path which requires a competitive admission process, a demanding curriculum and a complete set of skills, tools and materials to master. Usually Dentistry is in the top 5 careers in terms of admissions difficulty and the same position for career costs at any country in the world.

Due to the clinical nature of the profession, an important portion of the education is based on clinical activities on actual patients under academic supervision. The students provide dental treatment to actual patients and they are evaluated on diagnostics, performance, and results as part of their academic progress. In Chile, Universities usually have their own dental clinic to perform these academic / clinical activities with the proper supervision and equipment. Also, most of Dental Schools clinics represent an alternative for dental treatment with lower costs for the patients and also a relief to the overwhelmed public system.

However, there is one important flaw in the system on which the students are evaluated. Students are required to fulfill with a determined number of treatments as part of their training. As a random example, a last year student may be required to complete 4 dental crowns and 3 dentures. These are challenging processes for a trained dentist, and even more for a student. Unfortunately, they are also expensive treatments for the patients.

Due to many factors, patients some times are not capable to pay their treatments in the time frame required for the student (the semester), or they have to forfeit the treatment for personal, financial reasons. That is a situation common for any dental professional anywhere in the world. Dental students also face this situation, but the consequences are different: the Universities usually follow the policy of stop the clinical progress of the student if the patient does not pay the treatments. Or even worse, some institutions do not include the treatments completed to the student's record if the procedures are not fully paid, even if the procedure was successfully finished and approved.

The situation described is common in many Chilean Dental Schools. It is the challenge the authors faced as students, and it exposes a strong ethic challenge. A registered student of any university has passed an admission process, and in the case of dental schools, the student showed his/her fit for clinical training after passing a comprehensive set of courses and examinations. During the clinical training, the student is evaluated on the quality and quantity of dental procedures completed over the semester or year. This policy represents a link between the academic progress of the students and the financial situation of the patients. If the patient cannot afford the treatment, the students see their academic performance affected. Why should a student academic performance be subject of modification or penalty because of the financial standing of a third-party, in this case, the patient?

ETHICAL ISSUES IN RENDERING DENTAL CARE IN REMOTE AREAS.

Shashidhar Acharya, MDS
Professor and Head, Department of Public Health Dentistry, Manipal College of Dental Sciences, Manipal Manipal University, India 576104, sh.acharya@manipal.edu

The concept of informed consent prior to dental care is a relatively recent concept and it is more prevalent in developed countries where patient rights are paramount. However the same cannot be said about developing countries especially Asian countries where paternalism runs deep. Paternalism originates from the deeply ingrained respect for elders which is considered sacrosanct in Asian cultures. Informed consent is not followed widely even in urban areas of India, let alone rural areas. Issues of paternalism cropped up during the course of the Amchi program held in Ladakh. The barren and high altitude region of Ladakh in the Indian Himalayas is one of the most inhospitable and remote places in the world. This program was the outcome of a collaborative effort involving, Manipal University, India and the European Dental Students Association, the student body of the Association for Dental Education in Europe (ADEE).This program aimed to deliver basic dental care to this remote region and also inculcate basic oral hygiene skills and knowledge among the children. During the course of the program we came across numerous cases

where school children had extensive untreated dental caries, some with abscesses which need treatment like root canal or extractions or incision and drainage. Since the region was remote with no dental care and parents were usually living far away, treatment decisions had to be taken without the informed consent. The school authorities' permission was obtained for treatment as waiting for consent would mean depriving the children of even the rudimentary dental care that was desperately needed. In this case the treating doctors exercised paternalism and the school authorities, some degree of proxy consent, both of which were not the ideal course of action. Informed consent may not be the best course of action and in some cases may be counterproductive in situations where the patient is completely unaware of the severity his or her oral problems and regular and accessible dental care is far away.

GENOMICS, ETHICAL ISSUES, AND THE PRACTICE OF DENTISTRY

Alexander J. Schloss, DDS, MSB[1], and Anthony T. Vernillo, DDS, PhD, MBE[2]
[1]New York University College of Dentistry, Department of Periodontology and Implantology, New York, NY
[2]Department of Oral & Maxillofacial Pathology, Radiology & Medicine, New York, NY

Medicine and dental medicine are moving rapidly into a new era of dramatic change in the delivery of healthcare. Instead of treatment in a generic "one-size-fits-all" approach, the model of care will "flip" to one in which physicians and dentists provide care tailored to the individual patient. In the practice of medicine, cancer therapy is now targeted to that patient's specific disease based on its genetic make-up (genomics) thereby reducing life-threatening side effects while improving treatment outcomes. In dentistry, biotechnological advances in salivary diagnostics and rapid oral fluid testing may lead to improved treatments in the management of periodontal disease or susceptibility to certain systemic diseases through the detection of genomic transcripts. Genomics is thus no longer an esoteric topic confined only to research laboratories. This burgeoning field is ushering in a new era of personalized health care and our profession must be at the vanguard in using this new discipline to benefit our patients. Genomics and its advances present opportunities and ethical challenges to clinical practitioners. Dentistry must adapt to and manage these advances in a manner consistent with our principles of ethics. This presentation will discuss how dentistry should manage the following issues as these pertain to clinical practice, and include to wit: (1) Direct-to-consumer genetic testing companies and the doctor-patient relationship; (2) Counseling patients on incidental and actionable findings; (3) Ethical and legal considerations to report test results to patients and potentially their next-of-kin; and (4) Inclusion of the ethics of genetic counseling in the dental school curriculum given advances in salivary diagnostics.

GLOBAL HEALTH GATEWAY: ETHICS IN GLOBAL HEALTH"

Dr. Shilpi S. Shah, MDS
Periodontist and Private Practitioner
Reader, Ahmedabad Dental College and Hospital,Gujarat, India

The changing pattern of oral diseases, their frequency and severity, and the disparity of distribution between developing and developed countries require changes in the strategies of dental education and oral health care delivery systems. The current situation features huge unmet treatment needs, striking inequality in delivery systems, and absence of an adequate community-oriented prevention system. People in developing countries are burdened by a significant number of oral diseases, which are further aggravated by poverty, poor living conditions, lack of dental awareness, and the absence of appropriate policies and funding to provide basic oral health care.
People in deprived communities, certain ethnic minorities, homebound or disabled individuals, and elderly populations, however, are not sufficiently covered by the oral health care system globally. Also the Dental diseases are a costly burden to health care services, accounting for between 5 and 10 percent of total health care expenditures and exceeding the cost of treating cardiovascular disease, cancer, and osteoporosis in industrialized countries. The "ethical focal point",for a class of deprived patients, at a regional level in India is an organization called Ahmedabad Dental College and Hospital(ADCH) which highlights on providing the basic to complex dental treatments(at reasonable cost) keeping in mind their cost of living and basic requirements. Therefore free food is provided to all patients along with free transportation.

Health ethics has been an integral part of the activities of many units and departments at WHO.ADCH works at community based level by organizing camps called "VATSALYA" for old people, "JAGRUTI ABHIYAAN "; for awareness in patients about periodontal conditions, "ANTI TOBACCO PROGRAMS "and the list goes on.

Our mission on global health includes the examination of the ethical issues raised by activities throughout the organization, including the regional activities regarding a wide range of global bioethics topics for a fair access to health services.

MEDICAL ETHICS & HEALTH POLICY IN MILITARY AND VETERANS HEALTH

CAPT Mark B. Lyles DC USN
VADM Joel T. Boone Professor of Health and Security Studies
U.S. Naval War College, Center for Naval Warfare Studies, Newport, RI

Modern military medicine has seen unprecedented advances during the last forty to fifty years largely due to new discoveries in biology and developments in medical technology. New advances have extended the ability to save lives in combat and brought improved quality of life for our wounded combat veterans. However, these advances in science, medicine and technology have also brought new pressures on our limited resources. Our increased knowledge in epidemiology, toxicology, and adverse health risks has directly challenged our ethical and moral values and our oath to 'first do no harm'. We must be prepared to understand and deal with the financial reality when technology is available to expose health risk and diagnose not only disease, injury and pathology but also the healing and repair of damaged tissues. The political ramification of 'speaking truth to power' almost always ends with the whistleblower scientist/clinician being ostracized, ridiculed, or even fired. The advances in science has had an amazing impact on military and veterans medicine, however the use and abuse of information and data still continues today to the detriment of our warfighters and veterans. Scientists and health care providers should, of course, a part of that debate sharing in common the truth and scientific data of the impact that medical information will impart. The ability to regenerate or replace biological components, to heal and repair tissue is useless without the courage to admit that wound-injury-pathology exists. What are the ethical considerations of our ability to diagnose disease yet refuse to treat the patient? What are the moral, ethical, legal, and professional obligations of military/veteran's health care providers under such situations? These possibilities are not the future but the present. Can we prevail under policies and politics that consider funding over obligations and promises?

MADE-TO-MEASURE PALLIATIVE CARE: AN ETHICAL IMPERATIVE FOR GROWING CULTURAL PLURALITY IN THE U.S.

Nathan A. Boucher, PA-C, MS, MPA, CPHQ
Doctor of Public Health Candidate, SUNY-Downstate, School of Public Health, Nathan.boucher@downstate.edu

Delivering culturally attuned *palliative care*, or non-curative support for the dying and those in need of serious symptom management, which is "made-to-measure" is an ethical imperative if that care is to be just. Drivers of health-related decision making are embedded in individuals' culture. These differences in culture play a role in the way people perceive the death and dying process. Standardized approaches to health care are not always congruent with a patient's cultural identification and this can result in suboptimal care delivery that can affect patient outcomes as well as patients' and families' satisfaction with care. The 2010 U.S. Census data indicates further rapid growth of racial and ethnic diversity, especially among those of Hispanic and Asian origins. Six tiers of influence are identified and discussed as areas where change must occur to achieve system-wide improvements in the delivery of culturally attuned palliative care that is just. These are: *individual, environment, direct care providers, organization providing services, community* and *health systems & governments.* Affecting change on each of the identified tiers may, individually and through synergistic effect, achieve the most concrete changes towards improving culturally appropriate, made-to-measure end-of-life and palliative approaches to care. When clinicians and health care systems know more about the people they serve they can provide the correct *amount* of care -

impacting savings, expenditures, and health outcomes - and the correct *approach* to care that incorporates cultural values and is more ethically sound.

