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Media coverage and public awareness on bioethics perception of emerging biomedical therapies

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Abstract

Bioethics falls within the controversial ethical issues from the new advances and emerging technology in pre-clinical and clinical settings which inspired medical policy and practice. The purpose of this paper is to present an overview of ethical issues in stem cell-based therapies and to provide substantial argument for the need of a Bioethics Research Consortium that will be tasked with convening a disciplined board of experts that will apply their principles to biomedical research, and emerging technology to further stipulate the socioeconomic influence of such entities and their therapeutic impact to society. Not too long ago, the successful therapeutic studies in Parkinson's disease and stroke were the highlights of bioethical issues. The precedent for study selection was based on public feedback, government reception, and scientific analyses developed by these spearhead studies. From all the negative publicity that researchers have been getting before, the whiplash from decades of fear and misunderstanding has hindered the progress of scientific study. There is a huge figurative tug of war between what is making profit and what is needed to improve the health of afflicted patients worldwide. Poor management of education and funding may have actually hindered potential life changing cures and treatments from coming to fruition. We propose the creation of a Bioethics Research Consortium that would determine how ethical matters are handled with careful consideration to public need. The goal is to restructure drug development policy, and improve upon the ways in which research methods and funds are handled today.

Keywords: Ethics, Embryonic stem cells, Adult stem cells, Transplantation

Background

With novel discoveries and technological advances, there will come new legal, social, and ethical issues. Prior to the breakthroughs that helped advance the scientific communities to publicly display the need for their research, media coverage was unfortunately ill-managed and ethical concerns emerged as a result. Negative media coverage has led to public concerns that may have been misconstrued, and pre-clinical/clinical progress of novel treatment studies has been averted despite the favorable intent behind such studies. Cell based therapies have been studied for decades and have only recently caught the disinterest of the public opinion in the late 1980s. Public concern arose during the period of human fetal tissue being harvested from elective and spontaneous abortions that were obtained for the purpose of donor cell transplantations in Parkinson's disease (PD). One of the few medical centers world-wide that would conduct fetal cell transplantation was the University of South Florida Department of Neurosurgery and Brain Repair [1, 2]. We were well aware of the ethical concerns that were surrounding fetal tissue research, bearing particular sensitivity to the public's views on aborted fetal tissues, as well as the approach handled in regards to donor mothers [3]. There were other research academies such as Georgetown University that would contend to the use of fetal tissue in research and medical treatment procedures on the grounds of ethical and scientific study. Public opinion and media coverage hugely distorted the scientific reports, claiming that the use of fetal tissue used in medical treatments, as well as research, would not only display no regenerative properties, but would even

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exacerbate the symptoms of PD patients in comparison to the control group [4]. There were many counterclaims via the standpoint articles and stem cell community discussions from the research community, including that of the USF department of Neurosurgery and Brain repair. USF called for the resolution of these "negative" connotations to clarify that some studies involving cells implanted in patients were prepared adversely compared to other studies involving fetal cell transplant procedures, due to a lack of extensive cell culture manipulation. Severity of patient illness, and stem cell dosage need to be taken into careful consideration when troubleshooting stem cell transplantation protocols [5, 6]. In conclusion, it is critical to handle the entire stem cell transplantation scenario properly, and adhere to the ethical issues in a proper manner so that stem cell treatment outcomes do not confuse the general public about the clinical findings and studies.

Bioethical issues that accompany cell therapy over the last Two decades

There were several concerns raised against the use of fetal tissues. For instance, several fetuses were needed in order to transplant them into a single patient. In order to resolve this issue, an alternate non-fetal cell sources was sought out. The alternative was to find nonfetal cell sources that could differentiate, being able to be manufactured under quality control, and guaranteed conditions in order to have an ample and clinical grade nonfetal stem cell supply for transplantation. This kind of approach has many practical implications that would not only avoid ethical concerns, but also solves the public health and research/scientific problems that commonly arise when using a limited source of stem cells such as fetal cells. Accordingly, we provided crucial research studies for the world's first clinical trials allowed by the U.S. Food and Drug Administration (FDA) whereby cultured human neural progenitor cells were implanted in patients suffering from stroke [7, 8]. However, the problem was that these cells were immortalized neural cells, leading to public concerns of tumorigenesis [9, 10]. Therefore, safety because the number one concern in cell therapy controversy.

