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INTERNATIONAL STEM CELL SCIENCE AND POLICY

HIGHLIGHTS AND RECOMMENDATIONS FROM THE 2012 QATAR FOUNDATION-BAKER INSTITUTE EVENT
“QATAR INTERNATIONAL CONFERENCE ON STEM CELL SCIENCE AND POLICY”

Since 2007, the Qatar Foundation has worked with Rice University’s Baker Institute to develop the institute’s International Stem Cell Policy Program. This program analyzes stem cell research, policy, and ethics in an international context—with a focus on the progress in the Middle East and North Africa (MENA). To this end, the two groups have hosted five discussions in Houston, Texas, and two international conferences in Doha, Qatar.

At the first one-day conference in 2009, “The Qatar Stem Cell Workshop 2009,” participants reviewed current stem cell research and regulation. The aim was to guide Qatar as it developed policies compatible with its cultural, religious, and ethical standards (Matthews, Lane, and Haoudi 2009). The second conference, in February 2012, expanded previous discussions on policy, ethics, and research during the four-day event “Qatar International Conference on Stem Cell Science and Policy.”

The goal of the 2012 conference was to inform and engage scientists in an array of stem cell issues as well as bridge the gap between science and policy in an international context. Over 60 speakers participated in the event that involved more than 400 attendees. Participants represented 20 different countries, with scholars from the MENA countries: Egypt, Iran, Lebanon, Libya, Saudi Arabia, Turkey, United Arab Emirates (UAE), and over 300 participants from Qatar. Additional attendees hailed from Australia, Belgium, Canada, France, Germany, Japan, the Netherlands, Norway, Pakistan, the United Kingdom (UK), Ukraine, and the United States.

The conference was divided equally into science research sessions and policy and ethics sessions. Science sessions covered pluripotent, hematopoietic, and cord blood stem cell research;

stem cell transplantation; and the uses of stem cells in the treatment of cardiovascular disease and neurological disorders. Ethics and policy discussions were organized to address embryonic research and egg donations, stem cell banking, international regulation of stem cell research, and clinical trial oversight. There were also panels that specifically highlighted stem cell research and policies in the Middle East.

While a major aim of the conference was to bring attention to Qatar’s stem cell research program, the conference also provided regional scientists and ethicists an opportunity to discuss their religious and cultural views of this research. Moreover, the event helped encourage international collaborations, particularly between scientists in Qatar and visiting researchers.

This report will highlight different aspects of the conference proceedings, including novel stem cell research, current ethical discussions, and pressing policy issues that are region-specific. It will also describe the major themes of the conference and offer an outlook on the future of stem cell research and its obstacles both in the Middle East and globally. Finally, we will offer recommendations for sustaining international meetings that encompass broad issues in this important area of cutting-edge science.

STEM CELL RESEARCH AND CHALLENGES

Stem cells represent one of the hottest areas of biomedical research. Though the concept of stem cells has been around for decades, it was not until James Thomson’s publication describing the creation of the first human embryonic stem cell (hESC) and Shinya Yamanaka’s Nobel Prize-winning research creating the first human induced

pluripotent stem cell (hiPSC) that the public became excited about the research’s potential (Thomson et al. 1998; Takahashi et al. 2007). Since these discoveries, stem cell research has blossomed over the past decade, as many new scientists entered the field and hundreds of start-up companies were founded. In the United States, the National Institutes of Health (NIH), the major funding source for biomedical research, increased its funding of stem cell research from approximately \$135 million (in 2003) to an estimated \$1.2 billion in 2013 (Matthews 2005; NIH).

Stem cell research includes both pluripotent stem cells—such as hESC and hiPSC—as well as cells obtained from cord blood and adults (Matthews 2009). Each area has its own strengths and weaknesses. Adult stem cells can only be found in limited types of tissues, and many are difficult to isolate and grow. Pluripotent stem cells were more recently discovered, and researchers are still working to control their development effectively. Furthermore, hESCs face additional ethical and policy challenges due to the controversial nature of their source. Regardless of the cell type, all stem cells behave differently from the traditional cell types used in research laboratories, requiring careful study in the new field of regenerative medicine before therapies can be applied in humans.

The 2012 Baker Institute stem cell conference in Qatar delved into the latest stem cell research and covered a broad range of topics to highlight various innovations in the field. Specifically, research discussed was classified in four broad categories of stem cells: hESC, hiPSCs, neural stem cells, and hematopoietic stem cells. While only providing a snapshot perspective, the event demonstrated how this emerging field could impact the future of medicine and health.

Embryonic Stem Cell Research

hESCs are generated by harvesting cells from an embryo five- to six days after fertilization (Matthews 2009). The isolated cells can divide indefinitely and become any cell type in the body, such as a muscle or bone cell, in a process termed differentiation. Due to this potential, scientists, doctors, and patients believe that hESCs are the key to developing cures or treatments for diseases

like diabetes and Parkinson disease. Consequently, hESCs are being studied in numerous laboratories worldwide.

Several presenters at the conference discussed their research using hESCs. A focal point in this area was the study of the differentiation process of hESCs. Roger Pedersen, Ph.D., director of research for the Anne McLaren Laboratory for Regenerative Medicine at Cambridge University, presented his work on differentiation of both mouse and human ESCs, and his findings that mouse ESCs are in a less mature state than hESCs. The work of Ed Stanley, Ph.D., professor at Monash University, and David Elliot, Ph.D., faculty of medicine at Monash University, complemented Pedersen’s. Their laboratories are observing the effects of protein signaling on the differentiation of hESCs. Stanley and Elliot used an array of protein combinations to determine which permutations yielded specific tissue types. Research from Reza Ardehali, M.D., Ph.D., assistant professor at the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research Center at the University of California, Los Angeles, tried to define conditions for differentiating hESC lines into cardiac muscle cells using different combinations of growth factors and proteins.