CHANGING ATTITUDES OF DOCTORS IN THE US; DO WE REALLY UNDERSTAND WHAT SHARED DECISION MAKING MEANS AND ARE WE READY TO ACCEPT THE CONSEQUENCES OF THOSE DECISIONS?

David Dinhofer, MD, MDMI, Adjunct Assistant Professor of Biology
NYC Technical College of CUNY

Shared decision making (SDM) should be the ethical standard of medical care in the US. While most doctors accept and understand SDM from an intellectual perspective and it is being taught as the standard in medical school, they find it hard to let go of their position of advisor from the paternalistic perspective. The major reason doctors have trouble letting go of paternalism is because doctors want to do what they think is right for the patient and they know most patients won't understand the complexity of diagnosis and treatment. Other reasons include: limited time to explain with pressures to produce, old habits are hard to change, people in power are often afraid to do anything to affect their status, and doctors are afraid to look weak.

I witnessed these problems first hand when both of my parents fell sick and had to be hospitalized. As their health care proxy and a loving son, I felt duty bound to follow their wishes to the "T". Although both of my parents were advanced in age, they were both compos mentis. My job was to oversee the care and to explain to my parents what was going on. They made all their own decisions.

Both of my parents were patients in major teaching hospitals in NYC. Their staff should have been well aware of the change to SDM. Yet, doctors discussed options often without allowing for dissension.

I use my parents' stories as a means to point out decision nodes in their care and discuss how decisions were forced or partially forced for them. By looking at my parents stories, it personalizes the issues and shows how we are affected at the individual level. I would like to present them with a focus of what the key issues of the decisions were so as to point out where shared decision making was obfuscated and where shared decision making would have been a better process.

PATIENTS ARE FROM MARS, DOCTORS ARE FROM VENUS: PATIENTS PREFER PLACEBOS AND PATERNALISM; DOCTORS DON'T

Isabella Guajardo, B.A.
University of California, San Francisco

BACKGROUND: Current medical ethics, law and education all emphasize patient empowerment and shared decision making as a means of avoiding paternalism. But what if this is itself a form of meta-paternalism: that is, are doctors paternalistically deciding that patients may not choose paternalism by forcing them to be involved when they'd rather just feel better and leave it to the professionals?

METHODS: Two separate surveys were administered to a cross-section of adult Americans. The surveys measured attitudes towards paternalistic behavior in various scenarios.

RESULTS: Among other intriguing results, the data showed that over half of respondents state they would prefer that the doctor make all medical decisions for the patient using the doctor's best judgment, rather than coming to a decision together. Approximately half say their friends and family would prefer a combination of both approaches. Roughly 28% would prefer to a traditional model where the doctor makes the medical decisions, and fewer than 20% state that their friends and family would only want healthcare delivered using a shared decision model.

The shared decision model is seen as the preferred method for the rich. Over 70% stated that the rich would prefer shared decision making, while over 60% felt that the poor would prefer a traditional model. Over 80% think that people should be able to choose whichever model they want, and shouldn't have the shared decision or the traditional model forced upon them.

Patients' rejection of meta-paternalism extends from healthcare delivery models to the treatment itself. Over half of respondents want to receive placebos from their doctor if they've previously agreed that the doctor may do so. Approximately 33% of respondents would want their doctor to give them placebos even if they had never discussed it. More than 40% believe that doctors should give out placebos without discussing it with their patients if the doctor believes it is in the patient's best interests. Over 60% of respondents believe that doctors and patients should be able to agree to the use of placebos in situations where an illness has no treatment but a placebo may provide some psychological benefit. Asked to consider what other patients would prefer, well over half of respondents stated that patients in general would prefer placebos to be told there is no available treatment. Finally, when asked to consider what patients would want to be told in a situation where they were about to die, over 40% of respondents stated that patients would rather be told they were going to live in order that the patient dies happy.
CONCLUSION: The commonly accepted dogma in American healthcare that patients want to be fully informed about and share in their healthcare decisions deserves much greater scrutiny. This belief may be more the product of the biases of elite healthcare professionals than the wishes of actual patients.

ANALYSIS OF THE SUNSHINE ACT DATA PERTAINING TO NY ORTHOPAEDIC SURGEONS

Karkare A.[1], Karkare N.[1], Saha S.[2]
[1]New York Orthopaedic Partners, [2]Professor & Director of Musculoskeletal Research

The interactions between the physicians and device manufacturing industries are fraught with many ethical challenges. The Physician Payments Sunshine Act mandates that payments of value made to the physicians be reported publicly. The Centers for Medicare & Medicaid Services (CMS), through its Open Payments Program, released data pertaining to the orthopaedic surgeons in New York for the year ending in September 2014. A total of 3969 providers received cash or value items under various categories, including royalties or license, consulting fees, travel and lodging, speaking at unaccredited medical conferences, and education. The dollar amount ranged from $123.72 dollars to 1,706,174.71 dollars. Most of the recipients were affiliated with major teaching institutions. While the device manufacturing companies need physicians to develop products, this data underscores the potential influence on the doctors receiving payments from industry.

ETHICAL PERSPECTIVES: WITHDRAWAL OF LIFE-SUSTAINING TREATMENTS IN PEDIATRICS.

Danielle Brigham, MD[1], Shefali Karkare, MD[2], and Linda Siegel, MD[3].
1. Department of Pediatrics, Cohen Children's Medical Center
2. Department of Pediatric Neurology/ Epilepsy, Cohen Children's Medical Center
3. Department of Pediatric Chronic Pain and Palliative Care, Department of Pediatric Critical Care, Cohen Children's Medical Center

In children with serious or life-threatening illnesses, Withdrawal of Life-sustaining Treatment (WLT) may be requested by the family or recommended by the healthcare team. Decision making surrounding possible WLT is a complex process involving multiple, often conflicting factors including differing perspectives on quality of life, incomplete understanding of the various issues involved in care of a chronically ill child, and financial considerations. This poster reflects a comparison of two pediatric case studies. The first case involved a 7-month old female diagnosed with Acute Disseminated Encephalomyelitis (ADEM), who was quadriplegic and vent dependent, but appeared to be cognitively intact. The family requested withdrawal of care. The medical team requested an ethics consult and decided on a trial of treatment that would last several months. In the second case, a 1-month old with severe Hypoxic Ischemic Encephalopathy (HIE), medical staff recommended WLT, and the family eventually consented. Both cases raised ethical issues related to conflicts between the families and the medical teams.

These two cases are compared and evaluated against the four basic principles of ethics: respect for autonomy, beneficence, non-maleficence, and justice. In addition, the financial and emotional costs of prolonging life are assessed from the perspective of the patient, the family, the medical staff, and society at large.

OSTEOPOROSIS: A DIAGNOSTIC AND TREATMENT DILEMMA

Prashant S. Kota, B.S.[1], Barbara C. Steele, M.D.[1], Subrata Saha, Ph.D.[2], Nakul V. Karkare, M.D.[1]
[1]New York Orthopaedic Partners, Centereach, NY 11720
[2]Dept of Orthopaedic Surgery & Rehabilitation Medicine, SUNY Downstate Medical Center, Brooklyn, NY 10461

Osteoporosis is a metabolic bone disorder characterized by decreased bone mineral density (BMD) and is often underdiagnosed and undertreated. Treatment of osteoporosis is associated with improved mortality and decreased risk of fracture [1]. However, past studies have documented severe undertreatment of osteoporosis [2,3]. Undertreatment of osteoporosis by primary care and specialty physicians raise various ethical challenges in the management of osteoporosis. Physicians may feel they are not adequately reimbursed for managing a patient who has sustained an osteoporotic fracture. Furthermore, the nature of osteoporosis as a "silent" disorder, similar to hypertension or diabetes mellitus, may preclude physicians from treating an asymptomatic patient. Healthcare policy should be amended by adding Core Measures for osteoporosis management in inpatient and outpatient settings. Additional measures should include implementing incentive payments for healthcare providers in order to allocate adequate resources to the management of osteoporosis.

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THE BIOETHICS OF IMPLANTABLE ENGINEERED MECHANISMS IN ORTHOPEDIC SURGERY

Sarani Chatterjee[1], Dr. Ravi Balasubramanian, PhD[2], and Dr. Courtney Campbell, PhD[3]
[1]School of Chemical, Biological, Environmental Engineering, OSU, [2]School of Mechanical, Industrial, Manufacturing Engineering, OSU, [3]School of History, Philosophy and Religion, OSU

The primary motivation for developing medical implants is to restore human function for different medical conditions. For example, bone-shaped implants are used in hip replacement surgery for restoring hip function, pacemakers correct irregular heartbeats, and neuroprosthetics enable leg amputees to walk even after their devastating injury. The Robotics and Human Control Systems Lab at Oregon State University has developed a new class of implants that have the potential to replace the suture in orthopedic surgeries like total knee replacement and tendon-transfer surgeries. These implants are engineered mechanisms in the form of pulleys, levers or artificial tendon-networks for attaching muscles to tendons and bones in place of using a traditional suture to make the attachment. Since the implants can customize the transmission of forces between a muscle and tendons or bone, they provide the opportunity to re-engineer the body based on the patient's desired musculoskeletal function. It is expected that these implants will improve overall joint function and provide more options in surgery, thus improving quality of life.

