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Robert M. Nerem · Jeanne Loring
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David V. Schaffer · Peter W. Zandstra *Editors*

Stem Cell Engineering

A WTEC Global Assessment

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WTEC Panel on Global Assessment of Stem Cell Engineering

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WTEC Panel Report on Global Assessment of Stem Cell Engineering

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December 2012

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WTEC Mission

WTEC provides assessments of international research and development in selected technologies under awards from the National Science Foundation (NSF), the Office of Naval Research (ONR), and the National Institute of Standards and Technology (NIST). Formerly part of Loyola University Maryland, WTEC is now a separate nonprofit research institute. The Deputy Assistant Director for Engineering is NSF Program Director for WTEC. Sponsors interested in international technology assessments or related studies can provide support through NSF or directly through separate grants or GSA task orders to WTEC.

WTEC's mission is to inform U.S. scientists, engineers, and policymakers of global trends in science and technology. WTEC assessments cover basic research, advanced development, and applications. Panels of typically six technical experts conduct WTEC assessments. Panelists are leading authorities in their field, technically active, and knowledgeable about U.S. and foreign research programs. As part of the assessment process, panels visit and carry out extensive discussions with foreign scientists and engineers in their labs.

The WTEC staff helps select topics, recruits expert panelists, arranges study visits to foreign laboratories, organizes workshop presentations, and finally, edits and publishes the final reports. Dr. R.D. Shelton, President, is the WTEC point of contact: telephone 717 299 7130 or email Shelton@ScienceUS.org.

Executive Summary

In the last 15 years, our knowledge of stem cells has increased, seemingly at an exponential rate. The result is that there is an ever-increasing arsenal of stem cells. This arsenal includes embryonic stem cells, various types of adult stem cells, and what are called induced pluripotent stem cells; i.e., iPS cells, that are reprogrammed from fully differentiated cells such as a skin fibroblast. A few years ago, iPS cells were heralded as the "breakthrough of the year," and this year the key scientists whose work resulted in this technology shared the award for the Nobel Prize in physiology and medicine. There still are many questions to answer in regard to these cells; however, it is clear that they provide a unique tool for the stem cell field. Engineers have become increasingly involved in the area of stem cells, all the way from basic research to the variety of applications that are evolving. Concurrently there have been two other "streams of thinking" that have emerged.

One of these is that of interdisciplinary research. Here the 2009 National Academies report entitled "A New Biology for the 21st Century" makes the point that to achieve a deeper understanding of biology necessary to address the major problems that society is facing will require not just breaking down the "silos" within biology itself, but incorporating chemists, computational researchers, engineers, mathematicians, and physicists into basic biological research. Furthermore, only through such an integration of disciplines will it be possible to address major society problems. There is no area of biology where this might be more true than that of stem cells.

A second "stream of thinking" that has emerged is that of translational research. Not only are Federal agencies in the United States interested in fostering the translation of bench-top science into a variety of commercial/clinical applications, but this also has become a priority for many states. Furthermore, what is happening in this area in the United States simply "mirrors" what is taking place in the rest of the world. It is thus timely that a global assessment of stem cell engineering be conducted, and it is such an assessment that is reported here.

Study Objectives

What is stem cell engineering? As defined for the purposes of this study, it is not just tissue engineering and regenerative medicine, but the entire interface of engineering with the “world” of stem cells. It thus ranges from basic stem cell research to models and tools, to enabling and scalable technologies, to stem cell biomanufacturing and the development of stem cell-based applications and products. The objective of this global assessment of stem cell engineering has been to compare U.S. R&D with activities globally so as to identify gaps where engineers can make contributions, the major innovations emerging globally, barriers in the field, and opportunities for cooperation and collaboration. A major purpose is to provide information that can guide investments by funding agencies in the future. In this it again must be emphasized that stem cell engineering as addressed in this report ranges all the way from basic stem cell research to stem cell-based applications and products.

Panel Members

The panel was made up of the following individuals: Jeanne Loring, Ph.D., Scripps Research Institute; Todd C. McDevitt, Ph.D., Georgia Institute of Technology and Emory University; Robert M. Nerem, Ph.D., Georgia Institute of Technology (chair); Sean P. Palecek, Ph.D., University of Wisconsin, Madison; David V. Schaffer, Ph.D., University of California, Berkeley; and Peter W. Zandstra, Ph.D., University of Toronto.

