Distribution of hESC Lines: How, When, and Where

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Little attention has been paid to how national governments with widely divergent policy positions produce segmented markets for human embryonic stem cell (hESC) research, innovation, and product development. This segmentation may have strong and possibly negative effects on American research and economic competitiveness. Does national policy generate country-specific discoveries, intellectual property, and therapies? Which countries or regions will emerge as technological or bio-industrial leaders? Will America play a major or minor role?

At the heart of these questions is determining which hESC lines go where. Exchange and transfer of biological materials through material transfer agreements (MTAs) is a regular feature of how science gets done and is often essential for many research collaborations. Cell lines and their reagents are the “coin of the realm” for hESC research—starting materials needed to answer essential biomedical questions.

We are in the process of obtaining raw data describing the number of MTAs initiated and executed by the University of Wisconsin’s Wisconsin Alumni Research Foundation (WARF) and from Harvard University, including what lines are being requested and distributed, how many are being distributed, and to what countries the lines are being distributed.

We are particularly interested in hESC lines from these two sources for a few reasons, including:

The WARF lines are approved for US federally funded research while the Harvard lines are not.

Until recently the availability of the WARF lines included a licensing fee while the Harvard lines have been distributed at only the cost of shipping the material.

**Obtaining the data**

Launching the project required discussion with stakeholders at WARF and Harvard. We are near the end of working out an agreement under which data will be obtained. Because five institutions have been involved (Harvard, HHMI, Stanford, University of Michigan, and WARF), reaching a final agreement has taken time.

**Preliminary data**

Studies have suggested that national policy can influence how and what stem cell research is being conducted, and by whom. Owen-Smith and McCormick (Nat Biotech 24, 2006) demonstrate a significant gap in rate of hESC publications between the United States and the rest of the world, over time, and that this trend is on a trajectory of continuing. Levine (Nat Biotech 24, 2006) has shown that US stem cell scientists are 5 times more likely to receive job offers from abroad - many from permissive countries - more so than other biomedical scientists.

Other analyses indicate the countries such as China and India are increasingly targeting biomedical research efforts toward stem cell research (Murray and Spar, NEJM 355, 2006; Salter, Cooper, Dickens, and Cardo, Regenerative Med 2, 2007).

Preliminary data show that between 1998 and 2004, the number of MTAs executed by WARF went from 0 per year to 100 per year, with the numbers increasing almost four-fold between 1999 and 2000 and almost three-fold between 2000 and 2001.

Since Harvard has begun distributing their lines in early 2004, 93 MTAs have been executed domestically. These cover the distribution of 536 lines. There have been 135 MTAs executed with international entities, and these represent the distribution of 636 lines.

**Discussion and Future Directions**

We anticipate our analyses to reveal which countries and types of institutions are pursuing hESC research, whether demands for lines are increasing or decreasing, whether lines generated in US laboratories stay in the US, and whether investigators are switching from one cell line to another (e.g. presidential to other lines). This landscape of hESC research might suggest what nations are likely to be leaders in this area of research and indicate to national policy makers whether resources ought to be directed to hESC research, if the goal is to be a leader in the field.

In addition, our data might demonstrate that some lines are being requested and distributed more frequently, thus suggesting variance in usability of different lines, both between the two sets of lines and within each set. A comparison MTA data with publication records might suggest how materials are being exchanged, e.g. formally, informally, collaborations, etc. Given the current US regulatory environment for stem cell research, this might be insightful to administrators responsible for providing training to researchers about institutional policies.

Our expectation is that our initial examination of the data will lead to more questions and further analyses. We plan to conduct interviews with researchers, identified through publication data and publicly accessible websites, who have used either or both the Harvard lines and the WARF lines. These interviews will be focused on researchers’ perceptions of the material transfer process, the different cell lines available, and the role of IP in hESC research.