The objective of this paper is to explore the bioethical issues of the new implantable engineered mechanisms. This technology has significant engineering and ethical issues, including material and device design, determining the metrics to evaluate the implant, validating the surgical procedure that uses the implants, and reducing risk. While considering these engineering challenges, we will primarily focus on the following bioethical issues regarding the implants: Do implantable engineered mechanisms symbolize hybridization of the human body, and if so, might such mechanisms affect an individual's sense of self and cultural identity? As the risks and benefits of the procedure are being explored, how can human research subjects give an informed consent to a procedure based on disclosure of both risks and benefits? Do the implants raise social justice issues, such as differential access to new technologies, or diversion of scarce resources?

ETHICS AND TRUST IN THE PHARMACEUTICAL INDUSTRY: COULD RANKING NEW DRUGS AND COMPANIES ON TRANSPARENCY, ETHICS AND POPULATION HEALTH CRITERIA HELP?

Jennifer E. Miller, PhD
Assistant Professor, Department of Population Health, Division of Medical Ethics, NYU Langone Medical Center

Dr. Miller will map key ethics, trust, and governance challenges in healthcare innovation, focusing on how medicines and vaccines are researched, marketed and made accessible globally. A broad project to measure and rank new medicines, vaccines and companies on ethics, population health and transparency criteria to help recognize good practices in drug companies and healthcare innovation as well as incentivize reform where needed- will be introduced. Preliminary findings from the OpenPharma Index on transparency in clinical trials will be discussed.

ETHICS AS ANALYSIS AND ETHICS AS FEELINGS: THE INTERPLAY OF COGNITION AND EMOTION ON ETHICS EDUCATION IN BIOLOGY, ENGINEERING AND MEDICINE

William E. Kastenberg, Professor Emeritus
University of California at Berkeley, billkastenberg@berkeley.edu

Abstract. Analytical deliberation regarding normative ethical principles by scientists and engineers is often incongruent with society's perception and emotional reactivity to our emerging technologies. Recent advances in technology challenge a large segment of society's values, assumptions and beliefs, especially regarding the ecology of life. And the literature is not always clear about whether or not these incongruences and challenges are emotional, mental or spiritual in nature. In this paper we provide a context for incorporating both emotion and cognition in the resolution of ethical issues in science and engineering.

The context for the approach developed in this paper is partly based on this author's experience teaching an upper division engineering ethics course for nearly a decade, and moderating a freshman seminar for almost as long, where it became quite clear that students already arrive at the university with an implicit set of values, assumptions and beliefs. In many cases, these students have difficulty reconciling their intuitive beliefs and implicit frameworks with the explicit or normative ethical frameworks taught in class. Oftentimes class discussion evolved into emotional reactions to ethical issues, moral reasoning coming much later. To say it another way, when students, like most members of society, are presented with an ethical dilemma, they almost immediately make a moral judgment as to right or wrong, and then only afterwards, begin searching for reasons to validate (or in some cases, to invalidate) their initial judgment.

The context was formalized as part of an NSF Ethics Education in Science and Engineering (ESEE) Grant initiated in August 2012 at Berkeley. As will be described in the paper, the context engages findings from the philosophy of emotion that emphasizes the centrality of emotions to moral life, particularly with respect to scientists and engineers. In this presentation, the focus will be on "self-interest" versus the "social contract" as an example of the interplay of emotion and cognition. The objective of this paper then, is to describe the context and the implications of this approach for resolving ethical issues that arise in Biology, Engineering and Medicine, as well as providing a new definition of moral behavior.

A SOCIAL MEDIA PLATFORM FOR ETHICS ACROSS THE CURRICULUM

Kelly C. Smith, M.S., Ph.D., Da.D.
Department of Philosophy & Religion, Clemson University, Clemson, SC 29630

This Fall, the Clemson University (a community of some 25,000 students, faculty and staff) began a partnership with a private company, Novarete', to develop and implement an online system designed to foster campus wide awareness and discussion of ethics in general and our shared institutional values in particular. The system uses

weekly ethical dilemmas to lure students into a very sophisticated social media platform. Their responses to the dilemmas are used to compute each student's alignment with the classical values of virtue ethics as well as with the virtue "fingerprint" unique to the various campus groups to which they belong. The idea is to foster a campus wide series of discussions, not just about specific ethical issues, but about values in general and how our selection of values impacts the organizations we belong to.

The Ethos system has several key features which make it truly the first of its kind. To begin, there is a case bank of over 400 ethical dilemmas which have been analyzed in terms of their embedded virtues. One of these will be sent out each week to all members of the campus community in a variety of ways that will make it very difficult to miss. Everyone will be invited to respond to these with a simple multiple choice answer indicating their preferred course of action. Their responses will then be analyzed by the system in terms of the classical virtues. In addition, prominent groups within the community (e.g., student government, Greek organizations, departments and disciplines, etc.) will be asked to identify the values they feel are most important to their identity. Together, these two data streams will allow us to compare each individual community member's values to the ethical ideals of the various community groups. All this data will be accessible in a user friendly fashion, allowing any user to see snapshots, not only of how their responses break down in terms of classical values, but also of how they align (or misalign) with the avowed values of other groups on campus. Not only should this spark enormous interest in ethical discussions in general, but the way the data is presented will force the various groups to actively reflect on what they stand for and why. Finally, there is a "kudo" system embedded in the software that will allow every member of our community to easily reward meritorious acts by any other member with public recognition. So if someone loans you an umbrella on a rainy day, you can recognize their behavior with a public "shout out" sent from your phone as you walk through the rain that notifies everyone on campus of what your good Samaritan did and explicitly ties their actions to one of the community's shared values.

MITOCHONDRIAL DISEASE AND THREE-GENOME BABIES: THE SLIPPERY SLOPE INTO HUMAN GERM LINE GENE MODIFICATION

Sheldon Krimsky
Carol Zicklin Professor of Philosophy, Brooklyn College
Lenore Stern Professor of Humanities & Social Science, Tufts University

In 1997, a group of scientists specializing in assisted reproduction, reported the first human pregnancy following cytoplasmic transfer from donor oocytes into eggs of a patient who was having difficulty conceiving. In essence, they genetically modified a human egg by transplanting healthy donor mictochondrial cells into eggs with defective mitochondria. Compared to the tsunami of media attention after the first IVF baby and after the cloning of a sheep, there was barely a faint acknowledgment of this procedure in the popular press. But its ethical implications are profound. My talk will examine the pre-natal therapies designed to prevent the birth of a baby with mitochondrial disease and the ethical implications of genetically modifying human gametes on the long term health of the child and on opening up the floodgates for widespread human germ line modification.

BIOMEDICAL ETHICS AND LEGAL PERSPECTIVES

Bijayesh Haldar[1], Bishnanand Dubey[2], Durg Vijay Rai[1]
[1]Centre of Biological Engineering, [2]School of Law and Constitutional Studies, Shobhit University
Gangoh, Saharanpur, UP, India

Biomedical sciences have expanded considerably in the last few decades and received a special attention for improvement of quality of human life. In recent year, the biomedical sciences have emerged intogrowing field of innovative scientific research including clinical trials of various new medical devices and drugs. Therefore, it is very important to have a social enforcement to give importance of the contribution of morality, Ethics in governing laws, of biomedical sciences. The combined values will make a rule to regulate the use of different animals or humans for experimentation and/or trial of new drugs and vaccines. The new medical products must be used meticulously for any scientific experimentation and it should not infringe the basic human and natural rights. It has been universally

accepted that without any human clinical trials no vaccine or new drugs can be launched in the market. Similarly, it is also important that the participants in such clinical trials should be abreasted properly about the related consequences of the trial. However, there are various reports available by different global bodies to deal with law, ethics and morality, such as World Medical Association (WMA) guidelines, Nuremberg codex and United Nation declaration of Bioethics and Human Rights. But even with these rules and guidelines, a legitimate enforcement mechanism is required to provide equal priority to ethics and morality with law in legal framework. Ethics and morality are used as a part to create laws but the priority of ethics and morality are oftenly ignored. Although, the various countries in the world applied strict legal rules for scientific experimentation on human or animals, there is urgent need of implementing universal code for including them in scientific experimentation or clinical trials. An attempt has been made to initiate universal rules/guidelines, which could bridge the gap between law and ethics and morality to ensure, equality, freedom justice, and dignity for individuals and regulating the law in biomedical ethics.

TEACHING ETHICS IN BIOMEDICAL ENGINEERING: A JOINT-VENTURE APPROACH

Xavier Jackson, Zachary Jasensky, Vivian Liang, Melvin Moore, Jake Rogers, Geoffrey Pfeifer, and Kristen Billiar

Educating engineering students on how to identify and navigate ethical situations can increase their awareness of and ability to analyze ethical issues they will encounter in their professional lives. Many engineering programs lack a systematic incorporation of ethics into their curricula, which may leave students without an appreciation of the significance of ethics in everyday engineering decisions. The goal of this project is to develop a system of ethics modules that can be efficiently incorporated into engineering courses. Several methods of teaching ethics were piloted in a sophomore level biomechanics class, in which 80% of students felt they learned the most from a joint-venture method over alternative methods. The blended joint-venture module incorporates an ethics professional as a guest lecturer who exposes students to different tools to understand professional and ethical responsibilities. Currently, joint-venture modules, customized to course content, are being implemented in three biomedical engineering courses at the freshman, sophomore, and senior level. The professors indicate that the ethics analyses are easy to incorporate into their curriculum without distracting from the engineering content. Once the trials are completed and the results compiled, a more concrete conclusion can be made regarding the effectiveness of the joint-venture module.