The search for a nonfetal safe and reliable cell source brought about the research on embryonic stem cell therapy. Once again, cell-base therapy was filled with controversy which attracted the public attention. The main point of controversy was the lack of knowledge and communication to understand the difference between an embryo and fetal tissue, arguing that an embryo is in fact when human life begins. During this very debate, the media was setting the stage for an even greater public outcry of fear that stem cell research could develop and eventually reach the stages of human cloning. Therefore, this preconceived notion of human cloning led to the idea that human embryonic cell-based therapies would not only violate human rights but also human dignity. The research community took yet another blow when the National Institute of Health (NIH) was pigeon-holed as a result of the ban on funding to further support embryonic stem cell research. Through the Bush administration, this ban was thoroughly upheld for 8 consecutive years [11].

The strengths and weaknesses of stem cell-based therapy research was discussed in order to restart initiatives among states for funding. One of the most active states was California, which passed a legislation for the continual funding of embryonic stem cell research [12]. Meanwhile, nonembryonic adult stem cell research gained public and policy maker interest and thrive relative to embryonic stem cells [13, 14], with the FDA's approval of clinical trials in 2008 on our pre-clinical trial data on human bone marrow derived cell research [15]. This progression in stem cell research however lasted only until March 2009, when President Barack Obama put a hold on stem cell research funding, stating that there has been no sign of potential use or progression of stem cell studies that resulted in reliable data and treatment methods since funding was allocated [16]. Ergo, The NIH released the Guidelines for Human Stem Cell Research, which was put into effect on July 7, 2009 [17].

The media has a heavy influence when it comes to public opinion and cell-based therapies. These influences include an exploited absence of successful communication between the public and the scientific community, and immediate reactive resolutions by policy makers to gain popularity. The focal point of this flaw lies not within changing of opinions due to the media or policy makers, it lies within the need for a proper solution for the public dialog and policy making as technologies advance. Developing technologies are most stifled when the public is fearful of the new scientific breakthrough, or sets unrealistic goals that give a sense of false hope. These reservations are not always without validity, but the media often uses this as an opportunity to increase its ratings in light of the controversy. This is usually the case for stem cell based therapies, and the newly advancing technologies that revolutionize healthcare.

There is an underrepresentation of benefits for stem cell based therapies due to social, legal, and ethical issues. Consideration for privacy, risk analysis, intellectual property and many other categories have not been sufficient in terms of policy development or assessment protocols that involve stem cell therapy. This means that there is no solid guidance on prerequisites to satisfy ethical issues for large scale funding including NIH and the FDA.

The establishment of an Ethics Research Consortium for Emerging Technologies will bring forth guidance and understanding by identifying and analyzing legal, social,

and moral issues and through an interdisciplinary method. (See Fig. 1) This clarity will lead to a deeper respect and appreciation that will guide policy makers and public misperception. The consortium will address issues such as confidentiality of tissue donors, safety concerns about tumorigenesis in stem cell transplantation, conflicts of interest, intellectual property of patented stem cell lines, and the commercialization of stem cells. Once these issues are properly addressed they may be able to offer guidelines for stem cell research for the NIH and FDA.

Public opinion is not an easy issue to address when speaking on the issues of stem cell therapy. The first challenge to be addressed by the consortium will be the determination of what public opinion truly is for stem cell based research and stem cell based therapies. Once that is established, there are three things that must be answered: 1) what is the best way to recognize and incorporate public opinion and policy making; 2) determining the overall benefit of the research in the midst of a multitude of different opinions; and 3) whether there can be an integration of education and ethical public opinions that can lead to a common good.

