The clinician-scientist: professional dynamics in clinical stem cell research

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Introduction

Emergent biomedical technologies force the revision of boundaries between traditional disciplines and the creation of new alliances between experts (Keating and Cambrosio 2003, Lowy 1997). The ensuing professional re/configurations and tensions have captured the interest of sociologists: stem cell research (SCR) is a case in point. Alongside the considerable debate concerning its ethics, political governance and legislative frameworks (e.g. Gottweiss et al. 2009, Nowotny et al. 2007, Salter 2008), scholars started to recognise the contribution of different professional groups to the shaping of SCR (Cribb et al. 2007, Jasanoff 2005, Wainwright et al. 2006a, 2006b) and the position of key actors in the process: i.e. clinician-scientists who are involved in research to bring novel stem cell treatments into the clinic. This article examines the discursive repertoires some clinician-scientists employ to explain and reflect on their role, and argues that pressures to bring SCR-derived treatments into the clinic brings these actors to the fore and provides a renewed platform for their professional legitimisation. Our argument builds on sociological writing on professionalisation and professional dynamics in healthcare, medical literature on the decline of academic medicine and the position of clinician-scientists in translational research and interdisciplinary work on socio-economic issues in SCR.

We seek to contribute to the development of an updated conceptualisation of professional dynamics in translational medicine in two respects: by focusing on current experiences we offer an empirically grounded understanding of how clinician-scientists involved in clinical SCR rationalise their position. Secondly, by drawing on a specific case study – randomised control trials (RCTs) using adult, autologous

(patient's own) stem cells for heart repair, we explore clinician-scientists' sense-making strategies and claims of disciplinary expertise and jurisdiction (Abbott 1988). The development of professions is a matter of complex conjunctures with various resources being used for distinction practices (Burri 2008). We argue that clinical SCR offers clinician-scientists unique opportunities to consolidate their professional status, which must be examined if we are to gain a clearer understanding of how translational medicine is shaping professional hierarchies.

We present the argument in five parts: the first examines how sociologists have conceptualised professional dynamics in healthcare in general and in SCR in particular. The second discusses the role of clinician-scientists in academic medicine and translational research from a medical literature perspective. The third section introduces our case study and its methodological framework. Part four outlines the themes developed in the participants' accounts and the conclusion summarises how our case study exemplifies the position of clinician-scientists in translational research.

Professions, Biomedical Technologies and SCR

The sociology of professions has examined the ways in which members of professional groups distinguish themselves from those of other occupations through the special character of the knowledge required to perform their tasks (Abbott 1988, Freidson 1994, Timmermans 2008). The term 'professionalisation' is used to explain adjustments between occupational groups and social institutions in relation to specific socio-economic conditions within which powers of exclusion and demarcation are exercised, and conflict, negotiation and conciliation occur in the struggle for recognition (Light 2000, Starr 1982). Professionalisation implies the consolidation of positions through the conversion of expertise into market monopoly and social status, a process achieved through legislative and regulatory control

(Larson 1977, Larkin 1983). Professions are said to have the capacity to reconstitute their knowledge and redefine their boundaries as they adapt to new realities (Fournier, 2000). In accounting for professional power at different levels within national healthcare systems, sociologists have both highlighted the competitive, exclusionary basis of modern professionalism (e.g. Nancarrow and Borthwick 2005) and emphasised the changing structure of authority at the "end of the golden age of doctoring" (McKinlay and Marceau 2002).

Increased bureaucratisation, the democratisation of knowledge, consumerism and a rise in the power of related professions (Nettleton et al. 2008) are held responsible for what is seen as the loss of the 'monopoly of medical knowledge' and the de-professionalisation of medicine (Haug 1988) – i.e. the loss of medical experts' authoritative and regulatory influence. The recent impetus to standardise clinical decision-making (regarded as the core of traditional professional autonomy), and to change it from a reliance on peer consensus and case reports (among others), to decisions based on statistical evidence, has been intensely disputed (Armstrong 2007; Lambert 2006, May 2006). Randomised control trials (RCTs) are regarded as the backbone of evidence-based medicine (EBM) and represent ''the gold standard'' of biomedical research, the ultimate way to establish medical procedures and assess them in relation to the efficacy of the treatment (Marks 1997, Timmermans and Berg 2003).