Other researchers focused on aspects important in the clinic. The lab of Joanne Mountford, Ph.D., senior lecturer in the Institute of Cardiovascular and Medical Sciences at the University of Glasgow, attempts to use pluripotent stem cells to produce red blood cells for transfusions. While Gerald Schatten, Ph.D., director of the division of developmental and regenerative medicine at the University of Pittsburgh School of Medicine, investigates where stem cells migrate and how they function post-implantation by labeling the cells with a magnetic dye and imaging them under magnetic resonance. Schatten’s lab aims to understand how pluripotent stem cells could negatively affect patients, specifically if they travel to an untargeted location in the body and form an undesired tumor. Finally, work from Stephen Minger, Ph.D., global head of research and development (R&D) for cell technologies at GE Healthcare Life Sciences, highlighted the utility of hESCs as a tool for drug screens, differentiating hESCs into cardiomyocytes

to observe potential drug side effects and toxicity on the cells.

Collectively, this work provides a better understanding of the biology behind the differentiation process of hESC. This knowledge will prove critical in the development of cell-based therapies as well as in traditional medicine. Possessing a complete picture of the differentiation process not only helps researchers in the development of specific cell types, but also prepares them for all possible outcomes of stem-cell-based therapies.

Induced Pluripotent Stem Cells

hiPSCs, formed by reprogramming adult cells (e.g., skin cells), were first created in 2007 (Takahashi et al. 2007). They are very similar to hESCs in their ability to differentiate into all cell types in the body. The first techniques used to create hiPSCs involved turning on specific genes, some of which are associated with cancer, to revert the adult cell to an embryonic-like state. Since then, alternative methods have been developed, including exposure to specific chemicals, to trigger reprogramming. Because these cells share the properties of hESCs while avoiding the ethical controversies of embryo use, many researchers have begun to use these cells. But hESCs still remain the gold standard and are the cell line used to compare others to determine their pluripotent state.

At the Qatar conference, several researchers presented the successes and challenges of hiPSC research. Ludovic Vallier, Ph.D., director of Cambridge Stem Cell Initiative, provided an overview of his work on the creation of hepatocytes from hiPSCs. He identified four major challenges in taking iPS cells to the clinic: (1) measuring the quality of the hiPSC lines; (2) improving efficiency of reprogramming; (3) generating large populations of hepatocytes from iPS cells; and (4) determining the safety of the cells and the treatment. The laboratory of Chad Cowan, Ph.D., associate professor of medicine at Harvard Medical School, works on ways to efficiently differentiate iPS cells into functional adipocytes as a way to study cardiovascular diseases and diabetes. Interestingly, Cowan was able to induce insulin resistance in these cells by supplementing their media with a high concentration of fatty acids, thus creating a model for type II diabetes.

With a slightly different way of reprogramming normal (adult) cells, research from Deepak Srivastava, M.D., Ph.D., director of the Roddenberry Stem Cell Center at the Gladstone Institute and the Wilma and Adeline Pirag Distinguished Professor at the University of California, San Francisco, tries to develop cardiomyocytes, endothelial cells, and smooth muscle cells from those already present in the heart. This theoretically allows for quick and efficient cell regeneration to treat myocardial infarction and heart disease.

This new and innovative area of research is still in a nascent stage, yet already holds immense potential for therapies. Using hiPSCs supplies researchers with a potentially limitless number of cells with which to work with and can also provide them with pluripotent cells from a specific genetic background. Furthermore, the science that reprograms cells to specific differentiated points in development could make regenerative medicine more accessible and versatile. A variety of diseases and injuries such as spinal cord injuries, heart disease, and multiple sclerosis could be treated without the risk of implanting undifferentiated cells in the body.

Neural Stem Cells

Neural stem cells (NSCs) are able to differentiate into nervous system cells such as neurons and astrocytes, which are responsible for transmitting signals between the brain and the rest of the body. Isolation and culture of NSCs for therapies would make them ideal for the treatment of spinal cord and brain traumas—injuries in which the nervous system is damaged and cannot regenerate on its own.

Several scientists presented their NSC research at the conference, which focused on the link between their research and major diseases. Mark Kotter, Ph.D., clinical lecturer for the department of clinical neurosciences at Cambridge University, spoke about his research on the differentiation of oligodendrocyte precursor cells and the myelination of neurons—which could be used to help understand multiple sclerosis and other neurological disorders. The lab of Stefano Pluchino, Ph.D., lecturer for the department of clinical neurosciences at Cambridge University, discussed the interplay of NSCs and the dysfunctional

environment characteristic of central nervous system (CNS) disorders. Francis Szele, Ph.D., university lecturer and associate of the Oxford Stem Cell Institute and Oxford University, investigated the role of stem cells in the repair of post-stroke neural injuries. He found that inhibiting the migration of stem cells exacerbated the severity of the stroke.

Additionally, Ann Tsukamoto, Ph.D., executive vice president of R&D at StemCells Inc., discussed several ongoing and imminent clinical trials using NSCs developed at her company. The NSCs appeared to have promising results for treating lysosomal storage disease, Alzheimer's disease, spinal cord injuries, and age-related macular degeneration (AMD).

Research in NSCs shows great promise in treating neural disorders and diseases, therapies that are among the highest in demand. The further development of these technologies could lead to cures for patients with spinal cord injuries or Parkinson disease—disorders for which treatments relieve symptoms, but do not restore proper function of the neural system.

Hematopoietic Stem Cells

Hematopoietic stem cells (HSCs) are the blood-forming stem cells found primarily in the bone marrow. They are capable of differentiating into all blood cells and have been used therapeutically in bone marrow transplants to treat blood cancers for over 50 years (Appelbaum 2007). The HSC field boasts a number of renowned researchers, two of whom presented keynote addresses on their research at the conference: David Baltimore, Ph.D., the Robert A. Millikan Professor of Biology at the California Institute of Technology, and Irving Weissman, M.D., director of the Stanford Institute for Stem Cell Biology and Regenerative Medicine.

