2015 AEMB ETHICS SESSION REPORT

The 2015 AEMB Ethics session at the BMES Conference in Tampa, Florida revolved around the topics of ethics in biomedical engineering and decision making. While many different ethical dilemmas were touched upon, the main topic for the session was Genomic Testing. Dr. Robert Frisina Jr., Director of the Biomedical Engineering Program at USF was the keynote speaker. The talk was followed by an interactive situational discussion by the students who attended the session.

2015 BMES Conference. Ethics of Genomic Testing: Tampa, FL

Keynote Speaker:

Dr. Robert Frisina Jr, Director of Biomedical Engineering at USF.

Session Chair:

Bhavit Vora, National Student President AEMB.

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The Keynote Speaker: Dr. Robert Frisina

Introduction: Alpha Eta Mu Beta (AEMB), the National Biomedical Engineering Honor Society, is committed to promoting ethics in the field of biomedical engineering. This year, AEMB was honored to host Dr. Robert D. Frisina. Dr. Frisina is a Professor and Director of the Department of Chemical and Biomedical Engineering and also the director for the Communication Sciences and Disorders lab at the University of South Florida. In addition, Dr. Frisina is the director of the Global Center for Hearing and Speech Research and holds joint appointments as Professor at the National Technical Institute for the Deaf, one of two colleges for the Deaf in the world, and at the University of Buffalo Center for Hearing and Deafness. Dr. Frisina's research is focused on the function and disorders of the auditory system, more specifically in the critical areas of hearing loss and deadness for which there are is no existing cure.

Abstract: Today's biomedical engineers are advancing many technical areas of bioengineering at a very rapid pace. Impacts of recent and ongoing advances in tissue engineering and microelectronic fabrication are revolutionizing progress in the arenas of personalized medicine, especially with regards to molecular genetics and genomic testing. Technological progress in these areas have significantly improved quality of care and the efficacy of treatment. However, one of the professional conundrums in the area of genomic testing pertains to moral and ethical challenges, especially with regards to newborns and children. The basic dilemma here focuses upon the decisions that parents have to make for their young children, since children cannot make the decision themselves, about how much genetic testing should be carried out, and what can or should be done with the results of that genetic testing. Genomic testing in children is becoming faster, more efficient and less expensive. So, now instead of testing for a few obvious genes for children who are born with birth defects, possible genetic syndromes, or easily diagnosed problems such as hearing loss or deafness, genetic screening immediately on the horizon will be able to screen for mutations in hundreds or thousands of genes routinely. So, for example, what if a newborn is discovered to have a gene that causes an age-related disorder such as Alzheimer's disease? Should the parents be told? Should the child be told when they are old enough to know? What is the point of telling the family now, when there are still no preventative or curative treatments of Alzheimer's? Should it go in the child's medical record, where future employers, insurance companies or hackers can gain access to it? And you can imagine a number of biomedical scenarios where it is not obvious what to do with genetic information such as this. Another challenging issue is how to obtain the necessary blood samples from a newborn, which has a relatively small blood volume. Umbilical cord blood has been mentioned as a good source, since the umbilical cord is normally cut (sometimes by the proud Father) and discarded with the placenta. However, even this seemingly innocent, harmless procedure has now been called into question as some new evidence suggests that babies do better when the cord blood is allowed to flow into the baby for a while, precluding a quick cutting of the cord, as has traditionally been done. So, as biomedical engineers work with nurses, doctors, insurance companies and other players in our healthcare system, these issues will come up without clear-cut answers available to them.

Summary: Dr. Frisina's talk revolved around the importance of ethics in the future of biomedical engineering and specifically focused on Genomic testing and the decisions that future biomedical engineering will have to make regarding the policies governing Genomic Testing. Dr. Frisina's abstract above outlines the overall topics that were covered. Overall, he posed many interesting questions to the audience and challenged them to use those questions at a jumping point for igniting discussions in their own individual forums. AEMB then used the platform set by Dr. Frisina to lead an interactive activity where AEMB officers led student groups to discuss specific questions regarding genomic testing in order to come up with some sort of a policy governing that particular question.

Discussion Group 1

Group 1 was posed the following question to discuss: What information should be shared from a genetic test with the parents?

Format: AEMB Student Treasurer, Morgan Elliot, led a group of 20 individuals to discuss this topic in some depth. While tough to cover all points of the topic in a 15 minute discussion, Morgan allowed the students to take control of the direction of the topic. The ideas that came from the discussion are summarized in the write up below. Furthermore, two students presented the ideas that came out of the discussion to the rest of the forum and alluded to the many challenges regarding this complex topic that a group encountered in their short discussion. It helped the forum realize the difficulty of the topics presented by Dr. Frisina earlier in the session.