In order to successfully accomplish this groundwork the consortium will need to establish baseline data on public opinion by conducting three initial focus groups with opinion leaders (The Baseline Focus Group). This means that the focus groups cannot be generalized, but key issues will be identified and further explored. A second set of three community focus groups (Educational Focus Group), with the same individuals from the Baseline Focus Group, will be educated by the consortium. Education will include scientific information and policy recommendations developed by the panel from the feedback of the Baseline Focus Group. The focus group members will then be asked to return to their communities to think about the issues at hand. After a reasonable amount of time has passed, a final focus group will be made (The Educational Follow-up Focus Group). This group will give their feedback that will be incorporated into the final policy of the Consortium Report.

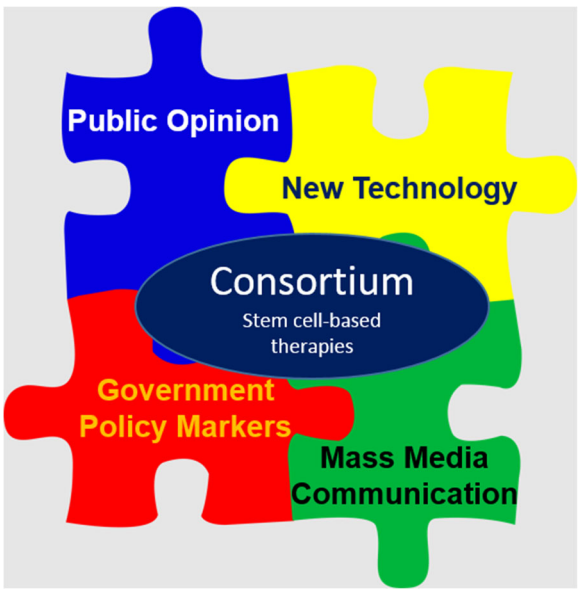

Fig. 1 Consortium bioethical issues based on stem cell-relevant therapies

The secondary interviews will determine will assess beliefs, opinions, and concerns about stem cell uses by using the same questions asked in the Baseline Focus Groups. The data collected will determine if the education provided was impactful their original conclusions.

In order to confirm the data, each of the focus group members which participated in all of the first three groups will be asked to determine who in their association will be inclined to aid in the final focus group to baseline opinions on stem cell research and its potential therapies. The beginning focus group members will be tasked to arrange educational materials that will be presented to the constituents in a kit that will contain all of the following: A brochure that contains explanations to the scientific information, recommendations that is expertly crafted by the Panel that addressed ethical issues, links that identified informational website (s) where the ethical issues are addressed, and other training modules that are determined by the Conglomerate. Than the initial group members will be needed to debate the issues with the established board. Next the Conglomerates will oversee a Conglomerate Opinion Focus Group with the mindset of achieving the guideline opinions, beliefs, concerns, and views of the board about stem cell-based tissue engineering. In addition, data collected data will be analyzed to determine the beliefs, opinions, and views the board focus group members may have. This approach was necessary in order to assess whether the majority opinion on ethical issues represents in the selected focus groups is fixed, or if it changes in correlation to the educational materials given on scientific data, as well as the groups' analysis on the pros and cons of the related research.

The basis for creating an Ethic Research conglomerate is so that we can establish a proactive public conclusion about stem cell research. Which in turn would form the structure for revisions to or creation of an intuitional state, or even national regulatory procedure that grows in parallel to the rapid progression of technological advances and discoveries. The stem cell Conglomerate should not only be able to recognize various grounds that would address all the critical barriers that the community and researchers may face, but also to achieve a consensus between the two society where any unanswered questions

may linger. For instance, government policies are highly persuaded by the mass media, whose misperceptions about stem cell-based therapies are communicated to them and the general public. The concept of the Conglomerate's design is to link the gap between the general public ideas of what is the "common good" and to provide scientific facts and correct information not only the mass media but also to the government. Therefore providing the public with evidence based on ethical tools for policy constructing. In order to keep up with various challenges that is brought up with emerging technological advances, the Conglomerate must tackle the situation head on with multiple spearhead approaches. This strategy will not only be able to steer public symposiums but also to critically observe the social costs that alternative options may hold. Develop training programs on the ethics of emerging technologies all the while focused on the overall goal of closing the gap between science and the "common good" as well informed and educated individuals approach making government policies through evidence based ideals.

