Stem Cell Research in the Greater Middle East: the Importance of Establishing Policy and Ethics Interoperability to Foster International Collaborations

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Conflict of Interest: This project was supported, in part, by the Baker Institute International Stem Cell Policy Program, which was endowed by the State of Qatar in collaboration with the Qatar Foundation for Education, Science and Community Development.

ABSTRACT

While fossil fuel reserves have strengthened the economies of numerous countries in the Greater Middle East (GME) for decades, multiple nations within this region are now increasingly investing in internal science and engineering programs as a mechanism to develop more extensive knowledge-based economies. One of these newly pursued disciplines is stem cell research. Nations such as Saudi Arabia and Qatar have founded

nascent programs while Iran, Turkey, and Israel are more established in the field. The extent to which these investments have been productive, as measured by publication quantity and impact, remains unknown. Here we assess the state of stem cell research in the GME, report on the policy and ethical considerations facing the region, and determine the impact of international research collaborations in this area. In the majority of the region, there is no legal framework regulating stem cell research. Instead, scientists often rely on religious decrees outlining acceptable practices. These guidelines do not provide the necessary structure to foster international collaborations with nations that have enacted formal laws recognized worldwide. Our results illustrate that international collaborations in the GME produce publications of greater impact despite the fact that political tensions and issues unrelated to science have the potential to dramatically hinder cross-border relationships in the region. Overall, we conclude that the national governments of countries within the GME have the unique opportunity to establish stem cell research policies which confer interoperability between nations to foster crucial international collaborations throughout the region.

KEYWORDS

Stem Cell Research, Policy Interoperability, International, Collaboration, Ethics, Regulation

INTRODUCTION

In recent years, several nations in the GME have begun establishing a presence in science and technology to better develop knowledge-based economies. In this article we chose to

define the GME as the region bridging northeastern Africa and southwestern Asia comprised of the nations defined by the U.S. Administration for the 2004 G8 summit including: Afghanistan, Algeria, Bahrain, Djibouti, Egypt, Israel, Iraq, Iran, Jordan, Kuwait, Lebanon, Libya, Mauritania, Morocco, Oman, Pakistan, Palestine, Qatar, Saudi Arabia, Somalia, Sudan, Syria, Tunisia, Turkey, the United Arab Emirates (UAE), and Yemen [1]. The extent to which efforts to improve or create research and development in the GME have been successful remains unknown.

For this paper, we analyzed the state of stem cell research because of the increased interest the field has generated internationally, including within the GME, over the past 10 years related to medical therapies and treatments [2-5]. Stem cell clinical trials in the region have more than quadrupled to over 400 registered clinical trials in January 2010 (www.clinicaltrials.gov - keywords: “cell therapy”) from less than 100 in June of 2006 [6]. Furthermore, several countries in the GME are now actively trying to establish a presence in this field through new funding initiatives, the construction of new research facilities, and establishing research programs [7].

To investigate this dynamic period of change in the region, we surveyed regional publications from 1998 to 2008 and determined the quantity, significance and classes of stem cell projects conducted. In addition, we analyzed the political, religious and ethical considerations facing the region as well as determined the impact of international collaborations on recent research.

OVERVIEW OF THE STATE OF STEM CELL RESEARCH IN THE GME

Searching the ISI Science Citation Index operated by Thomson Reuters, we determined that approximately 75% of all stem cell research performed in the GME from 1975 to 2008 was produced from 1998, when human embryonic stem cells were first derived, through 2008. These publications comprised approximately 2.1% of all stem cell research performed worldwide.

