

RESEARCH PAPER

Managing innovation in the stem cell sciences: Australian views from the field

Olivia Harvey*

Department of Sociology and Social Policy, University of Sydney, Sydney, Australia

Recent research has shown that governments around the world are implementing a range of strategies intended to maximise national competitive advantage in the growing global stem cell bioeconomy. There are two reasons for this: on the one hand, the global expansion in neoliberal economic policy since the 1970s has resulted in an increasing reliance on the free-market economy for national growth and prosperity; and on the other hand, the crisis of the ageing population and the spiralling costs of healthcare have placed increasing pressures on governments to rationalise precious resources. By indicating support for the growth of nationally competitive industries in a new technology that promises to revolutionise healthcare, such as stem cell science, governments are able to meet the twin demands of neoliberal economic policy and care for the health of national populations. The governments of the UK, China, India, Singapore and Australia were among the first to develop deliberate strategies designed to enhance their local and regional stem cell industries. While most strategies contain quite similar elements, there is yet to be any systematic evaluation of how effective they might be at building support for the stem cell industries. Drawing on interviews conducted in 2009, this paper will examine how stakeholders engaged in the stem cell sciences in one of these locations – Australia – view the effectiveness of state strategies from the front-line of the stem cell innovation process. The aim here is to identify what evidence exists to support specific strategy development.

Introduction

Governments around the world have been increasingly targeting innovation in the stem cell sciences as a means of building national competitiveness in the global stem cell industry (Gottweis *et al.*, 2009). While governments around the world have been adopting various strategies for improving overall economic performance through enhancing research and development since the late 1970s (Birch, 2006; Benner and Lofgren, 2007), government management of innovation in specific industries became a significant driver of national research and development policy worldwide only in the early 1990s (Godin, 2009). The aim of selectively targeting specific industries is to build a platform for future economic growth, while at the same time balancing the risks and benefits of new technological development (Asheim and Isaksen, 2002; Benner and Lofgren, 2007; Hekkert, *et al.*, 2007; Godin, 2009; Gottweis *et al.*, 2009).

*Email: olivia.harvey@sydney.edu.au

The transformation from the welfare state to the neoliberal state has been a key driver underpinning the emphasis on strategic support for innovation (Birch, 2006; Gottweis *et al.*, 2009). The desire to reduce the cost to governments of investing in science and technology resulted in an enhanced push to achieve more economic benefit from state investments. Changes to the laws surrounding patenting of public funded research in the US in 1980, for example, were one attempt to secure better market performance for high technology industries (Rai and Eisenberg, 2003; Nelson, 2004).

Biotechnology is seen to be especially amenable to government policy support because of its high potential for market failure and the cultural anxieties produced by new developments (Birch, 2006; Benner and Lofgren, 2007; Gottweis *et al.*, 2009). Factors within the biotechnology innovation system that are seen to be amenable to government intervention include the strategic support of networks (Asheim and Isaksen, 2002; Gilding, 2008); the development of regional and sectoral specialisation (Marceau and Manley, 2001; Cooke, 2007); the implementation of specific regulations designed to enhance business opportunities and increase investment benefits (Gans and Stern, 2002; Terziovski and Morgan, 2006); improving the science-base of a nation (King, 2004; Nelson, 2004; Marceau, 2007) and the creation of new regulatory regimes that support the entry of novel products into the market through the development of robust regulatory systems (Faulkner, 2009).

The recent global shift towards building national competitiveness in biotechnology in particular is reflective of a broader trend towards maximising economic advantage within the emerging 'knowledge based bioeconomy' or KBBE (see European Commission, 2005). It is argued that such a policy focus on the knowledge based bioeconomy will result in improved health outcomes, safer food, better food security, sustainable agriculture and alternatives to fossil fuels (DG Research, 2009). Current applications under development include biopharmaceuticals, genetically modified food, innovative uses of crops and the development of biofuels (DG Research, 2009). Current estimates put the value of the knowledge based bioeconomy in the European Union alone at €1.5 trillion a year (DG Research, 2009). Predictions are that by the middle of the twenty-first century, the global bioeconomy will be a vital feature of almost every facet of human life (Morgan, 2006).