Study Scope

The basic purpose of this global assessment of stem cell engineering has already been noted; however, to expand on what was earlier stated, the study will include not only relevant scientific/technical topics, but the role of engineering in the translation of our knowledge of stem cells to applications and, as much as possible, education and training in this area and government policies. The scientific and technical topics of interest included the following:

- Application of engineering and physical science principles in stem cell R&D
- Scalable expansion and differentiation of stem cells
- High-throughput screening and the application of microfluidics
- Real-time, non-destructive phenotyping
- Systems-based quantitative analysis
- Computational modeling approaches
- Bioprocessing and biomanufacturing
- Targeted delivery of stem cells

The above list is not meant to be totally inclusive, but to indicate the breadth of topics of interest in this study. All of the above as well as many others represent areas where engineers and the engineering approach either are or could be making contributions.

Study Process

There were many components to the process used in this global assessment of stem cell engineering. A foundation of course is provided by the knowledge of each of the panelists, knowledge not only about activities in the United States, but knowledge each of them had about activities in other parts of the world. To this foundation was added the following four components:

- Site visits in Asia and Europe
- Workshops in Atlanta and in Seoul, Korea
- Participation in the 3rd International Conference on Stem Cell Engineering
- Virtual site visits

For virtual site visits, information was gathered solely though the internet and/or by e-mail exchange. Examples of this are Australia and Iran. The term virtual site visit was also used for a site visit where only one panel member visited.

Although the WTEC panel was able to see much of the stem cell activities going on around the world, they certainly did not see everything. Even so, one can make the argument that the process outlined above in terms of the various components as well as the knowledge base each panelist had coming into this study provided for a global assessment of this field of stem cell engineering.

Principal Findings

From this global assessment of stem cell engineering as conducted by the WTEC panel, it is clear that engineers and the engineering approach with its quantitative, systems-based thinking can contribute much more to basic stem cell research than it has to date. As stated in the National Academies report on “A New Biology for the 21st Century,” to achieve the deeper understanding of biology required in this century, there will need to be an integration of many disciplines into biological research, and this certainly includes engineering. Engineering analysis can be used to identify the components of highly complex stem cell systems and provide an understanding of how these components work together. Furthermore, computational models will be increasingly important in our efforts to achieve a better understanding of complex biological systems. In all of the above engineers are in a position to take a leadership role.

Engineers also can take the lead in developing new, innovative enabling technologies. This includes high-throughput screening techniques, improved culture and differentiation systems, and *in vitro* models engineered to be more physiologic. The last of these include organ-on-a-chip models and engineered *in vitro* tumor models that can lead to a better understanding of cancer.

Finally, for stem cell biomanufacturing there is a need for further advances in culture systems, techniques for real-time monitoring, and for process automation. Underpinning these specific application areas, computational modeling has an important role to play throughout the spectrum from discovery to translation.

One of the interesting things that came out of the site visits and this global assessment was observing some of interesting models that have been developed to translate bench-top stem cell science into clinical therapies and into commercial products. Four such models discussed in the report are as follows: the Berlin-Brandenburg Center for Regenerative Therapies, the Cell Therapy Catapult in the United Kingdom, the Centre for Commercialization of Regenerative Medicine in Canada, and the Tokyo Women's Medical University. There are of course other models for translation; however, it is these four that are discussed in the report.

It is clear to this WTEC panel that, for engineers to be accepted by biologists, they need to be viewed as understanding biological mechanisms and making a contribution to biology. Thus, for training programs to be successful, they need to include what might be called a "high level" of biology, and this is certainly what is done in the leading bioengineering programs in North America. Outside of North America an excellent example of a unique training program is that at Loughborough University. One of the outcomes of the Atlanta Workshop on Stem Cell Engineering was the agreement to establish an international school in the area of cell manufacturing. The initial offering of this school will take place at the end of April 2013 in Portugal.

Research today in general is very interdisciplinary, and this is certainly true of biology and the stem cell field. As part of this, collaborations almost become a necessity. These might be with an investigator at one's own institution, somewhere else in the city, or even at a longer distance. In today's world where research and the development of technology is done within the global community, collaborations can also exist between investigators in different countries. In fact, US investigators need to leverage the excellence of activities in other countries, and it thus was encouraging for the WTEC panel members to see the hosts of the different site visits being so open in the sharing of information and very interested in the possibility of collaborating.

Whatever the United States decides to do, there is urgency to it. This is because of the global competitiveness that exists in the area of stem cells. Not only are China, Japan and Korea making significant investments, but so are European countries such as The Netherlands and the United Kingdom. Furthermore, as important as basic bench-top stem cell research is and recognizing the major contributions that engineers and the engineering approach can make to basic research, ultimately the competition will be in terms of creating the enabling technologies, the new clinical therapies, and the innovative commercial products. It is here, i.e., in moving stem cells to the front of the bioeconomy being created for this twenty-first century, that engineering can play a critical role.

Conclusions

The assessment conducted by the WTEC panel confirms that there is a need for an increasing involvement of engineers in the field of stem cells and related technologies. Although one might argue that the United States today has a leadership role, to capitalize on this and build on the current existing momentum, and most importantly, to accelerate the translation of bench-top research into various applications including clinical therapies and commercial products, will require the United States to take bold steps. The panel thus offers the following conclusions.