The bases for the Consortium will be formed within an educational/research institution which will be integrated by ethicists, academic scientists, experts on policy making, as well as leaders from both public and private opinion. Through the use of surveys and discussion based forums, assessing the public opinion, we can use ethical criterions that were mentioned above (e.g., Intellectual property, commercialization, the common good, research participation, risk analysis, privacy, and conflicts of interests), to form the framework for suggestions towards the Conglomerate and its regular oversights. In order to establish this message, a position paper will be published in the peer-reviewed journal, and send as an open letter to the FDA, NIH, and other agencies in stem cell research. The strategy is to tackle the current guidelines with available NIH and FDA agencies to compromise and have an overview that would satisfy the public and ethical issues that surround stem cell research for grant protocol and IND applications.

Through this proposed Conglomerate, the public opinion will be able to get integrated and recognized into the policies concerning stem cell research. The goal is to let the public and funding agencies comprehend our results aiming to the promotion of accountability of stem cell research and its need for public funding.

Conclusion

In conclusion, the overall goal of the Ethics Research Conglomerate is to merge public opinions and desires with researching methods and goals to reach a continually evolving process as technology and societal views changes. Utilizing an evidence-based study and a proactive government policy making in response to proper communication between researchers and the mass media to the public. The Conglomerate's efforts will be the evidence necessary in order to prove for the need for an ethics board within an institution that is assigned with the application of ethical questions in terms of technology by certain ruling panels. The efforts of the Conglomerate is in stem cell technology advances and pits proposed research tools such as public forums, risk assessments, surveys, and interviews can be later modified as societal views changes and technology advances. Such as bioengineering and nanomedicine [18, 19]. A small scale trial study for the Conglomerate can begin at the community level and eventually reach a more large-scale study that should target a national level as the end desire for a better understanding of nations opinion on such emerging technological advances. This transition from community level to a national scale that reflects the benefits from a philosophical standpoint and policy reflections of involved democracy. In order to have the Conglomerate at such a scale, it is critical to present a solid and comprehensive guide from the American population that will be critical to the policy procedures of the public. Lastly, the awareness that with rapid progression of medical breakthroughs in stem cell research, would not only be at the mercy of the socioeconomics and political motives, but as well as public opinion. These are all the keys that open the doors to an assembly of a proper Conglomerate to promote better coordination with the public opinion and its policies to ensure that the public communication does not inhibit the progression of stem cell research for the greater good of the public.

Abbreviations

FDA: U.S. Food and Drug Administration; IND: Investigational new drug; NIH: National Institute of Health; PD: Parkinson's disease; USF: University of South Florida

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Availability of data and materials

This paper is a review article. Referred literature in this paper has been listed in the references part. The datasets supporting the conclusions of this article are available online by searching the PubMed. Some original points in this article come from the laboratory practice in our research centers and the authors' experiences.

Authors' contributions

The authors contributed equally to the conceptualization and write-up of this manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Not applicable.