The first country to develop a specific stem cell strategy was the United Kingdom, with China, India, Singapore, Australia and others following suit (Salter *et al.*, 2006, 2007; Salter and Harvey, 2008; Gottweis *et al.*, 2009; Waldby, 2009; Harvey, 2010). Strategies that have so far been adopted have generally included many of the same features. These might encompass developing comprehensive regulatory regimes; introducing new licensing schemes; encouraging international harmonisation in intellectual property; developing biological product regulations; designating specific funding programmes targeted at facilitating basic science; aggressively pursuing technology transfer; and developing innovative new investment programmes (Salter *et al.*, 2006, 2007; Salter and Harvey, 2008; Gottweis *et al.*, 2009; Waldby, 2009; Harvey, 2010).

Yet these strategies remain largely untested in their impact on improving the national competitiveness of the stem cell industries. During fieldwork conducted around Australia in 2009, it emerged that the idea of a dedicated government approach to enhancing or supporting an emerging industry was seen by interviewees to be highly questionable, given that scientific research is a global enterprise. In this paper, the views of stakeholders in the field of stem cell innovation and the

role of governments in enhancing this process are explored. The goal here is to identify an evidence base that might be drawn upon to build effective policy strategies for the future success of the stem cell industries.

A short history of Australian stem cell science

Specific capacity building in the stem cell sciences in Australia began with the implementation of a comprehensive national regulatory framework and licensing system for research using embryos and embryonic material in 2002 (Harvey, 2005, 2008). Other features of strategic capacity building have included the establishment of the Australian Stem Cell Centre in Melbourne in 2002 (see http://www.stemcell-centre.edu.au/About_ASCC.aspx), and the National Adult Stem Cell Centre in Queensland in 2006 (Abbott, 2006); as well as the commitment of significant financial and material resources by regional state governments over the last 5–10 years to the stem cell sciences (Harvey, 2010). A new federal government strategic competitive funding initiative was announced in May 2010 worth \$A21 million (Carr and Butler, 2010). There are also local and national stem cell networks across Australia, such as the NSW Stem Cell Network (<http://www.stemcellnetwork.org.au/>) and the Australasian Society for Stem Cell Research (<http://www.asscr.org/>). Researchers in Australia are also engaged with important regional and international networks; Stem Cell Network Asia–Pacific (SNAP, <http://www.asiapacificstemcells.org/>) and the International Society for Stem Cell Research (ISSCR, <http://www.isscr.org/>) are two specific examples.

The regulatory framework covering the use of embryos in research in Australia provides researchers with legal and ethical justification for work that might otherwise be considered quite controversial. The new regulations established a comprehensive licensing system for the use of ‘excess’ assisted reproductive technology (ART) embryos in research and provided legal restrictions around the kinds of research that would be permissible; in particular, the 2002 legislation specifically prohibited the use of somatic cell nuclear transfer (SCNT) in research (Harvey, 2005). The legislation was reviewed in 2005 (the *Lockhart Review*) and some amendments made, mainly regarding the types of research practices that might be undertaken with excess ART embryos (most notably, the use of SCNT) (Harvey, 2008). A further review of the legislation is scheduled for the end of 2010, yet it has been suggested by a member of the previous review committee that not much is likely to change in the near future as consensus has largely been achieved (Dayton, 2009).