Baltimore discussed several of his ongoing projects, including the treatment of HIV/AIDS by removal of the CCR5 receptors from CD4 cells, and the treatment of cancer utilizing the body's own immune system to attack cancerous cells. The CCR5 receptor plays a large role in the ability of the HIV/AIDS virus to infect cells; without this receptor, the virus cannot survive in the host. This research was inspired by a HIV-positive patient who was subsequently

diagnosed with leukemia (Hütter et al. 2009, 5). His doctors attempted to treat the HIV and leukemia simultaneously using a bone marrow transplant from a donor whose CD4 cells lacked the CCR5 receptor. The therapy succeeded, and the patient was effectively cured of both HIV and leukemia. Baltimore's lab is using this idea in the development of a treatment in which a patient's own CD4 cells are isolated, altered to remove the CCR5 receptor, and transfused back into the patient. This process is currently being optimized for clinical use and will be ready for clinical trials soon.

The second project from the Baltimore lab is the engineering of immune cells to recognize cancer cells, thereby using the body's own immune system to destroy malignant tissue. To accomplish this, researchers transferred a specific T-cell receptor domain that recognizes malignant cells to T cells. This method has been used to treat several patients in clinical trials and showed tumor regression during the first couple of months. However, at later time points, the tumors returned, and the T cells began to attack normal tissue. Future work will involve targeting HSCs that differentiate into T cells to ensure lifelong production of these cells. Additionally, a different target on the cancer cells could be chosen to prevent detrimental side effects.

Weissman also discussed the numerous research aims of his laboratory. His lab demonstrated that the use of pure HSC transplants in cancer treatment showed greater success rates than the transplantation of heterogenous cell populations, preventing graft-versus-host disease, a common complication of bone marrow transplants. A major hurdle to these types of transplants is the required removal of the host immune system, which is achieved by irradiation. Weissman's research looks into tagging the host stem cells with antibodies for removal instead of using techniques that damage all cells indiscriminately.

He also proposed the use of HSC transplants in tandem with organ transplants to prevent immune rejection and eliminate the need for lifelong immune suppression regimens. One project in the Weissman lab involves the transplant of HSCs for the treatment of diabetes, which is an autoimmune disorder. His laboratory found that

when HSCs and pancreatic islet cells (the insulin-producing cells destroyed in diabetic patients) were transplanted into diabetic mice, the mice were cured of diabetes.

Finally, the Weissman lab has investigated leukemia stem cells and discovered that many of these cells express a protein called CD47, which helps them to escape destruction by macrophages and other immune cells. By injecting an antibody against this protein into leukemia patients, the CD47 avoidance signal is blocked and the leukemia stem cells can be destroyed.

Overall, these leaders in the stem cell field presented a broad body of work. The range of research, from basic science to clinical trials, demonstrates the great potential of stem cells for therapeutic applications. The conference enabled scientists in the field to share their research and optimism regarding the future of stem cells in medicine. But many challenges must still be addressed, including ethical and policy challenges.

ETHICS AND POLICY

hESC research has a long history of political and ethical controversy due to the destruction of human embryos in the creation of cell lines. The most publicized debate has centered on the moral status of the embryo (Gottweis 2010). This still remains a prominent issue, evident in the *Sherley v. Sebelius* (U.S.) and *Greenpeace v. Brüstle* (EU) cases, in which the federal funding (U.S. case) and patenting of hESC research (EU case) were challenged on grounds of public morality (Matthews et al. 2012).

Other areas of concern are also coming to the forefront. Today, the debate on stem cell research includes discussions on the challenges arising from the translation of research into therapies, including informed consent, the regulation of egg donation/exchange, and clinical trial safety; the consequences of commercialization; and the distribution of benefits arising from the technology.

In an environment filled with new ethical and political issues, scholars must keep abreast of scientific developments and facilitate discussions between scientists, policymakers, and the public when questions arise about the societal impact of new scientific advancements. Conference

participants discussed the challenges of translating stem cell research into therapies in light of critical conceptual issues such as intellectual property rights to the cells or technologies (including how cells are cultured) and the role of long-standing religious traditions.

Regulating Stem Cell Research

Many ethical issues arise from the transition of research to therapy, including the ethics of oocyte (human egg) retrieval, payment to women for their eggs, chimeras (mixing human and animal cells and DNA), commercialization, and patenting. Regional and national policy differences addressing these issues often further complicate collaborative efforts.

Often described as a “patchwork of patchworks,” stem cell policies range from restrictive (no derivation of hESC lines permitted, and either tight or blanket prohibition on hESC research), permissive with limits (funding limits on hESC research and line derivations as well as limits on therapeutic cloning), and permissive (allowing the derivation of hESCs for research within strict oversight systems) (Caulfield et al. 2009). For instance, it is a criminal offense to derive hESC lines in Germany, although the importation of lines is permitted. In contrast, UK policy currently facilitates and funds research (Gottweis, Salter, and Waldby 2009; Matthews and Rowland 2011; Isasi and Knoppers 2006). As hESCs have become a hot button political issue over the past decade, countries in general are shifting toward more permissive policies, most commonly allowing research on supernumerary in vitro fertilization (IVF) embryos.

Much of this research is collaborative. In studies on stem cell research and international collaborations in the United Kingdom, United States, and MENA countries, Kirstin Matthews, Ph.D., fellow in science and technology policy at Rice University’s Baker Institute, confirmed that international collaborations garner higher citation rates on average. It is thus extremely beneficial for scientists to collaborate internationally (Luo et al. 2011; Flynn and Matthews 2010).