To evaluate the state of stem cell research in the GME, we conducted a systematic literature review of regional publications from 1998 to 2008 using the ISI Science Citation Index. Stem cell research articles were identified from the GME by entering search entries with the keyword string "TS=("stem cell*") AND CU=*Respective Country* AND Document Type=(Article)." Country attribution for each publication was determined by the corresponding author's institutional affiliation. These publications were then examined by hand to eliminate those that did not derive or use stem cells in an experimental context or did not report original research such as reviews. Excluded publications include articles not indexed by ISI, non-English language journals, book chapters, abstracts and conference proceedings. Of the 26 nations composing the GME, only 12 countries—Egypt, Israel, Iran, Jordan, Kuwait, Lebanon, Morocco, Pakistan, Saudi Arabia, Tunisia, Turkey, and the UAE—were identified as having published stem cell research articles (full listing of publication numbers by country included in Table 1).

Our data indicate that the leading producers of stem cell research in the GME were Israel (58%) followed by Turkey (23%) and Iran (12%). The remaining nine countries produced

in total 7% of the articles from the region (Table 1). Israel and Turkey were expected to be the major contributors in the field due to their well-developed economies and research cultures, but the presence of Iran was notably unexpected considering its political isolation from the United States and much of Europe.

During the survey, we also examined the classes of research being pursued based on the model organism employed and developmental stage of the cells (Table 1). We determined that a great array of organisms was utilized including human, murine, chick, rabbit, canine, bovine, plants, and quail. Across all countries, human stem cell research was most common, constituting 65% of all publications followed by murine at second with 31%. This may be the result of these nations supporting institutions committed to basic stem cell research enabling them to devote a large portion of their resources to non-human studies. In contrast, although Turkey proved to be the second largest producer of stem cell publications, it focused an overwhelming majority of its research on human models (90%). Israel and Iran utilized murine animals frequently, at 38% and 47% respectively, compared to their regional counterparts. Of the remaining countries, a large portion of the publications utilized human models (76%) compared to murine animals (17%) or other organisms (7%).

The large number of human publications can largely be accredited to case studies and clinical trials utilizing stem cells to treat a number of medical conditions including leukemia and heart disease. This may be due to a common partiality amongst newly initiated research programs towards applied research using human cells with the aim of

producing results which directly impact disease treatments. As a result, basic scientific research utilizing lower organisms geared toward elucidating molecular mechanisms often becomes a lower priority.

Diversity of stem cell research within the GME was also found to exist in terms of the developmental time point of stem cell employed (Table 1). Unsurprisingly, adult stem cells were most commonly utilized comprising 67% of the total publications probably due to the ease of obtaining and manipulating them compared to the other sources. A number of countries also conducted work on embryonic/fetal and post-natal/cord blood stem cells. Notably, Israel and Iran stood out for their large percentages of embryonic/fetal stem cell research, at 23% and 28% respectively. Both of these nations have permissive policies regarding human embryonic stem cell research and support this work in their institutions. Additionally, although cord blood stem cells are thought to hold great potential for the treatment of numerous medical conditions, very few resources in the region have been committed to studying these cells. Thus cord blood stem cell research comprises only a small percentage of the total stem cell research performed in the area. However, several cord blood banks have been established in the past few years including locations in Saudi Arabia [8], the UAE [9], Iran [10] and Qatar [11] indicating such research may be soon to come.

GME STEM CELL RESEARCH NATIONS ON THE RISE

Israel and Turkey have long-established histories in science and technology research and development with stem cell research as an area of focus. Indeed, the first human

embryonic stem cells in the world were created in 1998 in collaboration with the Rambam Medical Center in Israel [12]. Several other countries within the GME have begun focusing on science and technology as a means to transition their economies towards a knowledge-based workforce. Here we highlight three countries, Iran, Qatar and Saudi Arabia, which have utilized funds from fossil fuel resources to create science institutes and fund stem cell research within their borders.

A recent but quickly established player in the region is the Royan Institute in Tehran, Iran. In 1991, the Royan Institute was created as a non-profit infertility clinic, and in 1998, the Iranian Ministry of Health approved the organization as a "Cell Based Research Center" [13]. The Royan Institute has since become one of the leading stem cell research centers in the region, creating a human embryonic stem cell line in 2004 [14]. Furthermore, Royan Institute scholars engage with other stem cell researchers by both attending and hosting international meetings, including organizing the annual Royan International Twin Congress in Tehran.