FACT: IT IS UNLAWFUL TO TEACH ID OR CREATIONISM AS SCIENCE IN A TAX-SUPPORTED SCHOOL. OPINION: IT IS ALSO UNETHICAL

H. Winet
Departments of Bioengineering and Orthopaedic Surgery, UCLA

Classes in biomedical engineering at UCLA usually include engineering and pre-med majors. As demonstrated at this meeting in 2013 and in a follow-up paper, these two fields attract a large fraction of individuals disposed toward highly structured beliefs such as fundamentalist/literalist versions of religions based on the bible or the Quran1. Since the 16th century followers of these religions have resisted the growth of our scientific understanding of the natural world. Such resistance became a war in the 19th century when Charles Darwin derived the theory of natural selection that postulated a random mechanism driving evolution. Evolution itself had become accepted as fact by a number of scientists in the 18th century, but it was given a deistic interpretation, allowing for supernatural guidance. Natural selection replaced this deism with a model devoid of supernatural mechanisms.

In the 20th century, when public education became universal in the United States all children were required to attend school. Science, in particular biology, became part of the curriculum in most schools and Darwinian evolution was included because of its central role in understanding biology. Fundamentalist parents felt threatened by this biology and, driven by their ministers, pushed to get laws passed to drive evolution from the public schools. The famous Scopes trial of 1928 showcased one of these laws. In the aftermath of this trial evolution teaching was downplayed in communities dominated by fundamentalist groups.

In the 1950s the threat of Soviet scientific advances pushed the U.S. congress to mandate enhanced science education in the public schools, including teaching of the neo-Darwinistic model of evolution. Fundamentalists countered the mandate by trying to introduce a bible-based alternative to the scientific model, "creationism" into local science curricula. A series of court cases McLean v. Arkansas Board of Ed. (1982), Edwards v. Aguillard (1987) resulted in making the teaching of creationism in science classes unlawful.

To counter these judgments, creationists developed a reworded form of creationism "intelligent design" (ID) that argued that life is too complex to have evolved by a random process and, therefore, must have been designed by a supernatural, but unnamed, "designer". In a 2005 trial Kitzmiller v. Dover Board of Ed. the district court of appeals found that ID was merely a reworded version of creationism, was not science and was in violation of the first amendment of the constitution.

Despite this history, there are engineers and pre-meds (and even some public school biology teachers) who are creationists/ID-ists. They may object to being taught natural selection. However, it would be unethical for a science professor at a public university to not require the same demonstration of understanding class material from these individuals as for any other class members. They certainly have a right to their beliefs, but these are not a valid part of class material and must be downgraded as would any irrelevant component of an exam answer.

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UNHEARD VOICES OF WILLOWBROOK: A BIOETHICS EDUCATION PERSPECTIVE ON NEW YORK'S INFAMOUS STATE SCHOOL, 1947-1987

Obiora N. Anekwe, Ed.D, M.S Bioethics
obiora.anekwe@gmail.com

Edmund Burke once stated that "the only thing necessary for the triumph of evil is for good men to do nothing." This prolific statement reflects our ethical obligation as medical professionals and bioethicists to shed light on and educate our colleagues about human medical atrocities so that similar medical wrongdoings are not repeated again. The Willowbrook State School, located in Staten Island, New York, once represented one of the most egregious medical crimes against mentally and physically challenged patients. Human experimentation at

Willowbrook took place among patients who lacked the capacity to provide informed consent for participation in a clinical trial. From 1947 to 1987, Willowbrook's patients were subjected to inhuman residential care and subversive medical experimentation. As a living and learning residential facility for the physically disabled and mentally challenged, most of what occurred at Willowbrook negatively affected the medical and psychological conditions of its residents. As a state sponsored institution, Willowbrook existed in an era of negative eugenics and harsh treatment for physically disabled and mentally challenged patients who were seldom medically treated and often experimented upon without informed consent. Throughout the first decade of its operation, outbreaks of hepatitis, primarily hepatitis A, were common at the school. This led to a controversial medical study carried out there between the mid-1950s up to the 1970s by medical researchers Saul Krugman and Robert W. McCollum. A public outcry forced the study to be discontinued.

Within my presentation, I plan to provide a historical background about Willowbrook's unethical human experimentation projects in order to provide ethical solutions and remedies to challenges in educating and medically treating those who are mentally challenged and/or physically disabled. In light of this perspective, I will explain the impact of patient's unethical treatment at Willowbrook through a visual presentation of my original photographs and archival visual representations about Willowbrook and its historical relevance to bioethics, medical ethics, and health care ethics. By presenting Willowbrook through this lens, the viewing audience will metaphorically hear and feel the voices of the institution's former residents. As a result, my goal is to present a transformative argument for global health care ethics reform for the physically disabled and mentally challenged. In addition, I want medical practitioners and interested ethicists to learn from the Willowbrook Experiments and its ethics framework in order to promote a culture of medical justice inherit in fair and equitable treatment for all patients.

ETHICAL CONSIDERATIONS REGARDING INFORMED CONSENT DISCLOSURE IN A RESIDENT TRAINING PROGRAM

James P. Gurtowski, MD, FAAOS; Adam Bitterman, DO

We undertook a project to examine factors affecting the disclosure content of Informed Consent in three aspects of Orthopaedic Practice. With a unique opportunity of surveying 20 residents and 40 attendings in a training program across five clinical settings.

The first aspect of disclosure was regarding the informed consent of the patient with respect to common pharmacologic agents in Orthopaedics. Analyzing the common knowledge, disclosure and off label use of Lidoderm patches and gabapentin.

The second aspect of the study analyzed the disclosure of indicated and off label use of orthopaedic mechanical implants. We looked at the knowledge level of the resident and attending staff as well as aspects of patient education in the informed consent disclosure for the use of common products, type of implant to be used and off label use of implants such as the Endo Button.

The third aspect of practice reviewed was the informed consent disclosure regarding biologically active implants. This focused on the disclosure of sourcing of allograft materials and the disclosure of FDA indications for manufactured biologically active materials. We were interested in comparing the disclosure rates of active vs. mechanical implants.

The surveys showed wide variability not only between practitioners knowledge level regarding each aspect of practice, but also variability in disclosure based on patient education level as well.

We conclude that residency programs should include didactic training regarding the FDA approval process, off label use knowledge base and the ethical disclosure of the use of products across the spectrum of orthopaedic practice.

BRAIN STIMULATION FOR PEDIATRIC TREATMENT VERSUS ENHANCEMENT: IMPLICATIONS FOR THE MORAL PERMISSIBILITY OF INTERVENTIONS IN CHILDREN

Hannah Maslen
Research Fellow in Ethics, Oxford Uehiro Centre for Practical Ethics, University of Oxford, UK

There have been calls for “extreme caution” in the use of non-invasive brain stimulation to treat neurological disorders in children, due to particular gaps in scientific knowledge. However, empirical unknowns are not the only important consideration when deciding whether pediatric interventions are permissible. I argue that compensatory functional trade-offs associated with brain stimulation present a challenge to the permissibility of using this technology in children, insofar as such trade-offs limit the child's future options. I argue that the distinction between treatment and enhancement – and thus between pathology and ‘normal’ functioning – has some normative force here. As the intervention moves away from being a 'treatment' toward being an 'enhancement'—and thus, crucially, toward a more uncertain weighing of the benefits, risks, and costs—parental judgments of the child’s best interests diminish, and the need to protect the child's future autonomy looms larger. Brain stimulation for 'enhancements' involving trade-offs should therefore be delayed, if possible, until the child has reached a state of maturity and can make an informed, personal decision about the proposed intervention. Brain stimulation for 'treatment', by contrast, is permissible insofar it can be shown to be at least as safe and effective as currently approved treatments, which are (themselves) justified on a best interests standard.

ETHICAL BASIS FOR PATIENT CENTERED HEALTH INFORMATION TECHNOLOGY

David Dinhofer, MD, MSMI[1], Stephen Beller, PhD, NHDS[2]
[1]CityTech, CUNY, Brooklyn, NY, [2]Inc, Croton-on-Hudson, NY

The authors believe there is an ethical foundation that should guide developer to focus on Patient Centered Health Information Technology.

We are moving toward the ethical paradigm of shared decision making (SDM) and this shift needs help to progress. Unfortunately, HIT is becoming difficult to move and change even though medicine is quickly moving toward a complete makeover using electronic health records. At the same time, there is a paradigm shift in healthcare toward a patient-centered approach. Patient oversight will decrease medical errors by involving the patient, allowing review and correction of the record by the patient. Encouraging patient participation in their healthcare will additionally make patients more likely to follow their course of treatment. Access to the patient's health record enables patients to know the relevant medical issues. HIT is able to help educate patients about their health problems and risks by giving access to general information about medical conditions. Lastly, HIT can help with communication between patients and providers through tools that can bridge the knowledge gap between them. All of these HIT capabilities will foster SDM. As of today, the only HIT widely deployed for patient use is the patient health record (PHR), which is typically accessible via web-based portals. PHRs hold great promise, but most are currently little more than an EHR's clinical summary. As the HIT industry moves to support SDM, PHRs should focus on making tools mentioned above with the following capabilities: Easy access to a patient's personal health record in a secure environment, access to trustworthy and understandable information about a patient's condition, visualization tools that help the patient and doctor come to a joint understanding of a medical condition, and a secure means for the patient and provider to communicate. Engaged patients who understand their options, can correct record errors, and understand their condition and treatment options in their own milieu are more likely to adhere to the care plan. This increases the probability of good outcomes and greater patient satisfaction.

THE PHYSICIAN: BETWEEN ETHICS AND HEALTH SYSTEM

Constantin Ovidiu Gheorghisan-Galateanu, MD[1], and Ancuta Augustina Gheorghisan-Galateanu, MD, PhD[2, 3]
[1]Medical Center Family Physician, [2]Dept of Cellular & Molecular Medicine, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania, [3]"CI Parhon" National Institute of Endocrinology, Bucharest, Romania

Health is a major objective everywhere, in every country, for everyone. To accomplish this goal, health systems, public or private, were organized. None of them is perfect. Every health system has limitations and possibilities, and can be improved or modified.