Like elsewhere in the world, a focus on biotechnology innovation in Australia became particularly prevalent in the early part of the twenty-first century and was an attempt to leverage national participation in the global knowledge based bioeconomy. *Backing Australia's Ability* was a \$A3 billion policy initiative launched in 2001, under which the Australian Stem Cell Centre was formed in 2002 (Commonwealth of Australia, 2001). Key issues for *Backing Australia's Ability* were: (1) building the private sector via support for industry collaboration and entrepreneurship, providing bridging funding for commercialisation, raising tax incentives for R&D investment and improving the protection of intellectual property; (2) improving the science base via support for the school system, increasing enrolments in science and technology based university courses and providing funding for university research infrastructure; and (3) establishing a new competitive grants scheme for

major national research facilities (Commonwealth of Australia, 2001). The Australian Stem Cell Centre was the first National Biotechnology Centre of Excellence to be established under the initiative and has played an important role in developing the stem cell industries in Australia.

The strategies adopted in Australia are thus very similar to the strategies adopted in other nations in attempting to increase success in the global stem cell bioeconomy. At the time of writing, though, there is little evidence of the success of these strategies in building competitive advantage. This paper presents information collected from participants in the field in Australia in an attempt to bridge this gap.

The realities of doing stem cell research in Australia

Interviewees cited in this paper were identified via existing biotechnology and stem cell networks in Australia and sent participation information statements and consent forms. Nine interviews took place in Sydney, Brisbane and Melbourne between February and March 2009, ranging from one to two hours in length. The number of respondents was smaller than anticipated, but the individuals who volunteered to be interviewed for the project reflected a reasonable cross-section of members of the professional community and represent a response rate of around 17%. Respondents ranged in seniority and length of time in the field, and also represented a variety of stakeholders in the field. All of the respondents had scientific training to PhD level.

The small sample size obtained was a function of the methodology adopted, the limitations imposed by the ethics review process, and the necessarily limited numbers of potential respondents. From an established knowledge of the field obtained through previous research experience in the area, attending scientific conferences, contact with professionals, and finally, an Internet search of relevant organisations, a database of potential respondents was created of 52 individual names and organisations around Australia. Where specific individuals could not be identified, the organisation's administrator was used instead. By necessity, this process involves a certain amount of researcher discretion and 'purposive sampling' (Denscombe, 2007) (that is, non-random sampling).

The recruitment process was also somewhat complicated by the requirement of the ethics committee overseeing research at the University of New South Wales that respondents be approached only by indirect methods. For the purposes of semi-structured qualitative social science research, emailing a participant the information statement and consent form suffices as an arm's length approach. Denscombe (2007) suggests that response rates for research projects utilising indirect recruitment methods are often much lower than those using direct recruitment methods, citing evidence that between 10% and 15% might be considered average for a survey, for example, whereas a direct approach from a street-based researcher might result in a 100% response rate. With arms-length recruitment, interested individuals are invited to flag their interest by returning the consent form to the researcher. The time-consuming nature of semi-structured interviewing is a disincentive to participate for busy professionals. Finally, Denscombe (2007) argues that there are no hard and fast rules for an adequate response rate, and that often a research topic determines the numbers of potential respondents. The investigation in this project, focusing on the attitudes of industry professionals involved in a small and highly specialised area of scientific research in a nation with a relatively small population compared with the US or the UK, is therefore necessarily going to be limited.

According to Denscombe (2007, p.30), when purposive sampling and a special area of research are combined, the sample size is inevitably going to be small.

Interviewees were asked to comment on what they knew about the stem cell sciences in Australia, how they thought the industry was progressing, what they thought the strengths and weaknesses were in the industry, what barriers existed to commercialisation, and what they thought would happen in the future. Respondents were also asked to comment on what they thought the regulatory environment was like, what they thought of current innovation policy and how they thought it related to stem cell innovation. In the final stage of the interviews, respondents were invited to comment on what they thought were the immediate challenges for both governments and industry in stem cell science, and what role governments should play in developing the industries. Respondents were also given the opportunity to add any further comments they felt reflected on the topic of the interviews.