A newer contributor in the area is Qatar. In 2007, the state of Qatar and the Qatar Foundation for Education, Science and Community Development forged a partnership with the James A. Baker III Institute for Public Policy at Rice University to create the Baker Institute International Stem Cell Policy Program with the goal of bridging stem cell research and public policy [15]. After their joint workshop in 2009 [16], the Qatar Foundation announced plans for a new center of excellence for stem cell research in

Qatar focused on issues such as diabetes, neurological disorders, cancer and cardiovascular disease.

Another country initiating programs in stem cell research is Saudi Arabia. In 2007, the Stem Cell Therapy Program at King Faisal Specialist Hospital and Research Center in Riyadh was established and began engaging in collaborations with institutions including Harvard Medical School [7]. In addition, King Abdullah of Saudi Arabia created the King Abdullah University of Science and Technology (KAUST), which opened in September 2009 [7]. While there is currently no stem cell research at KAUST, the support and recruiting resources provided to the universities shows the dedication of the Saudi leadership toward improving science and technology research and development within the Kingdom [17].

THE IMPACT AND IMPORTANCE OF INTERNATIONAL COLLABORATIONS

When reviewing the publications, we found that international collaborations were relatively common. Our analysis determined that 21% of all GME stem cell publications involved international collaborations (Chart 1). Countries such as France, the United Kingdom, and the United States were often listed a co-authors for papers from the region. We also noticed there was an overall inverse relationship between the number of stem cell publications generated and the percentage of publications produced by international collaborations. Turkey, Iran and Israel produced more stem cell research publications, but

engaged in a lower percentage of international collaborations than nations such as Saudi Arabia, Egypt and the UAE (Chart 1).

Furthermore, we ascertained the impact of these publications produced by the GME based on the average number of times articles were cited. Our survey determined that Israel's publications had approximately six times the impact of articles from Turkey, Iran or the other countries in the region (Chart 2). With the exception of Turkey, the data also indicated that articles resulting from international collaborations are cited more often than publications produced from a single country, with the differences being statistically significant for Israel ($p=.032$) and the composite group ($p=.012$).

These data suggest that engaging in international collaborations benefits most institutions, especially newer institutions in the region aspiring to increase their visibility by publishing in higher tiered journals. The data also imply that stem cell research conducted within this region would advance at an increased pace if the countries of the GME engaged in international collaborations more frequently. For a case-in-point, in its first year of existence, the Stem Cell Therapy Program at King Faisal Specialist Hospital and Research Center established multiple international collaborations with institutions including Harvard University. Articles published as a result of these collaborations have been cited 70% more often. Consequently, this institution is quickly becoming one of the highest regarded research centers in the kingdom.

While Israel, Turkey and Iran were less likely to seek out collaborators from another country than the remaining collective group, they generally produced publications of greater significance when they did engage in international collaborations. Low participation in cross-border research may be the result of work visa restrictions and limitations on the use of research funds which can prove to be great hindrances worldwide [18]. Furthermore, some scientists prefer the convenience of interacting with researchers within the same institution or city allowing them to have personal interactions on a regular basis. Unlike other areas of the world, much of the GME faces political impediments impacting the ability of scientists to collaborate outside their own nation. Tensions between countries in the GME hinder scientific communication and travel worldwide. In addition, not all entities in the GME recognize each other as legitimate states, thus preventing the use of diplomatic relations to establish cross-border research policies.

GOVERNMENTAL AND RELIGIOUS POLICIES IN THE GME

The Need and Opportunity to Develop Interoperable Stem Cell Policies

Throughout the world, national governments are the primary entities which provide support for stem cell research through regulation and funding [19]. Very few nations within the GME have legislation regulating human embryonic stem cell research. Thus, they are in the unique and advantageous position of having the ability to assess already established policies of other governing bodies around the world and incorporate what they believe to be the most effective aspects into their own sets of regulations.