Maintaining scientific integrity at a distance, however, can be challenging. “Which rules should be followed when collaborating?” Jeremy Sugarman, M.D., Harvey M. Meyerhoff

Professor of Bioethics and Medicine at Johns Hopkins University, posited at the conference. To address this question, several guidelines for stem cell research have been created over the past decade by organizations including Johns Hopkins University, The Hinxton Group, and the International Society for Stem Cell Research (ISSCR). These organizations emphasize the importance of local oversight committees to ensure the responsible conduct of researchers. At Sugarman's university, the hESC oversight committees, much like an institutional review board (IRB), run in parallel with research so it does not slow the progress of science when reviewing all hESC research, somatic cell nuclear transfer (SCNT) work involving human cells, and all other research that may raise potential ethical questions. These professional guidelines exist to address the complex ethical issues involved in stem cell science, and the implementation of these guidelines can alleviate some of the ethical anxieties associated with stem cell research.

International collaboration also requires a high level of data sharing. Kazuto Kato, D.Sc., associate professor at Kyoto University, suggested that stem cell research follow the Bermuda Principle of free data sharing, which was used by researchers during the human genome project. Data sharing promotes research, but it faces challenges including privacy issues for donors, burdensome review processes, and a lack of incentive in many cases. While sharing should be encouraged, a balance must be maintained between sharing data and protecting the privacy of donors and patients.

Timothy Caulfield, professor at the University of Alberta, cautioned researchers against the increased pressure to commercialize stem cell research. Such pressure has led to the premature implementation of therapies, and can ultimately lead to a loss of public trust (Caulfield 2010). In general, Caulfield found public trust declined when a company was associated with researchers or their work. Additionally, commercialization reduces collaboration, encourages the withholding of information, and consequently impedes research progress. Caulfield advised researchers to be more aware of the potential harms of commercialization.

Embryonic Research and Egg Donations

Over the past decade, prominent issues facing stem cell research have shifted from a debate on the moral status of embryos to questions arising from the donation or exchange of human oocytes (eggs). Laurie Zoloth, Ph.D., professor at Northwestern University, highlighted three lessons we have learned from the human embryo debate: (1) some issues are not resolvable because they involve individual religious beliefs which are unlikely to change; (2) some issues are very difficult to resolve, and lengthy debates are often influenced by the changing political environment; and (3) some arguments are moot because the science being debated is far from being realized.

Like hESC research policies, a variety of egg donation policies exist, from an outright ban to more permissive regimes. Policies also range from those that permit compensation without insisting on the anonymity of donors (UK); to those that protect the anonymity of donors but do not permit compensation (France); and systems that employ both compensation and the protection of anonymity (U.S.) (Levine 2011; Human Fertilisation and Embryology Authority 2011). While the promise of anonymity does not result in a significantly higher number of donated eggs, systems employing compensation do. "Is there an ethical way to compensate?" asked Aaron Levine, Ph.D., assistant professor at Georgia Institute of Technology. Currently, egg donations are not tracked nationally in many countries, thus no systematic data exists on the use of donated eggs in research.

Informed consent in egg and embryo donation, highlighted by Ana Iltis, Ph.D., associate professor of bioethics at Wake Forest University, is not simply a regulatory obligation, but one needed to respect the rights and dignity of the donor. Questions to consider when creating policy include when and from whom informed consent should be sought, and whether it is possible to recontact the individual(s) for consent. In an embryo donation, informed consent may refer to the woman involved as well as the male gamete donor. And in egg donations for research, there are various different time points at which informed consent may be obtained. Should informed consent for research be obtained prior to or after the removal of eggs from fertility

patients? And for nonpatients, those donating for other couples, informed consent could be sought prior to donation or prior to use in research. The ISSCR Guidelines emphasizes that “persons should be afforded a fair opportunity to participate in research,” but “caution must also be taken to ensure that persons are not exploited during the procurement process, especially individuals who are vulnerable due to their dependent status or their compromised ability to offer fully voluntary consent” (Daley et al. 2007). Ittis argues that we need disclosure as well as measures to improve the capacity of individuals to understand the complexity of the decision in order to achieve free and voluntary decisions.

Stem Cell Banking

One new area of interest, as stem cell research translates into therapies, is the banking of stem cells. Nancy King, Ph.D., professor at Wake Forest University School of Medicine, noted that because stem cell banking is a form of biobanking—the collection of biospecimens or genetic material with the associated data—it will face many of the same issues currently associated with biobanks, including informed consent, confidentiality and privacy, ownership and benefit-sharing, scope and control of future uses of samples, and considerations of justice. As with other areas that require patient donations, debate surrounds the appropriate model of informed consent: presumed, specific, general, or tiered (Mello and Wolf 2010). With presumed consent, patients are informed that their samples will be used for future research and given the opportunity to expressly deny permission at the time of sample collection. General consent is similar, though patients are required to expressly permit use. Specific consent entails recontacting the sample donor each time his sample will be used in a new research context. And tiered consent, for which King advocates, provides patients with a variety of options at the time their samples are collected, including general permission for future use, consent for future uses related to the original study topic, and consent for future uses unrelated to the original study topic. Tiered consent, she argues, focuses on patient rights while limiting the power of researchers; emphasizes data security and public health; and involves an element of democratic

involvement from stakeholders. It also requires more paperwork and the ability to contact the patient months or years after donation, which could severely limit research.

The concept of informed consent in the Arab world, argues Katrina Aisha Chong, Ph.D., senior lecturer in medical law at the University of Lancashire, is being challenged as research has evolved from using a donated sample for a single project to having multiple uses for a donation. The current structure of informed consent is also incongruent with the Arab world, as it places autonomy solely on the individual, whereas Arab communities take a strong collectivist approach to making decisions on issues such as tissue donation. Furthermore, products of donations may be commercialized and subject to intellectual property rights, which is largely incompatible with the religious motivations behind many Muslim tissue donations. As more research is carried out in Islamic countries, it is crucial that each nation establish informed consent procedures that align with its cultural and ethical ideals.