Summary: During the Ethics Session at the annual BMES conference, the question "what information should be shared from a genetic test with the parents?" was discussed by one of the student groups. Undergraduates were encouraged to be the main participants of this discussion, which input and guidance from graduate students, professors, and clinicians. Additionally, at the end of the 10-12min discussion, two undergraduate students were asked to present the group discussion and conclusions to the other groups. For this question, the group first worked to establish a baseline of what information should be shared, from medically relevant information to more cosmetic information like hair and eye color. Many individuals argued that the patient should have full rights to know and it is their decision what to do with that information. Thus, these individuals favored full disclosure with the ability to stipulate not wanting to know certain information. Some other, related topics the students struggled with included: what to do with gender information in societies that have a history of female infanticide as in China and situations where sensitive information like fatherhood is revealed of which the family may not have been previously aware. These students clearly explained that society would need to be careful to avoid genetic discrimination, especially as healthcare is a medical and political focus.

A large debate focused on asking for specific information versus being given information by default. Two thoughts that were crucial to this debate were that eventually all information may be available from 1 test and that a patient may not know what medical tests to request or comprehend their meaning. Solutions posed included informed consent to attain the procedure and doctors being required to fully explain what tests mean. An example of the physician's duty was given with incidental findings from chest radiographs that the clinician is required to follow-up on. The conclusion the students came to was that it is a physician's duty to share medically relevant details, especially for life threatening conditions, and that the information should be kept in a repository for the patient as what is medically irrelevant now may be extremely relevant later as technology continues to develop.

Ultimately, the students were highly engaged in the topic of genetic ethics. The session brought to light several issues that need to be considered as genetics becomes a larger field. Students in the session were adept at picking out details relevant to the question and improved their abilities to verbalize concerns.

Discussion Group 2

Group 2 was posed the following question to discuss: With regards to genetic testing and personalized medicine for young children, what restrictions should parents have on decisions to be made for the children?

Format: AEMB Student Vice President, Justin Huckaby, led this group to discuss this question and try and look at all sides of the issues from both an engineering and ethical perspective. The group has approximately 15-20 members and they all participated and offered their opinions in a round-table type of setting. The discussion made it clear that many different opinions exist on this controversial and complex topics. While it is tough to determine a perfect solution in 15 minute brainstorming session the following write-up summarizes the topics that were spoken about by Group 1. The group focused on fail-safes and multiple approvals for information that should be disclosed. They agreed on the right of the patient to deny the information as necessary, and formed some guidelines on how to deal with minors who are facing this question. Justin Huckaby facilitated the group in summarizing the information and presented it to the forum at the end of the session.

Summary: Genetic testing is becoming an ethical concern in the medical field, especially as some DNA test kits become commercially available such as 23andMe. While genetic testing and personalized medicine have the potential to transform health care into a more optimized system for treating patients, many ethical concerns still surround the testing and disclosure of sensitive information to patients or their families. A question posed by many refers to how much knowledge of one's genetic makeup and history is too much. For example, genetic testing to determine a child's eye or hair color may not be an issue, but more sensitive information such as likeliness of Huntington's disease could be an unwanted fear for a child's parents. Furthermore, genetic testing is controversial with regards to cultural and religious backgrounds as well. As technologies develop and costs become more manageable for large-scale personalized medicine, policies must be in place to determine the most ethical use of these health care advancements. A constant question among patients and healthcare providers is: To what extent is knowing a good thing?

The decision to test and disclose sensitive information from genetic testing should not be made alone or by a single party. Instead, a board of individuals from different backgrounds should meet to establish a general procedure for which sensitive patient data can be disclosed. The board should consist of medical professionals, legal advisers, and researchers at the least. After this general framework for testing and disclosing patient-sensitive information is developed, individual cases should be judged further amongst a board specific to each hospital or testing facility. Even if genetic testing is performed, the patient should retain the rights to view or not view the results. Therefore, the responsibility should ultimately rely on the patient, but just as with young children and patients undergoing traumatic accidents, these decisions cannot always be made by the individual receiving the test. Children are too young to understand the results or magnitude of their decision, while a patient in a hospital after a traumatic accident could be in a coma or other state of unconsciousness. Instead, family members should have the rights to make unrestricted decisions in consideration of their loved one. This pattern should be followed in genetic testing and personalized medicine.

Young children are unable to make their own decisions about sensitive information usually. Thus, parents often have to give written consent until a child is 18 years old. From this structure, our group at the AEMB Ethics Session determined a similar pattern should be observed to make the most moral decision for children receiving genetic testing results. Parents or legal guardians will care for the child until he/she is grown and of age to be independent. Thus, parents or legal guardians should reserve the rights to either view or not view sensitive information from personalized medicine. If the guardians view this information and find an

alarming concern, such as likelihood of a debilitating disease, the guardians should also reserve the right to make a decision on behalf of the child. Prior to making the decision, doctors and medical professionals should be allowed to give their assessment and advice on the matter based on their knowledge of medicine and patient relationships. Medical professionals should give an unbiased opinion as to not sway the families, and the families should have no restrictions on their decisions as long as these choices remain inside the cost concerns. The idea of a board of professionals, not including any family members, is to provide a framework for which genetic tests to perform. The decision to review the results of these tests and act on them should be left completely to the patient or family member if the patient is unable to act for his/herself.