Governmental stem cell policies, supportive and restrictive, have been directly linked to research performance. Over-performing countries in the field of stem cell research often have long-established, clear, and supportive research policies. In contrast, many underperforming nations are marked by an assortment of varying policies and research environments that are commonly characterized by a quagmire of prolonged policy debates and uncertainty [20]. This suggests that national stem cell research policies, or the lack thereof, heavily influence the productivity of stem cell researchers in that country.

Thus far in the GME, only Israel, Turkey and Tunisia have recognized national stem cell policies. Israel and Turkey adopted permissive policies allowing researchers to utilize existing human embryonic stem cell lines as well as create embryos via *in vitro* fertilization (IVF) specifically for research purposes [21]. In contrast, Tunisia banned the acquisition of embryos for experimental purposes and only allows the preservation of gametes or embryos "for therapeutic purposes to help the couple procreate" [22].

Other governing bodies around the world have approached stem cell research regulation in a multitude of ways. The United Kingdom implemented a highly regulatory system [23] which may be overly strict for nations within the GME. The U.S. federal legislative bodies only addressed research performed with federal funding leaving many questions regarding private sector-funded research, which many argue is too limited [24]. Perhaps a more appropriate model for the region would be one similar to that of Spain, which

adopted comprehensive policies that oversee both private and public research activities, but did not create new regulatory agencies [25].

In addition, scholars in the field of stem cell research endorse the generation of regulatory and policy models focused on improving international globalization of research. With this comes a need for policy interoperability, where policies allow for and promote research within and between nations through the harmonization of ethical and legal standards [26]. Two sets of example guidelines were created by the International Society for Stem Cell Research (ISSCR) and a collection of scholars known as the Hinxton Group. In 2006, ISSCR, a nonprofit science society, released a set of guidelines for scientists, which can easily be applied to the creation of national policies [27]. That same year, the Hinxton Group, an international consortium of scholars on stem cell science, ethics, and law, issued a consensus statement outlining principles to "govern the ethical and legal regulation and oversight of stem cell and related research and its clinical applications" [28]. This statement emphasizes principles for fostering international collaborations, enacting flexible laws capable of accommodating rapid scientific advancement, adhering to internationally adopted codes of ethics, and requiring informed consent. Furthermore, interoperable policies can also be used to thwart medical tourism and unethical stem cell disease treatment practices, which ultimately damage the field as a whole as well as the reputations of associated institutions or nations.

Moreover, a regional consortium, along the lines of a scientific version of the European Union (EU), could be an effective mechanism for the nations of the GME to ensure

policy interoperability amongst its members while still respecting the national laws of individual countries. While the focus of the EU is broader than what would be necessary in the GME, a system such as this could be used as a model to develop a regional organization to address science policy issues and international collaborations. In 2004, the EU enacted Directive 2004/23/EC to implement "standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" [29]. Regarding stem cell research, EU regulations guarantee certain standards of practice are followed by all member nations which permit and conduct such experiments, but members are not required to sanction a particular form of research or therapy.

Religious Perspectives Regarding Stem Cell Research in the GME

When striving to create interoperable guidelines, ethical principles as well as the political, historical and socio-cultural contexts of the region must be considered [26]. The religious mindset of a nation or entire region can have great influence over the research policies enacted by that country's national government. An Islamic majority exists throughout most of the nations of the GME. Thus, the Christian perspective found in many of the countries at the forefront of the stem cell debate has limited influence over the policies GME countries may choose to adopt.