There were a number of common themes that emerged through the interviews. Overwhelmingly, however, the discussions tended to focus on the strategic approach to innovation of governments. These stakeholders tended to view the activities of government as either encouraging research or not, and from their point of view there are only a few opportunities for governments to intervene in the innovation process. The degree of apprehension about government support in facilitating innovation was striking, particularly given that governments around the world have been deliberately targeting stem cell innovation via specific policy approaches aimed at enhancing national competitiveness.

State strategies in the context of global science

Almost all of the respondents regarded science, commercialisation and innovation as being global, uniform and universal processes. The following is a sample of comments from the interviewees that highlights this point:

Stem cell science is, like all sciences, cannot be placed in a national context. . . . Basic science is international. (Retired research scientist)

First of all, it's a global industry. There's no question about that. The information is global. (Research scientist)

I'm of the view that all of the fundamental traits and drivers of innovation look exactly the same at a generic level. (Technology transfer specialist)

Thus, it seems counterintuitive to these respondents (if science, innovation and commercialisation are global) to insist on securing the performance of a given industry within a particular nation state. However, the thesis that the inexorable forces of globalisation are eroding the boundaries of the nation state is highly contested and there is some argument for the claim that the nation state is, in fact, just as strong as it has always been, and, moreover, that its primary role is to enhance national competitiveness in the global context (Cerny, 1997; Loeppky, 2005; Benner and Lofgren, 2007). For governments, this is the rationale for strategic investment, yet how might this position be reconciled with what the stakeholders cited here had to say?

Although deeply dubious of the nationalised approach to a given scientific endeavour, some of the respondents were still keen to indicate that creating the right

general conditions for innovation are crucial for facilitating the participation of local researchers in international science:

You have to foster an innovation culture. Ok? So you have to set up the right conditions to you know, to innovate. Ok? But ... it can happen anywhere, absolutely anywhere, if the conditions are right. (Technology transfer specialist)

These respondents accepted uncritically the national innovation systems model that has been taken up worldwide (see Lundvall, 2007). National innovation systems theory views innovation as the result of a number of different elements interacting together, with each nation state having its own distinctive innovation system (Marceau and Manley, 2001; Carlsson, 2006; Lundvall, 2007; Hart, 2009). Governments, however, believe that the judicious tweaking of various components of this system will improve economic performance, yet the key to the national innovation systems model is that the whole technical, social and economic system must be considered in its entirety (Marceau and Manley, 2001; Lundvall, 2007, pp.100–101); that is, it cannot be applied to specially selected industries. Thus, a national innovation systems approach fails to take into account why governments might choose specific industries to target for enhancing national competitiveness. The national innovation systems approach also fails to acknowledge the different needs of specific sectors (Marceau, 2007).

On the one hand, despite the reluctance of respondents to consider industry-specific innovation as capable of policy-directed transformation, there was general support for the idea that managing innovation is important. Intriguingly, then, despite the certainty that industry-specific strategies were not helpful in the global scientific context and that innovation is a systemic issue, there were still several key areas that stakeholders regarded as particularly important to the future success of the stem cell industries. More significantly, these themes were universal to all the discussions with stakeholders. They all cited the importance of funding; the role of star scientists in fostering a cutting-edge internationally dynamic scientific community; and the function of the Australian Stem Cell Centre in facilitating the development of the industry.

Funding

In commenting on the future success of the stem cell industries in Australia, one senior scientist said that:

My feeling is that ... the reality is ... that ... as long as you put in place ... the infrastructure to capitalise on what we can do in this country ... it's going to succeed. It comes down to resources. (Research scientist)

'Resources' in this context were generally limited to financial support. Securing funding was by far the biggest issue for the stakeholders interviewed. Some senior research scientists with significant experience in the field suggested that funding for the stem cell sciences in particular was hampered by a risk averse approach to undertaking scientific research in Australia.