These debates however have not yet been contextualised in relation to the clinical implementation of SCR. Analyses here highlight the disciplinary differences between clinical and scientific practices, their underlying factors, and the ways in which professional cultures come together. Wainwright et al. (2006a, 2006b), for instance, examine the landscape of human embryonic SCR in diabetes and neuroscience, and the discourses used by professionals therein to describe disciplinary and institutional

pressures experienced when working together. Their argument outlines the expectations surrounding collaboration in translational research and the distinct normative structures within which basic scientists and clinicians operate. Similarly, Cribb et al. (2007) emphasise the competing orientations, sets of dispositions and contrasting role positions made by such structures in medicine and biology. The technical dimensions of the science and its economic, political and social aspects are typically framed in the context of "regimes of hope" where the public promise of translational research to deliver cures is instrumental to the move into RCTs (Moreira and Palladino 2005, Martin et al. 2008).

Moreover, while the role played by regulation in the organisation of clinical trials using autologous stem cells for heart repair has been addressed (Wilson-Kovacs et al. 2010), the figure of the clinician-scientist in this process remains largely overlooked. In SCR, double-blinded RCTs represent the scientific medical standard for establishing new therapies in the clinic (Yeo and Mathur 2009). They involve complex articulations of expertise within the medical profession (in terms of ranks and specialisms), and between medical and biological sciences. Below we illustrate how in this process clinical and scientific skills are systematically ordered: clinician-scientists engage in jurisdictional disputes where RCTs provide a rhetorical strategy to create hierarchies of expertise and reinforce professional standing.

The Clinician-Scientist

The recent impetus on translating research from the laboratory into the clinic brings academic medicine and the figure of the clinician-scientist to the renewed attention of medical commentators (Lander et al. 2010, Zerhouni 2005). Clinician-scientists are seen as the essential conduit between the bench and the bedside and "natural leaders" in the translational field (Lemoine 2008: 12), as they lead active laboratory

research programmes and possess an understanding of the practicalities of clinical medicine. There is widespread recognition of the continuing need to nurture these specialists both nationally and internationally (Ley and Rosenberg 2005; Sheridan 2005, 2006; Tooke et al. 2007).

UK programmes, established in the mid-1980s, encouraged clinicians to pursue research careers, but raised wide criticism in the medical community (Bell 2003, Goldbeck-Wood 2000, Pudsey 2002). Problems of recruitment and retention were severe: clinicians in these schemes were subjected to inflexible training and work criteria and required to spend six years in research, followed by a further four to five years in full-time clinical training. During this time they were engaged principally in research, and provided minimal, specialised, clinical input (Smith and Shine 2001, Stewart 2002). Consequently, "they spend part of their week on the wards and part on the bench, achieving neither intended goal satisfactorily" (Sharma 1998:1168). Critics of the schemes urged for better institutional and financial support, stable career structures and clear incentives for young clinicians to follow the clinician-scientist path (Bell 2003, Sharma 1998).

Responding to these issues, the UK Academy of Medical Sciences made a number of recommendations of which the introduction of a new clinician-scientist scheme was key (Savill 2000). Subject to competitive entry, the National Clinician-Scientist Award Scheme (launched in April 2001), seeks to address perceived career disincentives by establishing a fast-track training programme to produce research-led clinical academics capable of directing research development in their disciplines (Pudsey 2002, Tunbridge 2004). The Scheme provides a maximum of five-year funded opportunities, with access to academic mentorship and a flexible academic career development alongside clinical specialist training.

Parallel initiatives have been implemented abroad to address similar issues of retention and career progression. However, clinician-scientists in all specialisms continue to be seen as an "endangered species", "a rare breed under threat in a hostile environment" (Lemoine 2008: 12). Considering the central paradigm behind the success of academic medicine (i.e. the two-way interaction between bench and bedside), the goal of reinforcing "clinical research not in isolation but as an integral limb of the totality of biomedical research and its application" (Sheridan 2005: 1339) remains to be achieved. Moreover, the conversion of SCR into new therapies is delayed by critical gaps, such as "bringing together basic stem cell biologists, researchers, and clinicians with disease-specific expertise; physicians and surgeons skilled in novel modes of cell delivery; and investigators experienced in developing and assessing animal models of human diseases" (Zerhouni 2005: 1357). Our findings elucidate aspects of this process in the context of clinical SCR with autologous stem cells for heart repair.