Another major issue in biobanking is confidentiality. Using genetic markers, samples can theoretically be identified and linked back to the donor or the donor family. Furthermore, the potential of research results to reify race in society could lead to the stigmatization of individuals (Epstein 2007).

In addition to ethical challenges to stem cell banking, there are also policy and regulatory issues. Regulation serves many purposes and can be used to ensure that international standards in biobanking are met, encourage donations, further enable international collaborations between researchers, and “integrate globally the biosampling work being done regionally,” commented Sarah Ellson, partner at Field Fisher Waterhouse LLP. There are many regulatory frameworks from which to choose and many limitations to what regulation can achieve, whether the standards are minimal, gold, international, or essential standards. While regulation is a necessity, it should also be seen as an opportunity through which research can be further advanced.

Clinical Trial Oversight and Regulation

One of the major shifts in stem cell research is the move from basic laboratory research to the development of therapies. Public oversight is a reflection of a society's perception of and response to risk relative to the expectations of benefit, stated Mark Frankel, director of the Scientific Freedom, Responsibility, and Law Program at the American Association for the Advancement of Science (AAAS). As different individuals have different perceptions of risk, promoting and protecting the public interest is a complicated balancing act. Public policy can influence science by addressing uncertainty. While they can easily address uncertainty in their research, scientists face difficulties dealing with policy uncertainties that influence their ability to carry out research. Patients have to contend with uncertainty regarding the safety of medical treatments. And industry faces uncertainty with regard to financial markets. A strong legal foundation, such as an international governance board, can alleviate some of the uncertainty (Isasi and Knoppers 2011). Frankel also cautioned against placing too much faith in a legally bound oversight system for clinical trials, which, while necessary, is limited and also occasionally burdensome for researchers. As those responsible for oversight are human, the system is fallible. What is ultimately needed is an amalgamation of law and ethics, and private and public oversight.

The role of the clinical trial is to test uncertainty in a reliable and objective manner. While trials serve various interests, there must be agreed upon endpoints and methods to measure effectiveness. Scientific challenges for stem cell clinical trials include inaccurate assays for cell potency, a lack of genetic stability in some manufactured cells, and the ability to detect the function cells after transplantation. It is also difficult to design a trial that demonstrates proof of concept, as well as to select the appropriate age and number of participants, and determine the duration of the trial. Insoo Hyun, Ph.D., associate professor of bioethics at Case Western Reserve University, highlighted some of the ethical challenges facing clinical trials at the conference, including the process of informed consent, withdrawal mechanisms, and the role of patient perspectives in trial design.

One of the most profound questions in translational research is, "who should go first in

human trials when the risks are not possible to estimate, the trial highly observed, and the effects of failure far-reaching?" Jan Helge Solbakk, M.D., Ph.D., professor at the University of Oslo, argues that translational research involving humans faces ethical challenges that cannot be resolved (Solbakk and Zoloth 2011). As of yet, there are no accepted standards to measure risk and benefit from Phase I trials. Consequently, patients in the interim are enrolled in clinical trials designed to determine the safety of the therapy, as opposed to providing benefits to the patient. Despite the creation of ethical clinical trial guidelines by the ISSCR in 2008, Solbakk argues that initial translational research faces inevitable fallibility. Attention thus should be focused on describing the inherent pitfalls of translation in a transparent manner that emphasizes accountability and minimization of harm to patients.

As the debate in stem cell research shifts toward the challenges arising from the translation of research into therapies, a plethora of issues, as highlighted by the speakers, will have to be addressed in order to protect the safety and well-being of patients, the human dignity of gamete and embryo donors, and research integrity. While there are extant guidelines from organizations such as The Hinxtion Group and ISSCR, it will be up to individual nations and organizations to establish policies and implement guidelines. As noted by many conference speakers, stem cell research raises many ethical and religious issues, thus there is no regulatory scheme and policy that is appropriate for all nations. The conference not only demonstrated the progress that has been made in stem cell science in the past few years, but also underlined many of the rising issues and possible methods to address them.

STEM CELL RESEARCH AND POLICY IN THE MIDDLE EAST

Over the past decade, stem cell research has expanded around the world, including to the Middle East and North Africa (MENA) region. Of the MENA nations, researchers from 12 countries—Egypt, Israel, Iran, Jordan, Kuwait, Lebanon, Morocco, Pakistan, Saudi Arabia, Tunisia, Turkey, and UAE—published at least one stem cell article (as the main and corresponding author) from 1998 to 2008 (Flynn and Matthews 2010). The major programs were located in Israel, Turkey, and Iran, with 58 percent of total

MENA stem cell publications originating from Israel, 23 percent from Turkey, and 12 percent from Iran. These countries were among the first in the region to establish religious or legal frameworks related to hESC research. The remaining countries accounted for approximately 7 percent of all publications from the region. Many nations, such as Saudi Arabia and Qatar, have more nascent programs and are in the process of developing their stem cell policies.

At the 2012 conference in Qatar, scientists, ethicists, and policy scholars from Iran, Saudi Arabia, Turkey, and Qatar presented their research and described their respective national policies. These discussions highlighted the research being carried out, as well as the ethical and policy discussions underway in the region.

Qatar's Emerging Stem Cell Research Center for Excellence

In the past decade, Qatar has focused on the development of a prestigious center for research and education. To this end, Qatar constructed Education City in Doha. Education City houses satellite campuses from several of the world's top universities, including Weill Cornell Medical College, Northwestern University, Georgetown University, and Carnegie Mellon University (Qatar Foundation). Through the Qatar Foundation, the country supports cutting-edge science and engineering research and is investing in the future by actively recruiting faculty from around the world to establish research laboratories. In addition, the Qatar Foundation has implemented the Qatar Student Leadership Program (QSLP), sending Qatari students overseas to study with highly regarded scientists in Europe and the United States (QSLP). The program offers students a prestigious internship to help them get into a reputable graduate program and encourages them to return to Qatar where they can begin their own research careers.