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References

1. Freeman TB, Olanow CW, Hauser RA, Nauert GM, Smith DA, Borlongan CV, Sanberg PR, Holt DA, Kordower JH, Vingerhoets FJG, Snow BJ, Calne D, Gauger LL. Bilateral fetal nigral transplantation into the postcommissural putamen in Parkinson's disease. Ann neurol. 1995;3:379–88. PubMed: 7668823.
2. Kordower JH, Freeman TB, Snow BJ, Vingerhoets FJ, Mufson EJ, Sanberg PR, Hauser RA, Smith DA, Naue GM, Perl DP, Olanow CW. Neuropathological evidence of graft survival and striatal reinnervation after the transplantation of fetal mesencephalic tissue in a patient with Parkinson's disease. N engl j med. 1995;332:1118–24. PubMed: 7700284.
3. Sanberg PR. Students' views on fetal neural tissue transplantation. Lancet. 1990;335:1594. PubMed: 1972514.
4. Freed CR, Greene PE, Breeze RE, Tsai WY, Dumouchel W, Kao R, Dillon S, Winfield H, Culver S, Trojanowski JQ, Eidelberg D, Fahn S. Transplantation of embryonic dopamine neurons for severe Parkinson's disease. N engl j med. 2001;344:710–9. PubMed: 11236774.
5. Borlongan CV, Sanberg PR. Neural transplantation for treatment of Parkinson's disease. Drug discov today. 2002;7:674–82. PubMed: 12110244.
6. Hagell P, Piccini P, Björklund A, Brundin P, Rehncrona S, Widner H, Crabb L, Pavese N, Oertel WH, Quinn N, Brooks DJ, Lindvall O. Dyskinesias following neural transplantation in Parkinson's disease. Nat neurosci. 2002;5:627–8. PubMed: 12042822.
7. Borlongan CV, Tajima Y, Trojanowski JQ, Lee VM, Sanberg PR. Transplantation of cryopreserved human embryonal carcinoma-derived neurons (NT2N cells) promotes functional recovery in ischemic rats. Exp neurol. 1998;149:310–21. PubMed: 9500961.
8. Kondziolka D, Wechsler L, Goldstein S, Meltzer C, Thulborn KR, Gebel J, Jannetta P, Decesare S, Elder EM, Mcgrogan M, Reitman MA, Bynum L. Transplantation of cultured human neuronal cells for patients with stroke. Neurology. 2000;55:565–9. PubMed: 10953194.
9. Hara K, Yasuhara T, Maki M, Matsukawa N, Masuda T, Yu SJ, Ali M, Yu G, Xu L, Kim SU, Hess DC, Borlongan CV. Neural progenitor NT2N cell lines from teratocarcinoma for transplantation therapy in stroke. Prog neurobiol. 2008;85:318–34. PubMed: 18514379.
10. Newman MB, Misiut I, Willing AE, Zigova T, Karl RC, Borlongan CV, Sanberg PR. Tumorigenicity issues of embryonic carcinoma-derived stem cells: relevance to surgical trials using NT2 and hNT neural cells. Stem cells dev. 2005;14:29–43. PubMed: 15725742.
11. National Institute of Health, U.S. Department of Health and Human Services. Human Embryonic Stem Cell Policy Under Former President Bush (August 9, 2001–March 9, 2009). http://stemcells.nih.gov/policy/2001policy
12. Sanberg PR. Stem cell research's reversal of fortune. Scientist. 2005;19:12.
13. Borlongan CV, Chopp M, Steinberg GK, Bliss TM, Li Y, Lu M, Hess DC, Kondziolka D. Potential of stem/progenitor cells in treating stroke: the missing steps in translating cell therapy from laboratory to clinic. Regen med. 2008;3:249–50. PubMed:8462048.
14. Willing AE, Eve DJ, Sanberg PR. Umbilical cord blood transfusions for prevention of progressive brain in-jury and induction of neural recovery: an immunological perspective. Regen med. 2007;2:457–64. PubMed: 17635052.
15. Borlongan CV. Cell therapy for stroke: remaining issues to address before embarking on clinical trials. Stroke. 2009;40:146–8.
16. Obama B. Executive order 13505. Removing barriers to responsible scientific research involving human stem cells. Fed reg. 2009;74(46):10667–8.
17. National Institutes of Health Guidelines on Human Stem Cell Research. http://stemcells.nih.gov/policy/2009guidelines.htm
18. Neuss S, Stainforth R, Salber J, Schenck P, Bovi M, Knüchel R, Perez-Bouza A. Long-term survival and bipotent terminal differentiation of human mesenchymal stem cells (hMSC) in combination with a commercially available three-dimensional collagen scaffold. Cell transplant. 2008;17:977–86. PubMed: 19069639.
19. Nolan K, Millet Y, Ricordi C, Stabler CL. Tissue engineering and biomaterials in regenerative medicine. Cell transplant. 2008;17:241–3. PubMed: 18522227.