The physician, an active part of the system, is in fact an interface between the health system and the patients. As interface, the physician must accept the constraints and limits imposed by system (laws, regulations, financial limits, technical possibilities), and in the same time must respect and apply his responsibilities towards the fundamental principles of his profession. From these reasons the physician is frequently placed in delicate situations and is forced to make a choice, whether he likes it or not. Almost every time, the choices he makes can generate to him dilemmas. We aim to present the complex relationship between the main actors of these dilemmas (physician, patient and health system), offering answers to a few questions. Are these dilemmas important? Have they some influence on the medical act efficiency? Can these dilemmas be considered as criteria in the improvement of health systems? To what extent these dilemmas are perceived, understood and accepted, by physicians, patients and the system? The fact is that there always is a difference between understanding and acceptance and that will remains a matter of debate. Despite that, the physician must act guided equally by professional and humanitarian values.

SPECIAL OBLIGATIONS IN MEDICAL CONTEXTS: THE CASE OF PATIENTS

Jörg Löschke, PhD
Institute for Philosophy, Berne University, Switzerland

Since the 1980s, ethical theory shows an increasing interest in what is often called "special obligations": Obligations that specific moral agents have against specific other persons, but not against persons in general. These obligations obtain in special relationships – most notably friendships and family ties, but also in professional relationships such as the patient-doctor-relationship.

There has been extensive discussion concerning the special obligations of doctors against their patients. An influential approach is the principlist approach put forward by Beauchamp and Childress. It identifies four principles which should guide the doctor's actions regarding the patients: Respect for autonomy, nonmaleficence, beneficence, and justice. These principles express universal ethical principles, but they also ground special obligations, as they define the role obligations that medical doctors have in the specific context of the patient-doctor-relationship.

However, there has been only little research concerning the question which – if any – special obligations patients have against medical doctors or other agents, such as medical care workers or their own relatives. The presentation aims at exploring this ethical dimension of the patient-doctor-relationship. First, it discusses the grounds for neglecting special obligations of patients in the literature and argues that this neglect is unjustified. Given that "patient" is a role just like "doctor", the concept implies role obligations. Second, it discusses which role obligations can be attributed to patients in their role as patients. Third, it briefly discusses whether patients also have role obligations against their relatives. It is argued that special obligations of patients in such contexts are not role obligations, but special obligations that stem from intimate relationships.

PERSONALIZED CONSIDERATIONS FOR PATIENT INFORMATION – WHEN ONE SIZE DOESN'T FIT ALL

Yalini Senathirajah
Department of Medical Informatics, SUNY Downstate Medical Center

Health information technologies have great promise for improving care and reducing costs, and recent government and private sector initiatives have fueled an explosion of data collection via electronic health records, sensor and consumer devices including cell phones, and other means. In general ethical considerations in the US include HIPAA rules and particular attention to information that is generally considered sensitive by the mainstream culture, such as HIV status. In these systems, 'sensitive' information may require additional permissions, reasons given, and auditing/surveillance of accesses and use.

However, various subpopulations and individuals can be at risk *via* mechanisms and cultural norms unknown or unpredicted by the system designers, who in general may be from privileged classes. The great eagerness for data to facilitate a wide variety of research agendas by well-meaning healthcare workers has fostered increased calls for access to data, repurposing of existing data, and even philosophical shifts calling for surrender of data as a condition for receiving care. The difficulty that the ordinary public has in understanding what may be done on the back-end of systems contributes to further lack of true awareness and consent.

Information systems can be built in such a manner as to give patients and other members of the public greater and more granular control over information access and display, and we make a case that this should be required in healthcare systems. It is important to consider potential harms resulting from exposures not consented to by the patient, and proliferation of data collection for uses unknown, in any data planning. Further, giving patients greater control of their information can contribute to greater patient engagement and increased understanding on the part of system designers. Providing patients tools which are geared to and increase their level of understanding of their own risks, privacy, information use, and healthcare contexts can foster truer shared decision making.

We discuss visual tools to promote shared decision-making and shared understanding of risk and preferences, with examples of how this could foster better outcomes.

WHY AND HOW TO SPECIFICALLY APPLY ETHICS TO VARIOUS PATHOLOGIES?

Mircea Leabu, PhD
Department of Cellular and Molecular Medicine, University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania, Department of Cellular and Molecular Biology, "Victor Babeş" National Institute of Pathology, Bucharest, Romania, and Research Center for Applied Ethics, University of Bucharest, Bucharest, Romania

Beyond the philosophical debate on existence *versus* non-existence, life is a beautiful gift and has to be lived in happiness. However, life is not a triumphant march, but often we have to find solutions for surpassing various difficulties, including illnesses. We must take responsibility for the difficulties in our life with wisdom, whether we are culpable or not of these misfortunes. Approaching various pathologies in ethical terms has to start by considering that the ultimate goal of ethics is a happy life. Therefore, we must find solutions to overcome the difficulties encountered in our healthiness. Most of these difficulties are due to the current stressogenic environment. Addressing the urges of virtue, deontological or utilitarian ethics, I will assess if we must concern ourselves if we have a duty to surpass the difficult moments in our life and if we can and/or may do this. I will discuss the shared individual and social responsibilities related to overcoming health's difficulties in our life. Some conclusions would be drawn that both patients afflicted with different conditions (together with their families and friends), and appropriate institutions of the society have to behave accordingly to successfully go beyond healthiness' difficulties, resulting in an increase in the level of happiness.

THE ETHICS OF PHYSICIAN INVOLVEMENT IN DEVELOPING NON-LETHAL WEAPONS: IS IT HURTFUL OR HEALTHFUL?

Benjamin Drew, BS, MD Candidate (2015)
Harvard Medical School, Boston, MA

Physicians have long employed their knowledge, skill, and compassion to ease the devastation and human suffering wrought by war. Today, a new generation of weaponry has emerged that may alter the future of warfare by reducing casualties and preserving life; a goal that coincides with what the medical profession has always endeavored to achieve. Non-lethal weapons (NLWs) have been gradually promoted and operationally employed as a way to minimize fatalities, prevent undesired damage to property, and deescalate violence.

Since NLWs are increasingly reliant upon biomedical advances in neuroscience, physiology, and pharmacology, their safe and effective deployment will heavily depend upon medical expertise, insight, and experience. Given that medicine is devoted to the goal of saving lives, physicians and medical scientists are confronted by an ethical dilemma as to whether they are permitted to support or unequivocally abstain from non-lethal weapons research.

Considering the stakes involved, it is unrealistic to examine the ethics of medical involvement exclusively in terms of a pledge never to do harm. Current guidelines from the American Medical Association (AMA) Code of Medical Ethics impose prohibitions against chemical and biological weapons research, but make no mention of NLWs.

Assuming non-lethal weapons fulfill their intended purpose to reduce injury and prevent mortality on the battlefield, there may be instances where physicians should be permitted to contribute to the development of non-lethal technology based upon theories of harm reduction, utility, double effect, and mixed agency.

BIG DATA AND BIOMEDICAL RESEARCH: BALANCING PRIVACY AND MEDICAL BREAKTHROUGH

Katherine Carpenter JD, MA

The analytical methods available to move research forward today are tremendous. "Big data" is a term which describes the storage and analysis of many datasets processed together, in novel ways. Big data has already demonstrated promise in the biomedical engineering world because it has allowed analysis comparing old and new datasets and cross-analyzing data resources to find information in longitudinal studies. Researchers and organizations may share data that comprises some datasets that are analyzed as "big data" and organizations collect and analyze their own data for varied purposes.

Big data is problematic because the analytics that drive the science, through linking data and drawing inferences about relationships, have the power to violate the privacy of individuals whose information is part of the datasets in one way or another. Despite attempts to anonymize some fields in a given dataset, when that de-identified data is then linked with other similarly "anonymized" datasets, individuals may be re-identified in unanticipated ways.

This paper discusses the balance between individual and/or research participant privacy and the forward momentum of medicine using big data analytics.

INSIGHTS IN TO THE EFFECTS OF SURGICAL FIXATIONS ON LUMBAR SPINE- A CAE-BASED STUDY

Gunti R. Srinivas[1], Malhar N. Kumar[2], Anindya Deb[1*], Subrata Saha[3]
[1]CPDM, Indian Institute of Science, Bangalore, [2]Hosmat Hospital, Bangalore, [3]SUNY Downstate Medical Center, Brooklyn, New York, [*]Corresponding author

Segmental spinal fusions - posterior, anterior and combined, with or without instrumentation have been widely employed in the management of degenerative disc diseases of the lumbar spine and for surgical stabilization of spine during vertebral body fractures. Unduly long and extensive spinal fusions increase the cost of operation as well as morbidity. In addition, the long term effects also seem to be deleterious to the adjacent discs. Often the surgeon, based on his/her experience may resort to more invasive and costly procedures which may have long term negative effects on the patient. In the present study, a Computer Aided Engineering (CAE) based approach was followed by using explicit finite element analysis to predict the maximum stresses in the adjacent lumbar discs under the following conditions: normal intervertebral disc without fusion; disc adjacent to non-instrumented posterior, anterior and circumferential fusion (with and without decompression); and, disc adjacent to instrumented posterior, anterior and circumferential fusion (with and without decompression). The changes in the adjacent discs were studied following the interventions mentioned at one, two and three levels. The insights obtained from the numerical simulations could be useful in avoiding unnecessary extension of the instrumentation to healthy disc segments. The study provides quantitative data which would be useful for clinicians to understand the effect of their choice of surgical intervention.