In areas that are not well established and which are really new territory ... it's harder to get committees to support funding ... because it's ... very high risk. (Research scientist)

In Australia, by and large ... we fund safe science; we don't fund adventurous science. ... It's relatively hard to get funding for things that are adventurous. ... There is no funding agency in Australia that will take risks and fund science that isn't really very much within the realms of what is thought to be almost certainly successful. (Retired research scientist)

In contrast, other senior respondents viewed obtaining funding as a strategic process, with suggestions that matching funding from other sources and obtaining funding from disease groups were other options available in Australia. Funding was considered to be such a significant issue for all the stakeholders, though, that questions were raised by respondents as to the effectiveness of even thinking strategically about national strategy when Australia is a small, geographically isolated country with limited resources. In other words, in comparison with California, for example, the resources that have been committed to stem cell science are miniscule, and most stakeholders regard this as the single biggest limiting factor to Australia's competitiveness in the global stem cell economy.

How funding scientific research will increase measurable economic benefit is disputed (King, 2004). Australia's overall research and experimental development (R&D) funding increased significantly between 1997 and 2007 (the latest available figures) from \$A8792 million to \$A21,000 million (Australian Bureau of Statistics, 2010). Research and development trends as a proportion of GDP since 2004 show a slight increase in business and higher education investment and a decrease in government funding for research (Australian Bureau of Statistics, 2010). How this maps on to improved economic competitiveness is not possible to determine from available data; yet, since the 1950s, the argument has been made that investing in basic research makes an important contribution to national economic development (see Nelson, 1959, 2004; Marceau, 2007).

Networking

Networking was also identified as a key issue by most respondents:

Within Australia, I think the formation of the Australian Society for Stem Cell Research is very right and first step in this direction ... I am not clear, I'm not quite sure why initially there was no such like strong networking within Australia. (Junior research scientist)

The Australasian Society for Stem Cell Research (ASSCR) is a peak industry body for scientists working in the stem cell sciences across Australia, first conceived at the International Society for Stem Cell Research (ISSCR) conference in 2007. It is thought to have a membership of around 100 (S. Hawes, personal communication, 11 January 2009). Networking activities of the ASSCR include a monthly newsletter, an annual meeting and other outreach activities for its members. The ASSCR is growing exponentially and is fast becoming established as one of the key industry bodies for professionals in Australia and New Zealand. The junior researcher cited above, though, points out that while this is a welcome development, networking opportunities have been comparatively slow to develop in Australia.

Another interviewee observed though that Australian scientists in the biotechnology sector are extraordinarily well connected overseas.

When we talk to companies and researchers about their linkages, the researchers have got huge linkages overseas, lots of linkages. (Biotechnology consultant)

This observation is supported by the fact that a significant amount of discussion with respondents focused on the role of senior professionals and particular star scientists (Zucker and Darby, 1996) in facilitating these international linkages.

In terms of facilitating innovation, networking and star scientists are important features identified in the innovation literature. Philip Cooke (2001) argues that there is much to be said for the geographically close relationships between venture capitalists and elite universities, citing Genentech's success as originating in an aggressive approach to sourcing intellectual property on behalf of venture capitalists as vital to the success of US biotechnology. Michael Gilding (2008) has explicitly researched the networking and internationalisation of one biotechnology cluster in Australia and suggests that regional networking takes on more importance when international networking is heavily reliant on personal connections. Star scientists are important because of the tacit knowledge they bring to the commercial arena (Zucker and Darby, 1996). Zucker *et al.* (1998) suggest that star scientists in Northern California have been more important than the proximity and role of venture capitalists in developing the region's biotechnology industry because of the knowledge and skills they bring to the industry (rather than just money).

The Australian Stem Cell Centre

In 2002, the Federal government committed almost \$A100 million over a period of nine years to establishing the Australian Stem Cell Centre (ASCC, http://www.stem-cellcentre.edu.au/About_ASCC.aspx). Though the ASCC was mentioned by all respondents as playing a central role in the development of stem cell science in Australia, its funding stops in 2011. For the interviewees, the establishment of the ASCC represented a significant policy commitment by the government, and provided new opportunities for drawing together expertise in the field.