Discussion Group 3

Group 3 was posed the following question to discuss: Where do you draw the line patient confidentiality versus a doctor's responsibility to share in Genetic Testing??

Format: AEMB Student Secretary, David Wolfson, led this group in discussing this question. This question allowed the students to think about what should be done with the results, and what possibilities and different scenarios exist regarding this question. David and his student group took a different approach to the question and listed all the different things to consider while making a decision regarding genetic testing. They made a list of questions that should be considered while looking at genetic testing as a whole, and then attempted to drive down from that list to determine what applies to the question that was posed. The write up below summarizes their discussion. David gathered the thoughts of the group and presented to the rest of the forum at the end of the session which again highlighted the many differing opinions on this sensitive topic.

Summary: Questions to consider:

<u>Use of human embryonic stem cells</u>

1. What is an ethical way to obtain hESCs from fetuses?
2. Is the embryo a living human being entitled to the same rights that a human would be granted?
3. Who should regulate the use of hESCs?
4. Where do we draw the line phylogenetically? How differently should we treat animals?

<u>Genetic Counseling</u>

1. Should seriously ill infants be kept alive?
2. Should treatment be stopped to allow the terminally ill to die?
3. Who should decide? Patient, family, doctor, or other?
4. Should humans be used in genetic experiments?
5. If so, what are the proper ways to use these experimental results?
6. Should genetic testing be done at all?

<u>Abortion</u>

1. For what type of conditions/illnesses should pregnancy be terminated?
2. What if quality-of-life is seriously compromised?

Many students began to wonder about the nature of patient confidentiality and how it is applied to pregnant mothers. Is confidentiality between the child and doctor, or the mother and doctor? There are many ways of interpreting and answering this question. Some religious beliefs may lead to sanctity and holiness of life that belongs to the fetus. Whereas others may argue a fetus, even if living, has no understanding or ability to comprehend the information that a doctor may have. As a result, this case is similar to what is seen in pediatrics where a parent may authorize consent and process confidential information for the child. Yet in another view, a fetus may be considered part of the mother's body, which is therefore her right to control and receive confidential medical information from the doctor. This discussion lead to many mixed opinions across the group, showing the complexity of the issue.

The group then shifted to discussion of how much information a medical professional should give. If the results of a test bring about additional information, should it be shared? At first the group struggled to agree on a viable

solution. Some arguing that all information should always be shared. Others arguing that this supplementary information may be harmful and was not requested in the first place, therefore there is no reason to share. Along this same line, most students agreed though that early detection of certain issues may lead to better treatment for a chance at better future conditions. From this reasoning, most students agreed that this type of information is vital for patient sharing in medicine. Cohesively the group found a compromise to settle the dispute by forcing doctors to have upfront documentation on all the possible information that may be found. This documentation would allow the patient/parents to decide what information would be shared if found, and take the responsibility away from the doctor. This method allows doctors to become a source of information for the patient while allowing the patient to keep control or responsibility of their own health decisions.

Conclusions

The format of this ethics session was highly successful as it involved the students and asked them to dive headfirst in to creating solutions for this complex topic. Dr. Frisina's keynote presentation was excellent and truly laid a great foundation for the discussions. The interactive discussions allowed the students to speak to and hear from those that are at completely different geographic locations and life stages than themselves. In turn, the diversity allowed everyone to realize the difficulty in governing such advances such as Genetic testing when there are so many different opinions available. Most sessions at the BMES conference focus on the key-note speaker, but this session had a dual purpose of having the key-note speaker as a resource for the student groups to access while attempting to come up with ideas and solutions to up and coming ethical solutions. It also started a pattern of discussion for this important topic, which, the students can take back to their individual campuses, jobs etc. and research some more. More than just hearing one person's thoughts, the students got an opportunity to hear an expert in the field speak and then apply the information in multiple different ways. Lastly, it engaged the students to be actively thinking about these topics and pursuing further knowledge in the topic as necessary. The fact that there were professors and faculty in some of the student groups further led to diversity in the groups, as they had a more knowledge to share from their own experiences as well as a different perspective on the questions that were posed. Interestingly, the students were able to lead the discussion with facilitation from the officers and come up with strikingly similar responses in all groups regarding patient confidentiality and personal choice regarding the topic of Genomic Testing.