Several Qatari stem cell scientists presented their work at the conference. Sir Magdi Yacoub, Ph.D., professor of cardiothoracic surgery at the National Heart and Lung Institute at Imperial College London, gave an overview of the Qatar Cardiovascular Research Center, a new center focused on translational research. Ongoing research includes the use of stem cells in creating new heart valves and tailoring gene therapy to treat cardiac diseases with iPSCs. Another researcher at the center, Jeremie

Arash Rafii Tabrizi, M.D., Ph.D., assistant professor of genetic medicine at Weill Cornell Medical College in Qatar, also described his work developing a way to differentiate ESCs into heart muscle cells. Once his laboratory optimizes the process, these cells can be applied in many other research ventures, including Heba Al-Siddiqi's work, which is to characterizing the native environment of heart muscle cells with the goal of someday being able to build a heart itself. The lab of Haitham Abu Saleh, Ph.D., at Weill Cornell Medical College in Qatar studies how endothelial progenitor cells can prevent clot formation.

Qatari Ethics and Policy

Qatar is developing a national stem cell policy as it builds a robust stem cell research program. In 2009, the Qatar Supreme Council of Health (SCH) was established by Amiri Decree Number 13 to set guidelines for human and animal research with the goal of protecting the welfare of all research subjects. Since its inception, the Qatar SCH has developed a stem cell research policy and formed the Research Ethics Committee, a multi-stakeholder committee that initiates policies and regulations for the ethical conduct of science and arbitrates on exceptional and often controversial issues such as stem cells. Some of the ethical challenges faced by the SCH in developing stem cell research policy include the rights of the fertilized ovum and the ensoulment of the fetus.

After considering scientific and Islamic perspectives, the SCH developed a stem cell policy in accordance with both scientific knowledge and religious views. From a scientific perspective, the pre-embryonic stage can be defined as the moment from fertilization to the widely accepted standard of 14 days. This, however, is not congruent with Islamic views, which sometimes holds that the human spirit begins at conception. In 1997, the Islamic Organization for Medical Sciences issued a fatwa that deemed human life to begin at conception, thus concluding that embryos cannot be produced or aborted for the purposes of research. In 2003, the Muslim World League Institute of Islamic Fiqh issued a fatwa that permitted the use of stem cells for therapeutic or scientific purposes, provided that the cells were obtained from permissible sources. This is the policy that Qatar has chosen to follow.

Faleh Mohamed Hussein Ali, M.B., assistant to the general secretary for policy affairs at SCH, noted at the conference that Qatar’s policies support the conduct of responsible and scientifically worthy human stem cell research, including hESC research. Permissible sources for hESCs include samples originally intended for reproductive purposes (IVF), as long as the individual donates them voluntarily; with no incentive for the donation, commercial or otherwise. Other permissible cells include nonembryonic, human adult stem cells; hiPSCs; cord blood and placenta stem cells; and cells from accidental/therapeutic miscarriage. Embryos not generated for IVF, therapeutic cloning, and the creation of chimeras are impermissible. Ali highlighted the flexible nature of Qatar’s stem cell policy, which allows the SCH to create new regulations in response to scientific advancements. Currently, the SCH is working to standardize research laboratory regulations, a legislative tool that Qatar hopes other countries in the MENA region will adopt.

Ali Mohayuddin Qaradaghi, Ph.D., former head of the Jurisprudence Department at Qatar University, elaborated on the views of sharia regarding stem cell research. He maintained that sharia does not oppose stem cell research, provided it is for life-saving purposes and does not harm another living organism. While sharia permits the use of cord blood, the issue of supernumerary IVF embryos remains controversial. Sharia opposes fetal stem cells except in certain controlled cases when the miscarriage is natural. Qaradaghi also discussed the introduction and legality of gene therapy. In line with sharia, therapy must not inflict harm on humans, though slight harm is permitted if it is significantly outweighed by the benefits. Qaradaghi emphasized the need for scientists to take any available technical measures to avoid harm and conduct therapy in moderation.

Stem Cell Research in the Middle East

Many other countries in the Middle East in addition to Qatar have begun to conduct stem cell research. This was evident in the number of MENA countries represented by scientists at the conference, which provided researchers with a unique opportunity to interact and network with renowned stem cell researchers from across the globe. The conference showcased regional stem cell research in a special

session, highlighting the work in progress in MENA countries.

Researchers from MENA countries are investigating stem cells for different applications. Many are conducting experiments to better understand the differentiation process of stem cells. Ghasem Hosseini Salekdeh, Ph.D., head of the Proteomics and Molecular Biology Lab at the Royan Institute, for instance, is identifying proteins that are crucial in stem cell differentiation. The work of Hossein Baharvand, Ph.D., head of the department of stem cells and developmental biology at the Royan Institute, attempts to develop an efficient way to generate mouse ESC lines to create lines with genetic diversity. And Ameera Gaafar, Ph.D., researcher at King Faisal Specialist Hospital and Research Center, presented her research on optimizing a process to differentiate HSCs into dendritic cells and, in turn, utilize the cells to trigger a better immune response.

Others are harnessing the properties of stem cells to treat diseases. Erdal Karaoz, Ph.D., professor of stem cell biology for the Institute of Health Science at Kocaeli University, described his efforts to use multipotent stromal cells (MSCs) to suppress the immune system and treat autoimmune disorders. Nasser Aghdami, M.D., Ph.D., head of the department of regenerative medicine at the Royan Institute, is using MSCs to regenerate heart tissue after a heart attack. He has also investigated the possibility of MSCs to repair damaged cartilage. Aida Al Aqeel, M.D., a physician in the department of pediatrics at Riyadh Military Hospital and the department of genetics at King Faisal Specialist Hospital and Research Center, is developing hESC lines from IVF embryos in Saudi Arabia to treat genetic metabolic disorders, a major cause of disabilities in children in the region.