Case Study

Improvements in heart repair represent an important clinical priority and the use of adult, autologous, (rather than embryonic) stem cells offers a potential route to achieve the regeneration of damaged tissue and repair of heart function. Due to the number of clinical trials developed in the last ten years using stem cells for heart repair, SCR is identified in the media as a potential solution to the growing numbers of patients with chronic heart disease and myocardial infarction (Allender et al. 2008, Lipinski et al. 2007).

The European Society of Cardiology has recommended the use of RCTs with autologous stem cells in large scale, double-blinded interventions to establish viable treatments (Bartunek et al. 2006). However, recent reviews highlight that although

these interventions show statistically significant effects (in infarction fraction), their mid-term patient benefit are clinically doubtful (Abdel-Latif et al. 2007, Yeo and Mathur 2009). Potential treatments remain contested, with critics from the medical community questioning the safety of the procedure, methods of delivery and speed of moving into patient trials. Equally, observers from the scientific community and embryonic SCR point out that the future of SCR and its financial backing may be compromised as a result of ambiguous trial outcomes (Cox 2007). These critiques emphasise the need for interdisciplinary expertise and an effective translational process where the connection between the basic research laboratory and the clinic is strengthened through mutual knowledge exchange and enabled by appropriate institutional set-ups. As we argue below, it is in this context that our participants' strategies of legitimisation of professional jurisdictions are crystallised.

Our data was produced as part of an ESRC-funded project which looked at the regulation of embryonic and adult, autologous SCR and its impact on scientific and clinical practices in Britain and Germany, and consisted of three weeks of ethnographic fieldwork in each country, in clinics undertaking RCTs with autologous stem cells for cardiac repair in Britain (3 sites) and Germany (4 sites), observations at scientific meetings and 32 in-depth semi-structured interviews with clinician-scientists and their medical teams. The analysis draws on the accounts of a small number of clinician-scientists specialised in cardiology (7, 4 of which in the UK and 3 in Germany) and hematology (5, 3 of which in the UK and 2 in Germany), and of 20 other members of their medical teams (9 in the UK and 11 in Germany). The emphasis is primarily on the UK participants, and quotes from their German counterparts are used to exemplify the salience of issues outside the UK context. Our sample is insufficient to allow generalisations regarding the position of clinician-scientists in translational research or to draw systematic comparisons between their positions in the two countries. While our analysis suggests that legitimisation

strategies are similar cross-nationally, the intricate ways in which nationally specific institutional set-ups may enable or disable the plight of clinician-scientists in each country are outside the remit of this paper. The data suffice to examine how participants describe their position in clinical SCR for heart repair, and provide initial insights into professional dynamics in this field.

Participants were encouraged to explore issues relevant to them during the interviews. The interviews, which lasted between sixty and ninety minutes, were taped, transcribed, (when relevant, translated from German), and analysed using a grounded-theory approach (Glaser and Strauss 1967). Transcripts were open coded in the first instance and examined systematically and sequentially. Concepts and categories were then developed though an analytic process of making comparisons to highlight similarities and differences between accounts (in relation to medical specialty, seniority, position in the clinical trials and national location). Field notes were used to document routines and events, compare incidents to identify regularities and fine-tune the generation of concepts and categories. Collaborative analysis (Strauss 1987), in the sense of opening up the analysis to the scrutiny of colleagues, led to the incorporation of different perspectives and increased theoretical sensitivity. The quotes used are representative of the ensuing saturated themes. The analysis was based on an understanding of narratives as polyphonic (Gilbert and Mulkay 1984) - illustrating each participant's different, sometimes conflicting voices and how these voices interlock, and as performative, in the sense that each account presents the opportunities and constraints of local clinical SCR and is used to delineate the positions, roles and trajectories of different actors therein.

Making the Case

a. Economic and Scientific Rationales

The clinician-scientists interviewed characteristically describe their role as "developing new ways of treating people and new understandings of the biology of human disease" (UK04, Cardiologist), which involves establishing the use of autologous stem cells for heart repair as a viable treatment. Discussions of potential treatments illustrate a carefully drawn distinction between embryonic and adult, autologous SCR. The emphasis on the choice of stem cell area reveals economic rationalisations that are typically employed to endorse our participants' key role in the translation process. Exploring the properties of adult, autologous stem cells was presented as timely and necessary with accounts highlighting the availability, safety and ethical transparency of these cells, in order to indicate their clinical utility and distinguish them from embryonic stem cells (which raise ethical issues and questions about intellectual property).