THE IMPACT OF FIREARM VIOLENCE ON THE HEALTHCARE SYSTEM OF THE UNITED STATES

Michael Lozovatsky[a], Subrata Saha[b]
[a]SUNY Downstate Medical Center, Brooklyn, New York; [b]SUNY Downstate Medical Center
Department of Orthopedic Surgery & Rehabilitation Medicine, Brooklyn, New York

The economic and human consequences of firearm-related violence extend beyond the boundaries of the immediate victims because this form of violence can impact every sector of a community, including the healthcare sector. Every year, these acts of accidental and aggravated assault contribute a disproportionate financial burden on the medical institutions that provide the lifesaving measures required to aid these victims. These expenditures, which total billions of dollars, exacerbate an already burdened healthcare system that projects annual expenditures equal to 17.6% of our national GDP. Our review of firearm-related injuries and the related financial cost suggests that the economic repercussions of firearm-related violence could be significantly reduced by enacting numerous policy initiatives that have been proposed within various state governments and their residing communities. As medical professionals, we have an ethical and moral obligation to bring this information to the public's attention and to encourage the development of policies that diminish the rise of firearm-related violence and its impact on this nation's healthcare system.

THE PHYSICIAN AND THE MEDICAL ETHICS COMMITTEE

Arthur B. Chausmer, MD PhD
Professor of Medicine (adjunct), Johns Hopkins University School of Medicine

In the world of medical ethics, ethics committees and institutional review boards function to provide structure in a generally amorphous environment. It is, in general, their role to weigh all of the considerations and regulations in order to provide guidance as to how abstract ethical and moral positions can be applied to real world situations.

Ethics committees generally consist of representatives of several disciplines: a religious member, who brings his/her own sectarian views patients, an interested attorney to provide information about legalities, a lay member with highly varying degrees of sophistication, an administrative member, and at least one physician. Frequently

they all believe they have "the answer," views which may frequently diverge. This is probably a good thing.

The physician can provide real world guidance, particularly where there may not be the depth of understanding, which can lead to agreement, or at least acceptance, of an opinion within a committee. It is up to the physician to provide, based on experience and responsibility which other members lack, a unique view and help lead to consensus if possible. He or she must exercise great care to recognize his or her own personal biases. Because of the emotional attachments held to personal believes, this is often very difficult to accomplish.

DATA MISUSE AND MANIPULATION: TEACHING NEW SCIENTISTS THAT FUDGING THE DATA IS BAD

Evan D. Morris[1,2], Jenna M. Sullivan[3], Anjelica L. Gonzalez[2]
1. Diagnostic Radiology, 2. Biomedical Engineering, Yale University, New Haven.
3. inviCRO, LLC, Boston

Academic laboratories and private sector research organizations have something in common. Much of the data processing is done by students or associates who have had little to no formal ethics training. Yet their work is complicated, demanding, and critical to the success and integrity of the overall project. Any unwarranted "trimming the data" could alter the result for the worse, discard a real finding, or sully the reputation of the lab or company. We all want to produce a good work product. What could be the harm in smoothing images or culling outliers? But the decision to clean up data - or even throw some out - may have serious unintended consequences and cannot be taken by the individual analyst.

One way to encourage good behavior in data analysis is to connect the individual's role to the wider effort of the lab, the field, and the scientific enterprise. By doing so, we highlight the underlying responsibilities that we all bear and the very real costs -in monetary and human terms- of not meeting those responsibilities.

We have designed an introductory lecture for new scientists and support staff to emphasize these responsibilities in an effective, engaging, and mature manner. The lecture is organized around four themes: (1) Data manipulation will be discovered; either through attempts to replicate or through statistical analysis. (2) There are objective rules for eliminating outliers but the key is to have an objective rationale that is developed and agreed upon by the research team. (3) The effects of improper data analysis are far-reaching, pollute the scientific literature, and damage other seemingly distant work. (4) Scientific fraud in biomedical science can injure people. Principles are illustrated with well-publicized episodes and discussion is prompted through the examination of our own (lab's or company's) histories.

Here, we present some examples of our lecture material using illustrations from the past (Mendel's data that are too good) and the present (false claims of a tie between MMR vaccines and autism). We also detail our experiences in presenting the material in both academic and commercial settings, compare the reactions of the respective audiences, and make recommendations for future refinements.

HOW DOES COLLABORATION ENHANCE OR IMPEDE RESEARCH INTEGRITY IN TRANSLATIONAL RESEARCH? VIEWS OF SCIENTISTS IN CLINICAL TRANSLATIONAL SCIENCE AWARDS (CTSA) PROGRAMS

Sarah McGraw, Ph.D. Research Scholar, The Hastings Center.
Sponsored by National Center for Advancing Translational Sciences (NCATS), R21RR026301

Background: Biomedical research increasingly demands collaborative translational research requiring scientists from disparate disciplines and institutions to work as an effective team. Relatively little is understood about how the collaborative translational research setting affects research integrity. The purpose of this study was to explore how collaboration in translational research impacts research integrity, as reported by scientists engaged in this work through CTSAs.

Methods: We conducted a qualitative interview study of 38 principal investigators whose research was funded through 11 CTSAs that were established in the first round (2006). Participants were selected from among

investigators who received novel methods, pilot, career development, or incentive awards and were determined through an online survey to be engaged in highly collaborative, translational research. The sample selection was stratified by CTSA program, seniority of investigator, and bench/non---bench science.

Results: Participants described experiences with questionable research practices that were not unique to collaborative translational science but features of their collaboration had both negative and positive influences on how they defined research questions, determined study design, monitored data quality, and interpreted study findings.

Features of collaborative translational research that helped to support research integrity included: a) Having more "eyes on" the study because collaborators functioned as internal peer reviewers for each other; b) Increasing capacity to think innovatively and critically by bringing together new disciplines, forcing scientists to explain and think critically about their methods and assumptions; and c) Motivation to perform at a high level to avoid damaging their relationships with their collaborators.

Features of collaborative translational research that impeded research integrity included: a) A hierarchical study team structure (based on seniority or discipline) that inhibited open communication among team members; b) Difficulty assessing their collaborators' work across disciplines; and c) Poor communication and assumptions about their colleagues work style and capacities.

Fairness in assigning authorship, accounting for ownership of intellectual property, and crediting collaborators for ideas was a common concern for scientists engaged in collaborative translational research. Trust was important in the decision about entering into collaboration and in assessing their comfort with the quality of their colleagues' efforts. The scientists used various criteria to qualify their trust in their colleagues including reputation, observation of work, and asking questions. Many noted a limit as to how much they could verify the quality of their colleagues work and ultimately had to rely upon basic trust.

DATA SECURITY, PRIVACY, INTEGRITY, AND INFERABILITY DETERMINING GLOBAL TO PRECISION MEDICINE

Faisal Reza, Ph.D.
Department of Therapeutic Radiology, Yale University, School of Medicine, 333 Cedar Street, HRT 316, #208040, New Haven, CT, USA 06520-8040; Email: faisal@alum.mit.edu

Targeted gene editing of chromosomes, i.e. genomes, and the ensuing engineering thereof, presents technical and technological challenges. In therapeutic settings, the scope of these challenges broadens from the aforementioned, i.e. how to safely and efficaciously engineer a living genome, to concomitant ones that are societal and personal as well, i.e. how to safely and efficaciously engineer someone's living genome. These concomitant challenges deal with data, namely how differential data drives the determinants from global medicine to precision medicine. These determinants can influence the choice of one or combination adjuvant therapeutics for global medicine, which have the potential to apply to and affect populations or large numbers of people, and for precision medicine, where smaller groups or single individuals are involved. Herein, it is demonstrated that data security, data privacy, data integrity, and data inferability influence what can be observed and be questioned from sets of societal and personal data. In turn, an information-theoretic and computational learning-theoretic treatment of these differential data drivers demonstrates their influence upon the therapeutic modalities that have the likelihood to be applicable and effective. Thus, these findings have implications upon the data presented by, and the therapeutic(s) used/dual-used on, a population or an individual.

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ETHICS AMONG SCIENTISTS IN AN INTERNATIONAL CONTEXT

Kirstin RW Matthews, PhD,[1] Elaine Howard Ecklund, PhD[2] and Steve W. Lewis, PhD[1]
[1]Baker Institute for Public Policy, Rice University
[2]Department of Sociology, Rice University

The relationship between science and ethics is complex and fraught with controversy. Diverse groups in science, industry, and the public sphere are engaged in ongoing debates about irreproducible results, conflicts of interest and pressure to publish research that encourage scientific fraud. Such tensions are especially significant for biologists. However, biologists are rarely compared to other disciplines to see if the particular issues they face related to responsible conduct of research are really unique. And US biologists are rarely compared to biologists in other national contexts to see if the ethical issues biologists face are truly global issues. In this paper we will examine: how do biologists compare to physicists in the way they perceive the meaning of research integrity and misconduct and under what conditions do biologists think they are obliged to act when research misconduct has occurred. We analyzed data from more than 200 interviews with scientists in the UK and India. We found that physicists and biologists rarely encountered what they saw as traditional ethics violation: fraud, fabrication and plagiarism. However, scientists often cite numerous lesser violations including issues with authorship, reviewer confidentiality and honesty, and irresponsible conduct of supervisors. Although the two groups of scientists identified similar issues, physicists, in contrast to biologists, tended to see ethical issues as irrelevant to them. Similar ethical issues arose in the UK and India, although UK scientists focused more on pressures to publish while Indian scientists addressed institutional issues including accountability and excessive bureaucracy. And under certain conditions, both Indian and UK biologists and physicists utilize religious and spiritual frameworks to think through ethical approaches to science.

INFORMED CONSENT TO COMPLEX GENETIC RESEARCH: WHOLE GENOME SCREENING OF NEWBORNS

Evelyne Shuster, PhD
Bioethicist,Veterans Affairs Medical Center, University and Woodland Avenue, Philadelphia PA 19104
, eveshuster@gmail.com; Evelyne.shuster@va.gov

The next big step in genetics is always around the corner, and as the price of whole genome sequencing (WGS) drops to the $1,000 level, researchers have devised new projects to take advantage of the ever-evolving technology. Studies in WGS of adults have revealed countless issues related to informed consent and interpretation of genomic data, and challenges pertaining to the integration of WGS into clinical care. However, one of the most novel research projects is an NIH funded venture to sequence the whole genome of newborn babies. The primary objectives are to explore the benefits and risks of WGS in newborns, and determine whether the sharing of all genomic information and integration into clinical care is actionable, causing more good (early identification of retreatable conditions, disease prevention) than harm (stigmatization, identification of anomalies that are not necessarily pathological). Before WGS of newborns is undertaken, the study protocol and informed consent procedure (including a risk/benefit assessment) must be reviewed and approved by an Institutional Review Board (IRB) or ethics board. Should an IRB approve such research, under what conditions and on what basis? This presentation will address the new ethical challenges created by WGS of newborns, and suggest a possible model of how parental informed consent can most reasonably and ethically be sought.