Ethics and Policy in the Middle East Countries

Additional perspectives on stem cell research and the view of MENA countries were provided by Abdulaziz M. Al Swailem, Ph.D., vice president for scientific research support at the King Abdulaziz City for Science and Technology. While Western frameworks of ethics employ principles including nonmaleficence, beneficence, justice, and autonomy, the Middle Eastern perspective utilizes three perspectives: (1) urf, “everything [that] people recognize as good,” (2) adab, “the application of what is praiseworthy by word or deed,” and (3)

khuluq, “the state of the person through which an individual does acts without contemplation or decision.” The guiding frameworks for bioethics from Islam highlight humanity as the caretakers of the universe and servants of Allah. Working principles in Islamic bioethics include the protection of sharia, preservation of life, protection of the continuity of species, preservation of mental faculties, and preservation of wealth. These guidelines and principles give rise to accepted practices, such as the tolerance of smaller harms in order to avoid larger ones and the tolerance of harm against the individual in order to prevent public harm. One key practice that may affect the development of stem cell research is the importance of preventing harm over the importance of bringing about potential benefits. This may affect the process through which and the speed with which research becomes translated to therapies.

Saleh Al-Othman, Ph.D., clinical scientist at King Faisal Hospital, highlighted stem cell research areas that MENA countries can focus on to become more competitive internationally. Many conditions that could potentially benefit from stem cell research, including diabetes, lymphoma, thalassemia, and sickle cell anemia, are fairly prevalent in the Middle East. In an effort to combat these diseases, countries such as Saudi Arabia and Qatar have spent billions of dollars creating the necessary infrastructure to support science and biotechnology initiatives.

Taking into account the guiding principles from Islam, Saudi Arabia formed the National Committee of Medical and Bioethics by royal decree in 2002 to address issues arising from stem cell research. The committee is charged with protecting individual and community rights by ensuring the confidentiality and safety of medical information, setting ethical standards, establishing medical research limits and controls, and supporting gene banks/databases. Committee activities have so far included implementing a national code of ethics, a master’s degree program in ethics, local IRBs, and online ethics courses. The committee has also held various workshops on stem cells, the ownership of genetic information, informed consent, biobanking, and clinical trials.

Rajan Jethwa, M.D., Virgin Health Bank’s CEO, discussed his vision for Qatar, using the concept of “build it and they will come” to describe

the characteristics of Qatari infrastructure that attract stem cell researchers to the Middle East. Virgin’s vision for stem cell banking is to create an ethical, long-term, sustainable, public biobank by partnering with the state of Qatar to create a social enterprise that would provide samples to public hospitals for free, educational seminars for consumers, and adequate testing and storage of samples. Jethwa said that in a social enterprise, there is no incompatibility between ethics and financial benefit; as government cannot fund the bank indefinitely, social enterprises can partner with public health care systems to ensure that such systems are financially viable. He sees the Virgin Health Bank in Qatar as a magnet for research and treatment in the Middle East, thus not only increasing research collaboration but also decreasing the time required for translational research to occur.

Hind Al Humaidan, M.D., director of blood bank and transfusion services and the Cord Blood Bank at King Faisal Hospital in Saudi Arabia, which houses a large bone marrow transplant center, discussed cord blood transplantation. The success of a transplant depends on various factors, including the recipient’s age, disease, disease status, and cytomegalovirus (CMV) status. Access to suitable donors is the largest limiting factor to the use of this potentially curative treatment. Because it is difficult to find donors from international registries, an alternative strategy is to use umbilical cord blood transplantation. Umbilical cord blood is the blood that remains in the placenta after birth. Collected at no risk for the mother or offspring, umbilical cord blood can be collected and frozen for 15 to 20 years, offering an excellent source of highly proliferative stem cells. Using umbilical cord blood as a source for stem cells is advantageous because it is widely available and its immune cells are immature. However, there are also disadvantages, including insufficient cell dose, a lack of donor follow-up, and an uncertain graft-versus-tumor effect. Today, there are over 54 public cord blood banks in different parts of the world, with over 14,000 patients benefiting from cord blood transplantation.

The cord blood transplantation program at the King Faisal Hospital in Saudi Arabia began in 2003. Initially, cord blood units were obtained through international registries or from international cord blood banks, costing approximately \$30,000 per unit. Due to the increase in cord blood

transplantations, King Faisal Hospital decided to establish its own cord blood bank. King Faisal Hospital is now home to a nonprofit public cord blood bank with an inventory of over 3,000 cord blood samples. While this is a relatively small number of samples, it is encouraging to find an increasingly large number of matches for patients.

Regulatory oversight in stem cell research is still underway, as Sunni and Shia Muslims have different perspectives on stem cell research. In 2003, the International Islamic Fiqh Academy declared that human stem cells can be obtained and grown for therapeutic purposes or scientific research if they are obtained from an acceptable source. These sources include spontaneously aborted fetuses and therapeutically aborted fetuses, as permitted by Islamic law, as well as excess embryos derived from IVF. They do not, however, include embryos that are created through IVF specifically for research purposes or those from therapeutic cloning (SCNT). In contrast to the International Islamic Fiqh Academy, Saudi Arabian biomedical law does not permit the use of stem cells from excess IVF and human embryonic germ cells. This policy is currently being reevaluated. Al-Othman recommends a regional center for stem cell research and therapy that would set standards and regulations for the region, promote knowledge-sharing in the Middle East and internationally, support regional stem cell banks, organize training programs for medical professionals in the region, and establish quality control mechanisms for cells and research.