> It's up to academics, without the organisation of industry for the first time in the history of therapeutics, to make sure this is looked at rigorously (UK01, Haematologist)

A similarly persuasive argument is made in the German accounts:

> It could be that, in future, industry will come forward with a patented engineered cell that will be sold to the health service, but might not have worked as well as autologous cells had we not done the autologous cell experiments. Foetal cells might come in the future with all their problems, but we might never have known whether the autologous cells work better than foetal cells. (German03, Cardiologist)

Not only is the autologous line of inquiry presented as having the potential of saving money for healthcare and facilitating unproblematic treatments, but also the lack of industry interest and the non-patentability of potential therapies here offer the opportunity for disinterested and collaborative enterprise:

> It becomes more a quest for knowledge and if you want, the better treatment for our patients and not this competition that 'I want to be the first one to do this, and keep it as a secret so that I can then sell it and get lots of money for patenting it' sort of thing. (UK01, Cardiologist)

Backing the concern for patients and healthcare systems, rather than private gain, large RCTs, whose double aim is scale expansion and the examination of existing evidence more rigorously, are presented as the mechanism "designed to put the whole show on the road" (UK04, Cardiologist), the way in which autologous stem cell therapeutic applications can be established as widely adopted treatments. Explanations of this endeavour outline the underlying scientific logic:

> The study we have is really quite well-designed because it has actually built in controls and blinding and is asking one or two fundamental questions like, does this work, obviously, but if it does work, can we at least pin down what components of the bone marrow or the cellular therapy is actually responsible for any benefits seen? Because it's really far from clear that the benefit is due to so-called stem cells. You know, it could potentially be due to other cells in the mixture or a serum factor. (UK02, Haematologist)

Perceived as upsizing efforts, trial protocols are described as conducive to a rigorous evidence-based practice that is equal (and to some participants, qualitatively superior) to that of mainstream healthcare. Additionally, RCTs address some of the anxiety of medical peers:

> A lot of cardiologists say 'well, this sounds like hocus-pocus and I'm not sure I really believe this'. But evidence suggests it works... So it is really important to do proper randomised control studies before everyone tries to jump on the bandwagon saying 'yes, this works.' Because once that happens it will be almost impossible to do the control studies to really answer the question 'does it work?' (UK03, Cardiologist)

The critical role of the clinician-scientist's position emerges above in the close interweaving of economic and scientific rationales. The money-saving potential of future treatments and their validation through RCTs reflect clinician-scientists as agents of change and outline the attraction of standardised solutions to the problem of variation attributable to individual decision-making and clinical practice (Light 1988, Timmermans and Berg 2003). Arguably, this envisaged potential is shadowed in this case by the initial costs of setting up and running such trials and the possibility of debatable clinical trial outcomes, although none of our participants raised these points straightforwardly.

Furthermore, understanding the biological mechanism behind the treatment is always "provisional, dependent upon the state of science at that time" (German02, Cardiologist). Consequently, making sure that the cells are safe, "work in a quantitative way" and "there is some indication that they might be efficacious" is paramount to the advancement of the treatment, "then we can go back and try and sort out the mechanism if we need to" (UK02, Cardiologist). Here, improving patient outcomes is presented as more important than unravelling mechanisms (Wainwright et al. 2006b, Hedgecoe 2004), an illustration of the pervasiveness of regimes of hope associated with translational medicine (Brown 2006, Martin et al. 2008, Moreira and Palladino 2005).

b. Hierarchies of Expertise

Our data illustrate how in the translation process, the strategic alliances formed between clinicians and scientists reveal more than institutional boot-strapping (Wainwright 2006a), i.e. the rhetoric of interdisciplinary partnership instrumental to securing funding. Such alliances are dependent on the nurturing of clinician-scientists to bridge two distinct normative cultures, a process within which professional

hierarchies are re/formed and strengthened. In this context, RCTs represent a tool to legitimise scientific discovery, help validate research and consolidate the authority of clinician-scientists in bringing new treatments into the clinic.