While at times new progress in biomedical research can be intimidating, Islamic law is quite supportive of obtaining and utilizing knowledge through scientific research. Unless directly prohibited, there are no restrictions regarding biomedical technologies as long as

they are shown to benefit humankind [30]. Regarding stem cell and human embryonic research, according to Dr. Abdelhafez Helmy Mohammad, professor emeritus at Ain Shams University in Egypt, no objection exists within the Islamic faith to the use of superfluous IVF eggs for research purposes or generating fertilized eggs specifically for the purpose of human embryonic stem cell research [31]. This is largely due to the Islamic view that a developing embryo does not become ensouled until at least 40 days after conception. Thus, very young embryos are of a different status than those 40 days or older. While some discourse does exist between various sects, an overall permissive consensus exists regarding stem cell research in the Islamic world.

These views are in contrast to the region's Christian minority perspectives, which discourage research on human embryos or human embryonic stem cells, but are quite similar to the general consensus of the Jewish faith. The Jewish religion, which guides policy formation in Israel, allows the use of human embryonic stem cells in medical research for the purposes of healing [32].

Regulation by Religious Decrees in the GME

While Israel, Turkey and Tunisia are the only countries with recognized national policies related to human embryonic stem cell research, some other nations use Islamic religious decrees or fatwas to guide this research by their peoples. A fatwa is an opinion or statement issued by an Islamic scholar or group concerning Islamic law and its interpretation. They are often created when a situation may be perceived to be controversial, such as the use of human embryos for research. While these decrees may

not be law, they carry great influence and are often country specific. Thus, they often effectively act as national policy. The Fiqh Council of the Muslim World League in Saudi Arabia issued a fatwa in 2003 detailing the requirements under which stem cell research could be conducted in accordance with Islamic sharia law in the Kingdom. It was translated into English as, "It is permissible to obtain, grow and use stem cells for therapeutic or permissible scientific research purposes if obtained from a permissible source…" [7]. In addition, Grand Ayatollah Ali Khamenei in Iran issued a fatwa in 2002 establishing that human embryonic stem cell research was permissible within the Shiite Islamic religion and encouraged scientists to pursue this research with the purpose of advancing technology to save lives [33]. Positive Iranian fatwas can ultimately be credited for active research programs and the creation of a hESC line in the country [34]. While these countries may not have formal laws in place regulating stem cell research, it is often these decrees which define a nation as either permissive or restrictive in the field of stem cell research.

Stem cell research guidelines created by fatwas may work well within a country, but these decrees are not recognized by many nations as legal or regulatory framework. Well-established frameworks defining the stem cell research policies of a nation are crucial to scientists interested in establishing cross-border research relationships. Creating formal governmental policies as well as fatwas would help foster international scientific collaborations by increasing other countries' perceptions of support within the GME for stem cell research. Thus, governmental and Islamic religious leaders in this region should

be encouraged to work together to adopt legal policies which adhere to Islamic beliefs and encourage interaction with researchers from other nations.

CONCLUSIONS

Overall, our data show that stem cell research in the GME is located in only a limited number of countries prior to 2008. Of the countries publishing, the majority only recently began contributing to the field and initiating state-funded programs. These newcomers enter this discipline not in its infancy, as the United States and the United Kingdom did, but at a much later stage of development. In order to compete for students and faculty with countries already possessing well-developed systems, they will have to provide additional resources and opportunities not available elsewhere.

We have shown that when the countries of the GME collaborate with other nations to research stem cells, the resulting publications are of higher impact than when these nations produce this research independently. National governments of these countries would be well advised to strive for policy interoperability regarding stem cell research regulation to enhance this effect. Nations composing the GME are in the fortuitous position of being able to study and learn from the history of stem cell research policy developments from already well-established countries and international unions. With such hindsight, they have the opportunity to create uniform and omnibus policies heightening existing fatwas in the region.