1. The United States has a unique opportunity to maintain a leadership position in the stem cell field through the continued support of R&D that will provide a foundation for the generation of new markets and that will lead to economic growth.
2. Because of the contributions that engineers can make in all areas of the stem cell field, as elaborated in the global assessment reported here, this needs to include increased investment in engineering, applied research, and commercialization as it relates to stem cell research and related stem cell-based technologies.
3. A major component in this could be that the Federal agencies that support R&D establish a broad interagency program for stem cell engineering, one that provides grants to interdisciplinary teams that include engineers, computational researchers, and biologists as well as individuals from other disciplines.
4. Another component that would be beneficial is the establishment of new, innovative mechanisms that support academic-industry partnership and unique translational models that facilitate the translation of research into the private sector.
5. To address national workforce needs, the development of training programs at universities and advanced short courses should be encouraged and supported by Federal agencies.
6. Finally, in today's global economy and with the excellent activities taking place in other countries, the United States would benefit from forming strategic partnerships with other countries so as to leverage the existing and emerging strengths in institutions outside of the United States; to implement such partnerships will require binational grant programs with appropriate review mechanisms.

These conclusions align with the National Bioeconomy Blueprint released by the White House Office of Science and Technology Policy. It is up to the Federal agencies to implement a plan based on the conclusions from this assessment study. Without the implementation of the above, however, this unique opportunity could be lost. In this case, it might be possible that the United States in the future is relegated to the second tier of countries in this critical area of stem cell engineering, and ultimately the application of stem cell-based technologies for health and welfare. On the other hand, if implementation takes place in some form, and there is an urgency to do this, then the United States can expect to continue to be in a leadership position and at the forefront in advancing the sciences, developing new, innovative enabling technologies and platforms that lead to clinical therapies, to commercializing the results of stem cell research, and to the generation of new markets and economic growth based on advances in the stem cell field. Some of the results from this will be:

- The acceleration of the development of new drugs while at the same time reducing the costs of this development process
- The development of cell therapies that address diseases and conditions of injury for which today there are no real treatment options available for patients in need
- The growth of the twenty-first century bioeconomy in the United States based on advances in our knowledge of stem cells and the translation of this into applications and products

This has been the dream for at least 20 years; however, with the right strategy by the United States it can be realized and be the reality of tomorrow.

November 2012 Robert M. Nerem

Preface

Research on stem cells has been an important topic in medicine since the 1960s, and over the last decade has become more exciting, and even controversial, as an increasing number of therapies based on them become available. Development of advanced treatments based on stem cells has the potential to cure a wide variety of serious diseases and infirmities that are virtually incurable today, for example reversing paralysis due to spinal cord injuries. Supporters in the Federal government, a number of US states, and many foreign countries believe that increased funding for stem cell research will lead not only to great improvements in public health, but potentially large economic benefits from new biotechnology markets. Thus, the focus today is shifting from supporting purely basic research towards biotechnology and commercialization of stem cell related products and therapies.

By definition, stem cells are biological cells found in all multicellular organisms that can divide and differentiate into diverse specialized cell types, and can self-renew to produce more stem cells. In mammals, there are two broad types of stem cells: adult stem cells, which are found in various tissues and act as a repair system for the body, and embryonic stem cells, which can differentiate into all the different types of specialized cells found in the body. The highly plastic adult stem cells can be harvested from the body and are now routinely used in medical therapies, for example in bone marrow transplantation. Stem cells can also now be artificially grown and transformed into specialized cell types with characteristics consistent with the normal cells of various tissues such as muscles or nerves. Embryonic stem cells generated through therapeutic cloning have also been proposed as promising candidates for transformational new therapies. Most medical researchers anticipate that, in the future, technologies derived from such stem cell research will be available to treat a wide variety of diseases including cancer, Parkinson's disease, spinal cord injuries, amyotrophic lateral sclerosis, multiple sclerosis, and muscle damage, among a number of other serious impairments and conditions. Today, however, there still exists a great deal of social and scientific uncertainty surrounding stem cell research, and further research and public debate will be necessary to clarify the way forward.

The study we summarize here takes an even broader and more unique view of this area. That is, it is an assessment of "stem cell engineering," which we define as all activities from basic stem cell research to models and tools, to enabling and scalable technologies, to stem cell biomanufacturing and the development of stem cell-based applications and products, and therefore areas where engineering research is a key enabler. The objective of this global assessment of stem cell engineering has been to compare such US R&D with similar activities globally so as to identify gaps where engineers can make contributions, the major innovations emerging globally, barriers in the field, and opportunities for cooperation and collaboration. A major purpose is to provide information that can guide investments by funding agencies in the future.