Our participants' emphasis on RCTs instances not only the "reformulation of what counts as scientific knowledge" in medical epistemics (Timmermans 2008: 173), but also how this reformulation involves the subordination of biological skills to clinical know-how in the task of bringing treatments into the clinic. Basic scientists are presented as collaborators who lack the vision to develop SCR further, and the skill to bring it to fruition. The missing broader translational perspective from scientists, essential in bringing treatments into the clinic, is seen as due to the discipline specific ways in which they have been trained to apply for funding:

> The researchers involved don't understand the necessary disciplined steps to go through in order to convince commercial backers that they do have a product at the end of it. They don't see that there is a chain of experiments, there are regulatory things to go through they just want the 'oh, that's a good idea, let's do some more experiments, that'd be a nice paper.' Zigzagging around instead of going into man. And the way research is funded academically encourages you not to go into man, because it's difficult and takes a lot of time and a lot of money. People apply for funding just to do another little experiment, which may be meaningless. (UK03, Cardiologist)

In this context, the clinician-scientist's role is to bridge the gap between disciplines, bring together different groups and types of expertise and advance an original vision. All these expectations may be difficult to meet. However, what clinician-scientists in other areas perceive as a "daunting double life" (Lander et al. 2010:5), is presented here as the prerequisite to success:

> It's an unusual position: you're expected to do two jobs...There's no point trying to compete as a clinician, because you can't, you haven't got the time and there's no point trying to compete as a full-blown academic scientist, for instance, 'because again you can't, you don't have the time. What you have to do is pick the important things from both areas and apply them in the middle in an attempt to bring both areas together otherwise we will to continue to face, and it's still very apparent that we do face, this massive void that exists between scientists and clinicians, that for the most part, certainly in our area, seems to exist, with no great understanding of the needs of both (UK02, Cardiologist)

Not understanding the needs of the other professional group is typically attributed to a different cultural modus operandi and scientific mindset, a point reinforced in our communications with basic scientists and evident from fieldwork observations:

> The clinicians, pure clinicians, are frightened in biology and have a different culture. They even have a different psychological approach. Basic biologists are in awe of these clinicians who they think drive around in Rolls Royces and have big private practices. (UK01, Cardiologist)

Clinician-scientists see themselves as orchestrators of the interaction between disparate professional cultures. Illustrating the distinct views of medicine and science (Cribb et al. 2007, Wainwright et al. 2006a, 2006b), the insularity of pure clinicians and basic biologists is emphasised here to highlight the role of clinician-scientists, who can constructively address cultural clashes and language gaps and deliver the agenda set by the translational challenge:

> People have to speak the same language, which normally clinicians and basic scientists don't do… If you go to a lab meeting and someone speaks about epigenetic control, nine out of ten clinicians will immediately look

> down. If someone speaks about how I can make stem cells fitter, wilder, then they're all listening. (German01, Cardiologist)

The exchange of expertise created in clinical SCRs is based on a clearly stated hierarchy, where clinical-scientists regard themselves as the key actors in establishing treatments scientifically and systematically, a task requiring vision, courage and skill:

> Many people don't want to take risks. And it's safe to do small, basic biological experiments that you're going to get funded for. It's the guts to take risks. (UK03, Cardiologist)

The expectation of risk-taking in elite scientific research (Wainwright et al. 2006a) is clearly represented in our accounts by the RCTs endeavour. Bringing disparate clinical and scientific cultures together and bridging them with an expertise rooted in the testing of potential treatments through RCTs and the ability to attract funding, reflects our clinician-scientist participants' understanding of their position as leaders of change in translational enterprises, who, while in short supply, shape the future of medicine (Lemoine 2008). The journey however, is by no means unproblematic.

c. Whose Interests?

As Timmermans observes, resources and peer recognition are "some of the most visible engines of research results" (2010: 20). We noted before that our participants face the criticisms of the SCR community - other members of the clinician-scientists' teams (registrars, consultants and research fellows in the UK, and doctors and study nurses in Germany) express skepticism regarding the findings current trials build upon:

> I'm not convinced of the clinical evidence that's been presented so far. I don't believe stem cells show a benefit. I think that's mainly a type 1 error being demonstrated as positive results. (UK18, Registrar)

And:

> The trial data so far hasn't been so overwhelmingly successful, so personally I'm not sure that stem cells alone is completely the way forward. For all we know we don't need the cells, we just need growth factors. (UK15, Consultant)

Members of the German research team show a similar reluctance:

> I think that the clinical promise of [autologous stem cells] as an actual tool is, in the way that's being demonstrated at the moment, very unclear. (German Doctor11)

These views illustrate the vulnerability of clinician-scientists' positions. They add to the clinician-scientists' own views on the toughness of their task, where the challenges raised by the infrastructure of the trials are invoked to illustrate the difficulty of the endeavour:

> Every single aspect that you can imagine has been a challenge, whether it's raising the funds to do it, finding the environment in the hospital to do it, dealing with the research and development department in the hospital, dealing with the ethics' committees to recruit patients, recruiting staff, there hasn't been an easy part in it (UK02, Cardiologist)

Reflecting others' difficulties in bringing treatments into the clinic (Zerhouni 2005), interviewees identify existing institutional set-ups as clearly detrimental:

> We're sort of left high and dry. When I took on this job, I thought I'd be joined by two or three colleagues over a period of five or six years. I'm still waiting and no plans to appoint those colleagues. Therefore you end up standing alone in a harsh environment between two very competitive areas wondering what it is you're actually doing, 'cause you can't fight that battle by yourself, you need a team, you need the infrastructure.... I'm supposedly based in the department of clinical pharmacology, which in itself is a

> dinosaur and dying specialty but it used to be [one of] the old academic specialties in the hospital, which did a lot of research at that time. There's no ... other than a very generic form of support...but not the sort of thing you need to make this work (UK04, Cardiologist)

Similar to clinician-scientists elsewhere (Lander et al. 2010), our clinician-scientist participants perceive challenges unique to their work. Being a clinician-scientist is presented concomitantly as being advantageously situated (in theory) and precariously placed (in practice):

> It's not a nice position to be in: you're doing, in theory, two things that you like. Which is great. The problem, of course, is that it's hard to perform well in both areas. Your time doesn't allow you to, resources don't allow you to, the academic side, well, you're at a disadvantage, because you have less time. [Same] if you're trying to perform, successfully in comparison with fellow colleagues who are, exclusively, NHS employees, who don't have academic commitments. So…at that level, as well, you are at a disadvantage. (UK01, Cardiologist)

The job "puts a number of demands which are physically impossible to fulfil" (UK03, Cardiologist) and typically interviewees present their position as 'at risk', both in terms of the time it takes to achieve results and the outcomes of RCTs. Careful calculations of collaboration represent the framework within which the fragile enterprise of translating stem cell treatments for heart repair using autologous cells is typically presented:

> What do I get out, personally? It would be nice to think that what I get out of it is potentially a better patient, but I'd be lying, really. I mean, clearly, the reason to do all this is because we think this might be useful therapeutically for patients who have sort of end-stage chronic ischaemic heart disease, which is true and we hope it might be beneficial. But I'm deeply sceptical and there's no doubt that a lot of cardiologists are too. There is laboratory

> research to be done. This is a study in the right animal, in other words, man, and it will, hopefully, give us some answers to some interesting questions. So there's a scientific aspect, there's the collaborating with colleagues aspect, which is very important. There's the potential for funding, because heart disease is a major health problem around the world, and there is government, research monies, available to support this sort of activity. And ultimately we'll publish some papers, some interesting data and that's all part of my remit. (UK03, Haematologist)

RCTs using autologous stem cells for heart repair involve the collaboration between cardiologists and haematologists, where existing infrastructures for bone marrow transplantation are adapted to meet emerging legislative requirements and relied upon in the process of extracting the stem cells. The fragments above illustrate both intra-professional exchanges and conflicting discourses of collaboration and competition. Contrasting with the persuasive economic and scientific rationales presented before, they reveal resistances and uncertainties from members of supporting teams and clinician-scientists themselves. They also indicate the extent to which clinical trials constitute the career of scientific workers (Timmermans 2010).

These views capture the tensions within which the trials take place and highlight the interplay between attempts to establish stem cell treatments, the uncertain position of those who develop them and the network of exchanges and dependencies in translational research. The rhetorical strategies employed outline how clinician-scientists justify their research approach and professional standing through the presentation of a selfless, fearless professional willing to risk everything for the wider public benefit. The undertaking of stem cell clinical trials involves fulfilling the professional responsibilities of two different positions (as an academic researcher and as a medic), the publishing requirements the research entails and the forging of

fruitful collaborative relationships, ultimately conducive to securing future funding. For our participants alongside the overall goal of SCR to provide viable therapies, considerations such as carving new career paths, sustaining established ones and achieving recognition become equally salient. These latter concerns are interwoven with those of clearer-cut scientific goals, achievable through the setting up of RCTs.