Establishing reciprocal policy agreements between nations of the GME or creating a regional consortium which requires compliance with defined ethical and legal regulations may prove to be effective mechanisms for resolving coordination problems [26]. These methods could deter the generation of inconsistent policies within the region and have been employed by a number of oversight bodies such as the European Union with considerable success. Alternatively, institutional policy agreements may currently be better suited for the region due to political unrest between nations. Political differences and tensions between national governments, although often unrelated to science, may dramatically hinder the progression of research in the region. In such cases, institutional policy agreements that balance respecting opposing national policies while cultivating research cooperation via upholding international ideals may be necessary [26, 35].

If the nations of the GME do not achieve some level of policy interoperability, they are likely to face jurisdictional issues limiting cross-border research already seen in other nations such as Germany [36, 37]. Scientists from restrictive nations who participate in international collaborations or travel overseas to perform research risk engaging in experiments determined to be unacceptable or even illegal in their native country [36, 38]. While apparently no researchers currently facing this issue have ever actually been criminally charged for this, such a threat does have an impact on their willingness to work with partners abroad [36].

As science itself knows no boundaries, fostering international collaborations not only benefits the nations involved, but it increases the rate by which knowledge and

understanding is obtained. Furthermore, favorable relations developed through science collaborations may benefit overall diplomatic relationships between governments and improve understanding amongst different cultures.

ACKNOWLEDGMENTS

We are grateful to Neal Lane, Ph.D., Matthew Chen, and Wasif Syed for reviewing this article and their advice on the content. We also would like to thank Baker Institute Intern Nathan Lo for his assistance in reviewing GME publications. This project was supported, in part, by the Baker Institute International Stem Cell Policy Program, which was endowed by the State of Qatar in collaboration with the Qatar Foundation for Education, Science and Community Development.

The final publication "Stem Cell Research in the Greater Middle East: the Importance of Establishing Policy and Ethics Interoperability to Foster International Collaborations" was published in *Stem Cell Reviews and Reports* 6(2): 143-150 and is available at link.springer.com.