ETHICAL ISSUES IN CONDUCTING PSYCHOLOGICAL RESEARCH IN PEDIATRIC POPULATION

Shruti Shivakumar, MDS and Vishal Shrishail Kudagi, MDS
Department of Pediatric Dentistry and Department of Orthodontics
JSS Dental College and Hospital, JSS University, Mysore, India

There has always been a strong correlation between childhood behavior and experiences and adult psychological well-being. Therefore, children are used in psychological research in order to gain better understanding of functioning and development of human mind. However, children are more vulnerable to psychological harm than adults and lack ability in decision making processes. This makes conducting psychological research in pediatric population challenging especially in relation to the ethical aspect of the study.

The researcher must take the moral responsibility to understand various issues regarding ethical consent in children and protect the confidentiality of the study. Researchers should respect the rights and dignity of the children participating and emphasize on efficient communication that can help go a long way in successful research outcomes. Being sensitive to the potential impact of the study's interventions and minimizing the effects is very important. There should also be a zero tolerance approach to any kind of deception in the psychological study.

Our presentation aims to revisit and discuss these sensitive issues when conducting psychological research in children which can guide researchers to design the study keeping the privacy and interests of the child as paramount.

WHEN BIOETHICS AND ENGINEERING ETHICS COLLIDE: SECURITY VULNERABILITIES IN WEARABLE AND IMPLANTED HEALTH TECHNOLOGIES

Katherine Carpenter JD, MA & David Dittrich

Health-related research is intimately linked with technology through the devices now known as "wearables" and through implanted medical devices that some people rely on for daily survival or comfort. Security of these technologies is especially salient because of the growing public awareness about information security and privacy, stemming from the increased number of widely publicized data breaches. Consumers and patients are increasingly aware and concerned about devices that interact with them biologically whether the device is implanted or simply collects information by monitoring the body externally.

This paper discusses the potential issues that could arise in research of medical devices and other health technologies. It uses the Menlo Report framework to demonstrate a way to create research studies that are useful, secure, and minimize potential harm to research participants.

THE ETHICS OF CONDUCTING MULTINATIONAL RESEARCH AND THE ETHICS OF RESEARCH WITH CHILDREN

Peter Loomer, BSC, DDS PhD, MRCD, DipPerio[1], Alexander J. Schloss, DDS, MSB (Bioethics)[2],
Jyoti Kansal, BDS, Candidate for DDS (2015)[3]
[1]Department of Periodontology and Implant Dentistry, [2]Department of Periodontology and Implant Dentistry
New York University College of Dentistry

The International Association for Dental Research (IADR) has declared that promoting global oral health must be a high-priority goal of the dental profession, with a focus being placed on the reduction of global health inequality. The New York University Global Institute of Public Health and its participating schools, including the College of Dentistry, seek to discover new innovative approaches to improve the health of low-resource global communities. Such approaches must be based evidence-based and thus, based on research.

In conducting research on human subjects, researchers must adhere to appropriate ethical standards. The ultimate aim of such research is not just to increase general scientific knowledge, but to improve overall human health and well-being. The fundamental ethical challenge in conducting human research is to balance the risks and burdens posed upon the research subjects with the benefits that will accrue to other human beings who have not assumed any of those risks and burdens. The risk of exploiting test subjects is problematic when the research is multinational and the test subjects live in low resource communities, and it is especially problematic when the test subjects are children.

The Department of Periodontology and Implant Dentistry at New York University College of Dentistry is presently embarking on doing a collaborative research study on paan/gutkha cessation with two Indian dental colleges: The Manipal College of Dental Sciences and the Ahmedabad Dental College and Hospital. The target study group is Indian school children.

Our presentations will focus on the following three issues of research ethics that must be managed in order to carry out the research in an ethically appropriate manner:

1. Responsiveness to global host community needs as defined by the host community (Dr. Loomer)
2. Defining risk and direct benefit in doing research on children:Common Rule 45 CFR Subpart D Additional

Protection for Children Involved as Subjects in Research (Dr. Kansal)
The informed consent/assent requirement in pediatric research (Dr. Schloss)

TESTING A TBL CURRICULUM FOR EFFECTIVE RCR EDUCATION

Michael F. Verderame[#1#], William L. Allen[2], Shane Connelly[3], Joshua Crites[1], Jeffrey Engler[4], Victoria Freedman[5], Cynthia W. Garvan[6], Paul Haidet[1], Joel Hockensmith[7], William McElroy[8], Erik Sander[8], Rebecca Volpe[1], and Wayne T. McCormack*[2]
[1]Penn State Hershey College of Medicine, [2]University of Florida College of Medicine, [3]University of Oklahoma, [4]University of Alabama at Birmingham Graduate School, [5]Albert Einstein College of Medicine, [6]University of Florida College of Nursing, [7]University of Virginia School of Medicine, [8]University of Florida College of Engineering, mccormac@ufl.edu

Education programs in Responsible Conduct of Research (RCR) are ubiquitous in biomedical and engineering education programs in the US. Most such RCR programs take a similar approach, with some combination of background reading assignments, lectures (typically by a content expert), and unstructured case discussions during class. Unfortunately biomedical RCR education programs structured in this way are not effective at improving ethical decision-making (EDM) and may even lead to less ethical decisions by the learners (Academic Medicine, 85:519, 2010).

The goal of our project is to develop RCR education materials that improve ethical decision-making and can be implemented by faculty members in a variety of disciplines. An additional important element is that faculty members should be able to implement the curriculum with modest training, taking advantage of familiar facilitation skills (as opposed to extensive training in sophisticated educational models). Using education materials for RCR in a Team Based Learning (TBL) format originally developed at the University of Florida College of Medicine (Accountability in Research, 21:34, 2014), we have obtained additional preliminary data from the University of Florida and the Pennsylvania State University Colleges of Medicine supporting improved EDM by biomedical doctoral students in three of four EDM dimensions. With funding support from the Office of Research Integrity we have extensively revised these educational materials incorporating two important additions: 1) case design principles that support appropriate metacognitive reasoning strategies underlying improved EDM; and 2) incorporating the *So Far No Objections* (SFNO) moral method.

Over the 2014–2015 academic year, learners in nine RCR courses in biomedical science and engineering programs at six universities are participating in pre/post-testing of EDM skills to determine if these revised materials significantly improve ethical decision-making. Results from the Fall 2014 semester will be discussed.

CONFLICT OF INTEREST DISCLOSURE IN ORPHAN DRUG RESEARCH

Daniel Patrone Ph.D.[1], Jen-Ting Wang Ph.D[2], Melissa Haig[2], Rosemary Harris[2], Rebecca LeFebvre[2], Matthew Vedete[2], and Taylor Zelka[2]
[1]Department of Philosophy, [2]Department of Mathematics and Statistics, SUNY Oneonta

Researchers in the biomedical sciences often have financial ties to industry. Such relationships give rise to conflicts of interest that may affect, or be perceived to affect, the objectivity of researcher judgment. One important strategy for maintaining the integrity of the biomedical literature and trust in the research endeavor is the requirement that authors disclose their conflict of interest fully in their publications.

Full and consistent disclosure of conflicts of interest is especially important in literature dealing with *orphan drugs* (drugs that are developed to treat specific rare diseases or conditions). Sponsors of drugs that qualify for orphan status benefit from considerable incentives for developing these products, while the development of such drugs also can carry significant professional and financial risks. Trust in the research process in general, and in the federally funded orphan drug program in particular, depend on researcher transparency about financial ties between authors and industry. Recent controversies have also shed light on the role that medical journal publication can play in the promotion of off-label use of orphan drugs, raising important issues relating to both trust and safety. Yet little attention has been paid to conflict of interest policies and practices in research dealing with orphan drugs, even though there are several considerations that might argue for particular scrutiny of conflict of interest disclosure in this field.

To examine the rate and consistency of researcher disclosure of conflicts of interest, we identified eight orphan drugs approved for the first time between 2009-2010 and examined the conflict of interest statements of journal articles published in English within 36 months of the drugs' approvals. This resulted in 346 articles listing 1969 authors (1517 total unique authors). While we observed much higher over-all rates of disclosure than reported in prior studies, we did find patterns of inconsistent disclosure among authors who were listed in more than one article, particularly among authors who disclosed industry employment in at least one of their articles. This paper discusses these findings and considers the unique importance of conflict of interest disclosure within the financial and regulatory contexts of research involving orphan drugs.

ETHICS IN MEDICAL RESEARCH. THE LOW FAT-DIET-HEART HYPOTHESIS. FIRST, HOW MUCH HARM HAS BEEN DONE?

Richard David Feinman[1] and Sara M. Keough[2]
[1]SUNY Downstate Medical Center, Brooklyn, NY, richard.feinman@suny.edu
[2]Maryland University of lntegrative Health, Laurel, MD, skeough@muih.edu

Ethical behavior or its lapse is defined by intention, the *mens rea* in criminal law. Intention is usually deduced from behavior but in medical research, or any research, it is easy to make a mistake and one must be circumspect about attributing motive to misleading or harmful research reports. Even Einstein admitted that we must all make a sacrifice on the altar of stupidity. Clear breach of ethics in science, then, is usually restricted to falsifying data or other gross malfeasance. On the other hand, real harm can be done as a consequence of poor scientific practice and recommendations from which they arise. This presentation will discuss serious breaches in research practice which, because motivation is unknown, will be described as something that might have been caused by unethical conduct. Insofar as the critique is correct, it may serve as guidance for future activities regardless of the intent of the original research.