Despite the policy challenges, the Middle East stem cell research portfolio has grown over the past decade as a result of increased investments and expanded infrastructure. New research programs and scientific publications are emerging, especially from Qatar, Saudi Arabia, and Iran. Moreover, Qatari and Saudi leaders are engaging policy and ethics scholars to help develop stem cell policies that adequately reflect the cultural and religious perspectives in these nations. These policies could help further establish the region as a player in this area of research.

CONCLUSION

Stem cell research is recognized as a field with immense potential. Growing numbers of scientists are working to better understand how these cells can be used for therapies and cures for debilitating conditions such as diabetes, multiple sclerosis, and heart disease. But their research also presents ethical and policy quandaries on the morality of using human embryos for research. It also poses questions about the effectiveness of current clinical trial regulation and practices in safeguarding the well-being and dignity of patients.

This report reviews an array of lectures delivered at the 2012 conference “Qatar International Conference on Stem Cell Science and Policy.” Sessions at the event highlighted novel stem cell research, current ethical discussions, and pressing policy issues that are region-specific. While a major aim of the conference was to bring attention to Qatar’s stem cell research program, it was also an opportunity for regional scientists and ethicists to discuss their religious and cultural views of this research. Over 400 people attended, and participants hailed from more than 20 countries.

The conference allowed scientists, ethicists, and policymakers from around the world to engage in dialogues through panel sessions, presentations, a poster session, and a conference dinner. We believe the event helped encourage international collaborations, especially between scientists in Qatar and visiting researchers. International collaboration can increase the impact of research, especially for MENA researchers in emerging research environments, as previous studies have demonstrated that publications produced with international co-authors had a significantly higher citation rate than those produced with authors from one MENA country alone (Luo et al. 2011; Flynn and Matthews 2010; Narin, Stevens, and Whitlow 1991; Glanzel and Schubert 2005; Katz and Hicks 1997; Goldfinch, Dale, and DeRouen 2003).

The event also highlighted the importance of programs that encourage students to pursue scientific research. Attracting young people to science is a problem many countries face, including the United States. Data on NIH investigators shows that the average age for first time investigators has risen six years over the past 30 years (from 36 years old in 1980 to 42 in 2008) (Matthews et al. 2011). This

indicates that scientists are waiting longer to become independent and establish their own laboratories. The QSLP model encourages young scientists, using an international and collaborative model, to begin their careers earlier.

The QSLP also fosters student cultural and science diplomats. By placing Qatari students in top research programs around the world, the QSLP offers individuals in the host country opportunities to engage and interact with young Qataris— hopefully helping both groups reach an improved cultural understanding. Although this program has only been in place since 2008, it could create a generation of educated scientists and engineers to lead Qatar’s research and development schemes in the future.

The conference was also unique in that scientists, ethicists, and policy scholars presented their work side-by-side. While researchers presented new discoveries, ethics and policy scholars presented information on the societal and ethical implications of these discoveries. We believe that international meetings such as these give experts from the scientific, ethical, and legal communities an opportunity to integrate their research and ideas. During the conference, topics such as adequate informed consent, pressures to translate stem cell research to therapies prematurely, and the impact of funding and regulatory policies on stem cell research were all highlighted. These issues can directly influence how scientists conduct research. Understanding the ethical implications of an emerging new area of research, such as stem cell biology, will also help scientists understand why guidelines are implemented and better safeguard against the unintended consequences resulting from the pressures to commercialize products.

Furthermore, this type of conference pushes ethicists and policy scholars to talk with scientists and become familiar with current research in an effort to help create and inform better stem cell policies and guidelines. Reading scientific literature, going to scientific talks, and engaging scientists will help scholars follow developments in the field so they can adequately understand and address emerging ethic and policy issues. Without understanding the science and new developments, recommendations developed could be outdated, inadequate, or inappropriate.

Overall, the conference gave researchers, ethicists, and policy scholars a unique opportunity to approach issues arising from stem cell research with different perspectives and motivations. This is especially salient in emerging stem cell research programs, such as the one developing in Qatar. By linking research goals to ongoing discussions of ethics and policy, researchers are more aware of the future implications of their work, who it will affect, and how it will impact society, strengthening the relationship between the goals of science and the goals of society.

While other meetings have included ethics and policy discussions, this dialogue is often separated from the scientific discourse and is not well attended. For instance, in 2012, the ISSCR ethics discussions were held prior to the annual meeting and concurrently with another panel discussing policy with overlapping themes making scholars chose between topics. Fortunately, the conference organizers did schedule a talk by ethicist Solbakk during one of the main lecture sessions, with over 3,000 attendees, to link policy and ethics to the research (Plath et al. 2012). The Solbakk talk, as well as the integrated talks in Doha, enabled scientists, ethicists, and policy scholars to interact with each other and discuss the future of stem cell research and regenerative medicine.

In future conferences, we hope to provide scientists, ethicists, and policymakers the opportunity to engage in workshops that will permit them to address the specific issues and scenarios they face daily and exchange best practices and experiences. As science itself is collaborative, the processes used to build and support the regulatory, legal, and ethical infrastructure addressing science can also benefit from an international perspective.

RECOMMENDATIONS

As a result of the conference, we have a series of recommendations for the advancement of stem cell research. First, we recommend the continuation of conferences such as these in the MENA region, which bring together regional scholars with their counterparts from around the world. These interactions can improve science research by bringing new views and perspectives to the table, and well as offering the opportunity for scientific collaborations. Second, we believe scientists in this

field gain immensely from engaging policy and ethic scholars and vice versa. A better understanding of how science impacts the world can guide research, and the science itself should be a guide as science policy is developed. Finally, we were highly encouraged by the students who participated in the QSLP, and recommend similar programs for other countries in the region as well as the United States. Programs that engage young and developing scientists are often neglected or absent from science research funding programs, and it was refreshing to find it a priority at the Qatar Foundation.

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