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FIGURE AND TABLES

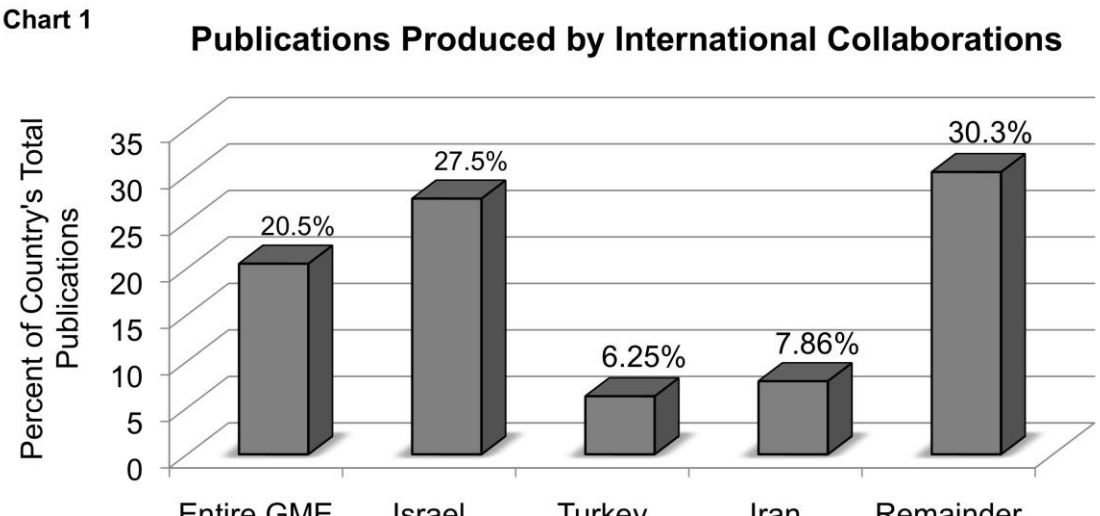

Chart 2

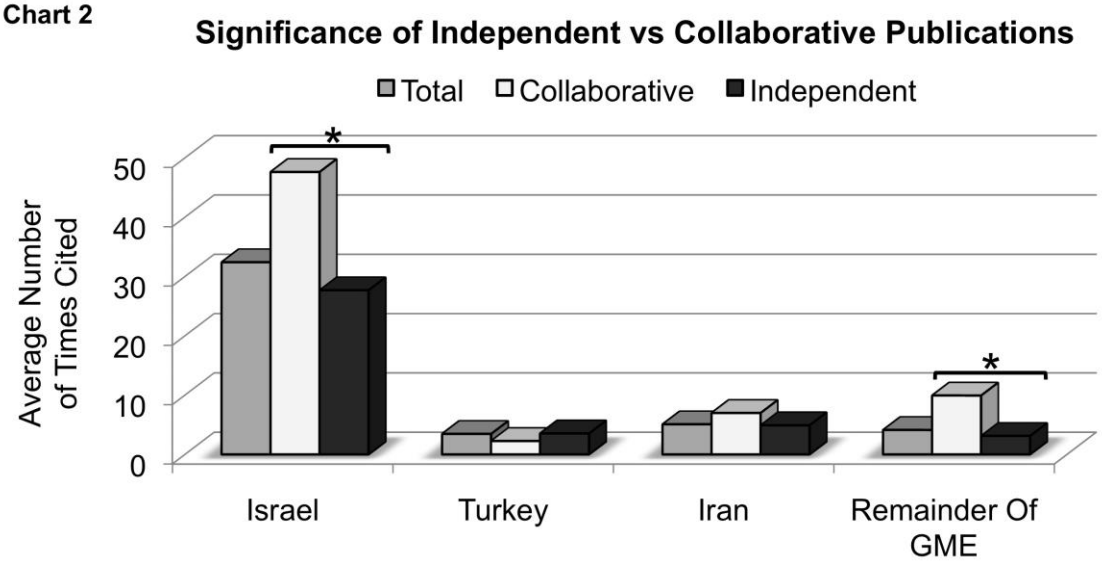

Table 1 Overview of stem cell research in the Greater Middle East (GME)

	Country	% Total Articles	Article Count	Model Organism (%)	Developmental Stage (%)
Primary Nations	Israel	57.8	440	•Human: 58.1 •Murine: 37.7 •Other: 4.2	•Adult: 57.0 •Embryonic/Fetal: 23.0 •Post-Natal/Cord Blood: 20.0
	Turkey	23.1	176	•Human: 90.1 •Murine: 9.9 •Other: 0.0	•Adult: 88.1 •Embryonic/Fetal: 7.4 •Post-Natal/Cord Blood: 4.5
	Iran	11.7	89	•Human: 47.2 •Murine: 47.2 •Other: 5.6	•Adult: 65.2 •Embryonic/Fetal: 28.1 •Post-Natal/Cord Blood: 6.7
Remainder of Published Nations	Saudi Arabia	2.5	19	•Human: 75.9 •Murine: 17.2 •Other: 6.9	•Adult: 89.5 •Embryonic/Fetal: 1.8 •Post-Natal/Cord Blood: 8.8
	Egypt	1.6	12		
	UAE	0.8	6		
	Pakistan	0.7	5		
	Lebanon	0.5	4		
	Tunisia	0.5	4		
	Kuwait	0.4	3		
	Morocco	0.3	2		
	Jordan	0.1	1		
TOTAL		100	761	•Human: 65.3 •Murine: 31.1 •Other: 3.6	•Adult: 67.2 •Embryonic/Fetal: 18.6 •Post-Natal/Cord Blood: 14.3

Surveyed nations without stem cell research publications were: Afghanistan, Algeria, Bahrain, Djibouti, Iraq, Libya, Mauritania, Oman, Palestine, Qatar, Somalia, Sudan, Syria, Yemen.