The discussion focusses on the so called diet-heart hypothesis, that circulating cholesterol is caused by high fat diet and, in turn, one or another cholesterol fraction causes heart disease. Government and private agencies have urged reduction in dietary fat, especially saturated fit for forty years. The flip-side of the diet-heart recommendations, objections to diets based on carbohydrate restriction has been an additional feature. On the one hand, large expensive studies have failed to show any significant benefit in the low-fat approach. Low-carbohydrate diets have, at the same time, out-performed low-fat diets for as long as they compared, as much as two years. Areas to be discussed are 1) harm to scientific principles 2) harm to the scientific literature, 3) harm to medical education and 4) harm to the patient. In the first two questions, numerous scientific articles and popular books have described the failures of diet-heart hypothesis but these experimental outcomes have had little effect on future publications or the recommendations of health agencies. At the same time, the benefits of dietary carbohydrate restriction for treating obesity, diabetes and metabolic syndrome have been ignored. This has produced a situation in scientific practice that no longer has the self-correcting ability that is considered its most important feature. The establishment of any dogma will necessarily restrain what is taught to students and textbooks in the undergraduate and medical fields reflect this. Finally, at least anecdotally, patients have described how they have been discouraged from trying low-carbohydrate diets and, conversely, how they were only helped in treatment of their health problems when they implemented carbohydrate restrictions. The ethics of "accepted practice" in the face of contradictory evidence is the essential question.

ON THE PRECIPICE OF LIFE: AN ETHICAL ANALYSIS OF SUSPENDED ANIMATION WITH BIOMEDICAL AND ENGINEERING IMPLICATIONS

Christian Aditya, Megan Centafont, Zane Gray, Hassan Omar, Jaskeerat Singh
Faculty Mentor: Richard L. Wilson
Philosophy Department/Engineering Management, University of Maryland at Baltimore County

Modern medicine has provided the public with state of the art drugs, treatments, and preventative measures, but these are not without limitations. In the event an individual sustains a fatal injury, doctors are granted an average of 15 minutes to respond before the likeliness of death greatly increases. Approximately 40% of traumatic injury deaths are due to blood loss and 35% of trauma patients die en route to the emergency room, which necessitates an alternative and immediate method of treatment.

Suspended animation (SA) is the process of inducing a drop in core body temperature by transfusing an individual's blood with a cold saline solution, effectively slowing metabolism to rates comparative to those of a legally dead person. This in turn awards physicians upwards of an hour of operating time before further risk incurs. Because of its significance in medicine and recent approval for human testing, suspended animation has warranted a considerable amount of attention and criticism as of late. For this reason, an anticipatory ethical analysis of suspended animation is necessary and will be performed from the perspective of multiple stakeholders; doctors, engineers, and patients alike. Futuristic applications of SA in regards to cryogenics and space travel will be hypothesized as well. This serves to elucidate any ethical dilemmas that may arise through application of suspended animation and in doing so, grant the public insight on this groundbreaking and potentially lifesaving methodology.

ETHICAL AND CURRENT ISSUES WITH ORGAN TRANSPLANTS IN DEVELOPED AND DEVELOPING COUNTRIES.

Mariane Espitalié, B.Sc., m.espitalie@gmail.com; Dr. Subrata Saha, PhD, Subrata.Saha@downstate.edu
Department of Orthopaedic Surgery & Rehabilitation Medicine, SUNY Downstate Medical Center

There is a worldwide gap between the number of donations and patients waiting for a transplant. However, challenges vary depending on countries and their educational level, poverty rate and health insurance. Thus, different solutions have to be considered depending on laws and policies to overcome the low rate of organ donations and the ethical issues linked to them.

In developing countries, due to poor diet, aging populations and no health insurance, diseases affecting divers organs are common and there is a particularly high demand for kidney transplants. For instance in India and Nepal, transplants are mostly taken from living donors and family members to ensure emotional attachment from the donor instead of monetary goals. However, many poor people give their kidney for pecuniary gain due to massive financial pressure. Thus, there is a real need for more donors to reduce this opening to illegal organ trafficking. To overcome the gap between the demand and supply of donors, there is a need to educate the population about cadaveric donations. In developed countries such as the USA, the same gap exists. Transplants are taken from brain dead individuals if they are identified as consenting donors on their car licenses. However because of the aging population, there are fewer donors available and the waiting list is increasing. One possible solution is to adopt the “consent statute” as in Spain and 24 other countries in Europe, which presumes that everyone is a donor once brain dead unless they indicate otherwise.

There is a need to consider living donors as well - thus the main issue is whether we should be free to donate organs for money, as our body is our property. Is it fair to get an incentive for a generous act? Shouldn’t medicine prevent people to harm themselves? This could be relevant in developed countries as policies and laws could control the procedure and the goodwill of people. However it seems impossible in developing countries. Despite the increase of donations this would only favor rich individuals and drastically reduce poor donors’ lifespan due to inadequate medical follow-ups.

At a distant future, we may be able to overcome the gap between supply and demand by engineering tissue reconstitution and developing artificial organs.

ANTICIPATING FUTURE ETHICAL ISSUES WITH PROSTHETIC DEVICES

Emily Canapp, canapp1@umbc.edu, Niara Comrie, Lailynn Reyes, Francois Rice, Richard L. Wilson

Prosthetics are important devices for the community of people who have lost limbs due to accidents and illness. Prosthetics can be important to rehabilitation, return to function and even augmentation of patients. However within the Prosthetic industry, there exist a number of difficulties that arise with regard to the use of prosthetics

and payment for them. By discussing technical, ethical, and social issues that result from the installation of prosthetics; the objective of this analysis is to inform the public about the current research findings regarding the concerns and issues confronting prosthetic patients. Through statistical analysis, data shows that prosthetic users are reinventing the way prosthetic devices are designed and developed. The installation, maintenance, and insurance claims of prosthetics users should be dictated by the needs and responsibilities of the prosthetic user. It seems to often to be the case that society's view of prosthetics involves chastising the user, which condemns them to a life of psychological discomfort and therapy. Data analysis shows that peer support and therapy, allow the user to develop coping skills and mechanisms both independently and collectively. An ethical analysis of the current issues confronting prosthetic users will be followed by an anticipatory ethical analysis of difficulties prosthetic users may face in the future. These 2 versions of ethical analysis will be used to develop recommendations that anticipate ethical issues that may arise for the prosthetic community in the future in the prosthetic field.

CONVALESCENT SERUM THERAPY: A DISSENTING OPINION

Andrew Hawkins

The acute outbreak of the Ebola virus in West Africa has been a disturbing event[1]. Ebola is a pathogen for which there is no known treatment[2]. Healthcare professionals are left without adequate clinical infrastructure to combat this high-mortality disease. In response to this reality, the World Health Organization (WHO) has turned to an experimental treatment: convalescent serum therapy and has been approved as a treatment for Africans suffering with Ebola. This decision was made without a thorough consideration of the historical precedent for provision of experimental therapy or scientific evidence for the safety and efficacy of plasma transfusion. Amongst the hysteria associated with the current outbreak, healthcare professionals are being pressured to provide an answer—fast. The medical ethicists who agreed that providing experimental therapies as an effective means to satisfy these demands overlooked the importance of maintaining the standards of clinical research. The Director of the Center for Disease Control in Atlanta, noted in a recent podcast on the JAMA website decisions "are based on data"[26]. In the U.S policy makers ultimately concluded that the public interest as well as the interest of terminally ill patients is best protected by allowing access only to drugs of proven efficacy. Given the dearth of evidence for the efficacy of convalescent serum therapy, the World Health Organization ought not endorse this unproven therapy. Their argument that if convalescent serum therapy were not effective, the secondary benefits of investment in the African healthcare infrastructure would be beneficial is wildly overoptimistic. Desperately grasping for a solution to the Ebola crisis without credible evidence that the treatment utilized works will not only fail the patients suffering from Ebola but will delay the resolution to a lethal epidemic.

ETHICAL ASPECTS OF CLINICAL TRIALS ANTI-TUBERCULOUS DRUGS FOR PEDIATRICS

Kunnaz Murzagulova, Professor, Marina Kim, PhD, A. Yanovich, Master
"Romat" Pharmaceutical Company, Pavlodar, 140011, Republic of Kazakhstan

Tuberculosis remains one of the main diseases that affect children in the world. Rifampicin and isoniazid are the main drugs to treat tuberculosis. They are the most toxic, LD_{50} in mice are 500 mg/kg and 133 mg/kg respectively. They are mainly used in fixed-dose combination. We have carried out a research to obtain the macromolecular rifampicin complex and β-cyclodextrin of different polymer brands, providing rifampicin dissolution in the areas of GIT with pH> 4, with the development of dispersible tablets of rifampicin / isoniazid for pediatrics. Preclinical safety studies of the drug demonstrated that LD_{50} in mice and rats is 5000 mg / kg. Clinical trials in pediatrics in Kazakhstan are conducted in accordance with the current "Rules to conduct clinical research and (or) trials of medicinal products. Clinical studies in children meet all the requirements for this kind of research in adults: the receipt of informed consent to participate in research, risk assessment for child-participant study, the reduction of this risk, as well as minimization of the fear and pain arising in the course of the study. Informed consent is required from both parents or his/her legal representative and the child, if he/she is able to sign. Any promotions or incentives, except for compensation in case of damage to his/her

health during a clinical trial are not used in clinical trials with participation of children. A researcher takes into account the apparent desire of the child to participate or not to participate in a clinical trial, or to withdraw from it at any time. Ethical review of pediatric clinical trials for the treatment of tuberculosis is carried out by a local committee of a health care center, then by the committee under the Ministry of Health**.**

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