I think, in this context, where we start is absolutely right – to try and get a national approach to it. So that, I mean, the Stem Cell Centre was a bold attempt. (Technology transfer specialist)

Although the ASCC has had some difficulties in achieving its initial objectives (Munsie, 2010), the idea that an Australian centre for stem cell science is an important component of increasing capacity in stem cell research in Australia still persists. The importance of having a dedicated, visible, centralised location for managing and distributing funds, if not increasing opportunities for collaboration on projects within Australia, was seen by the respondents as a key initiative in creating a national industry.

The importance of visible centres as a mode of clustering is also highlighted in the innovation literature. Cooke (2007) has pointed out the considerable benefits to be obtained from clustering in the biotechnology industry in particular, with much of this highlighting how knowledge parks and other opportunities for geographically concentrated knowledge building help capacity building in the industry.

A critique of dedicated biotechnology strategies in the European Union also emphasises the importance of facilitating capacity building through access to intellectual property and both managerial and laboratory resources among groups of

small biotechnology firms (Enzing *et al.*, 2004; Senker *et al.*, 2007). Importantly, too, the European Union study of biotechnology strategies explicitly highlights that state support should encourage capacity building, but stop short of market interference or providing bridge funding to enable small firms to enter the market (Reiss *et al.*, 2003). Emphasis here is on building robust and economically competitive firms that are free from reliance on government funding and will be able to function normally in the marketplace.

Conclusion: innovation and the nation-state

The dual imperative of government intervention as political strategy indicating support for the health of the nation and intervention as a means of maximising economic competitiveness in a globalising, neoliberal market was acknowledged by some respondents. For example, one of the respondents viewed developing national competitiveness in the stem cell sciences as a means by which expanding healthcare costs associated with an ageing population might be reduced:

As medicine offers more and more possibilities ... the reality is that people are looking at stem cell biology in terms of repair. It's about essentially enhancing ... the way your body works so you can get around the ageing process to a certain extent. ... If we're just consumers, we are going to be in a bad position. We need to be sure that we are part of the invention process and the commercialisation process. ... Because medicines get more and more expensive, if we are not part, we're not going to see our share of the return on investment in research that creates new medicines. It's just going to be really, really expensive for us. (Research scientist)

These interviewees generally did not consider just why state support for controversial medical research is important. This highlights a key discordance between how stakeholders regard state support for scientific research, and why states are attempting to intervene in the field. In particular, there is a tendency for the economic rationale behind state intervention in the stem cell sciences to be overlooked by scientists. Most respondents argued that individuals become involved with science because of altruistic motives and the desire to make a difference.

I think that most scientists, most basic scientists, most university and hospital based scientists, particularly in medical research, go into research because they want to reduce the burden of handicap, they want to see children ... get better. (Retired research scientist)

I guess personally I think that's probably intrinsic in what we do. Like, obviously we want to be practical and ... provide a solution to our patients or people who suffer from this disease and lacking this organ or this tissue ... so I'm not quite sure it's at the forefront of our minds ... but I have a feeling that it's part of what we do. (Recent tissue engineering PhD)

Although the economic value of investing in biomedicine is the justification used by neoliberal governments (Birch, 2006), the altruistic motives of scientists, coupled with the need for improved treatments for patients, are at odds with this economic agenda. What needs to be made more explicit is how state support for building international competitiveness might more effectively engage with how scientists view the international, collaborative, altruistic and social importance of what they do.

The observations from the field presented here are intended to contribute to the formulation of policy initiatives designed to bridge the gap between political strategy and actual practice. What comes through very clearly from respondents is that, despite their strong level of engagement as stakeholders in the policy debates in Australia, actual strategies for government support of innovation are viewed from a very narrow perspective. Opening up better dialogue between policy development and scientific practice would enhance the overall competitiveness of Australian stem cell science and result in a win–win situation for governments, scientists and patients.

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