These goals directly inform research being funded by our individual program offices. For example, the NSF Chemical, Bioengineering, Environmental and Transport Systems Division (CBET) generally supports research and education in the rapidly evolving fields of bioengineering and environmental engineering, and in particular expands the knowledge base of bioengineering at scales ranging from proteins and cells to organ systems, including mathematical models, devices, and instrumentation systems. Main themes include tissue engineering and the development of biological substitutes, biosensors, and devices that use a biological component, all of which are enabled by advances in stem cell engineering. Practical applications of stem cell engineering are potentially myriad, for example in research that will lead to the development of new technologies, devices, or software for persons with disabilities, such as the work supported by the CBET General & Age Related Disabilities Engineering (GARDE) program.

Similarly, stem cell engineering is directly relevant to the CBET Biomedical Engineering and Engineering Healthcare (BEEH) Cluster programs, which fund projects that integrate engineering and life science principles in solving biomedical problems, including deriving information from cells, tissues, organs, and organ systems, and new approaches to the design of structures and materials for eventual medical use, with applications towards the characterization, restoration, and/or substitution of normal functions in humans. Stem cell engineering is also a fundamental topic for the mission of the CBET Biomedical Engineering (BME) program, which seeks to develop novel ideas into discovery-level and transformative projects that integrate engineering and life science, including areas such as neural engineering and cellular biomechanics, with multiple goals which include development of technologies for tissue repair and regenerative medicine.

This study was conducted by a panel of experts of truly profound expertise and insight. It included Robert M. Nerem, Ph.D., Georgia Institute of Technology (chair); Jeanne Loring, Ph.D., Scripps Research Institute; Todd C. McDevitt, Ph.D., Georgia Institute of Technology and Emory University; Sean P. Palecek, Ph.D., University of Wisconsin, Madison; David V. Schaffer, Ph.D., University of California, Berkeley; and Peter W. Zandstra, Ph.D., University of Toronto. The breadth of their expertise, and the synergy with which they worked together, has created here a truly important product.

The study methodology itself was very well thought out and comprehensive. It involved physical site visits to over 40 research facilities in Europe and Asia. We would like to thank all of the hosts who welcomed us and shared information during our site visits. The study also included attendance by the panel members at relevant workshops in Atlanta and Seoul, participation in the 3rd International Conference on Stem Cell Engineering, and a number of "virtual" site visits which consisted of information gathering via the internet or by email exchange. In all, a very large body of high quality and topically diverse information was gathered, and subsequently synthesized into this report.

We would also like to acknowledge some of the WTEC staff who worked on the project. These include Duane Shelton, Frank Huband, Mike DeHaemer, Hassan Ali, Hemant Sarin, and Haydon Rochester, each of whom contributed significantly to the overall effort.

The report itself is structured so that each chapter provides a summary of a particular topic, written by one or more of the panel members. In summary:

Chapter "Introduction" is an introduction and overview of the study process and methodology, written by the panel chairman, Robert M. Nerem.

Chapter "Physical and Engineering Principles in Stem Cell Research" was written by David V. Schaffer, and discusses the physical and engineering principals involved in stem cell research.

Chapter "High-Throughput Screening, Microfluidics, Biosensors, and Real-Time Phenotyping" discusses technologies for high-throughput screening, microfluidics, bio-sensors, and real time phenotyping, and was authored by Sean P. Palecek

Chapter "Computational Modeling and Stem Cell Engineering" was contributed by Peter W. Zandstra and Geoff Clarke, and considers methods for computational modeling applied to stem cell engineering

Chapter "Stem Cell Bioprocessing and Biomanufacturing" covers the topic of stem cell bioprocessing and biomanufacturing, and was written by Todd C. McDevitt.

Each chapter of this report is supported by a comprehensive list of references, which in total cover many aspects of stem cell engineering activities assessed in the United States, Europe, and Asia. Other highlights of this study are to be found in the appendices, which present biographical information on the WTEC panel members and authors in Appendix A, the site reports of the panel's visits in Appendix B, and the reports of the virtual site visits in Appendix C, all of which contain a wealth of information. A glossary of abbreviations and acronyms is in Appendix D.

In addition to this report, the expert panel presented highlights of their findings at a public workshop at the National Science Foundation on May 24th, 2012. The meeting was webcast and video archived for convenient viewing by the public, which is available on the WTEC website, www.wtec.org.

Finally, we would like to thank other individuals who contributed resources for this study, including Anne Plant of the Biosystems and Biomaterials Division at NIST; Larry Nagahara, Nicole Moore, and Nastaran Kuhn, all of the Office of Physical Sciences-Oncology at the National Cancer Institute; Kesh Narayanan of

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