Discussion

Similar to other analyses (Cribb et al. 2007; Wainwright et al. 2006a, 2006b), we observed the ways in which actors situate themselves in the field of SCR. Adding to their findings which examine the collaboration between distinct groups in translational research, our argument outlined the position of a sociologically under-explored figure in the translational process: the clinician-scientist. Unlike previous analyses, we have not been concerned with divisions of ethical labour or the ways in which ethical positions are institutionally produced and socially constructed in embryonic SCR. Instead, we focused on the configuration of expertise and the tensions within adult SCR, and examine the professional positioning of clinician-scientists here and its tools of legitimisation.

Our inevitably partial analysis of the clinical implementation of SCR enhances other research findings which outline the tensions between different groups involved in the development of translational SCR in the UK (Cribb et al. 2007, Wainwright et al. 2006a, 2006b). Focusing on RCTs for stem cell therapies in heart repair sheds more light on clinician-scientists in this field and documents how professional jurisdictions and hierarchies of expertise are established at the clinical stage in the translational process.

We illustrated how stem cell RCTs are orchestrated by a distinct type of medical professional who devotes time to biological research and clinical practice, has knowledge of basic science and its applications and possesses the right skills to translate this knowledge into potential therapies. In our participants' views, such skills involve both the application of medical and scientific knowledge to demonstrate the viability of a treatment, and the ability to secure the necessary funding for this research. The division of working time between these overlapping goals makes their position more fragmented than that of other colleagues. Our data suggest that the position is dominated by uncertainty related to the success of the RCTs, which are devised to achieve the wider recognition of both stem cell treatments and the clinical-scientists leading them in the medical community. Assessed by their ability to produce valuable research, our participants address the practical challenges of collaborative enterprise hierarchically and in the process delineate their professional jurisdiction. Situating themselves at the intersection of clinical, academic and scientific work cultures, their strategies for professional legitimisation bring together economic and scientific rationales to highlight their role in a web of expertise, where distinct bodies of knowledge (the biological and the medical, the haematological and the cardiological) come together. In this process, distinctions are maintained between both established professional groups (basic scientists/ pure clinicians), and areas of SCR (embryonic/adult).

As clinical and biological research cultures become entangled in the production of new biomedical objects (Keating and Cambrosio 2003), biology is incorporated and subsumed into medicine, and professional hierarchies are crystallised. In this sense, translational medicine is illustrative of the demarcation of intra and inter professional boundaries where participants engage in boundary work through "strategic enlistments" (Star and Griesemer 1989: 389). More widely however, it can also be

seen as an instance of the ways in which the medical profession maintains its influence on other groups' scope of practice (Larkin 1983).

Professional jurisdictions and struggles for recognition are asserted through claims to expertise. Our case illustrates how RCTs provide the legitimacy on which such claims are made. The trials represent not only an essential step in producing an independent, autonomous and self-contained area of knowledge (Fournier 2000, Armstrong 2007), but also the means through which the clinician-scientists reinforce their key position at the intersection between traditional medical care, scientific research and academic medicine. This articulation of professional identities captures the interaction between the medical logic of individual patient care and the needs of a system of healthcare provision based on evidence-based practice, and reflects the ways in which these requirements are mobilised to consolidate professional standing. Commentators in the sociology of professions argue that a move toward the standardisation of clinical practice represents a two-edged sword, because what begins as a tool for greater rationality and autonomy may ultimately undermine the foundations of the profession's market shelter by exposing the fallacies of the professional norms and expert power (Armstrong 2007, Timmermans 2008). Greater transparency through protocols and standards may lead to outsourcing, cost-control measures, or professional downsizing.

In this instance however, RCTs and their overarching evidence-based framework are central to clinician-scientists' attempts to strengthen their positions, and as such represent the foundation of expert power in stem cell clinical research. RCTs and their overarching evidence-based framework may be interpreted as an "elitist strategy" (Armstrong 2007: 76), developed by university-based clinicians who arguably possess the necessary skills and resources to produce it. They have both a concrete and a symbolic significance, as they present the outcomes of an

intervention and create a shared vocabulary of meanings which links medical interests with potential cost-effectiveness and other policy values. As May (2006) observes in his analysis of clinical trialists of tèlè-healthcare, clinical trials help professionals depict themselves as undertaking work that links methodologically clinical interests with policy values. This is also evident here where, on the one hand, the economic rationale is presented as a money-saving strategy for managing the healthcare of a population increasingly at risk of heart disease and, on the other hand, the scientific rationale (encapsulated in the experimental protocol, RCTs and their build in controls) displayed as the starting, validating point of evidence-based stem cell therapies. The prohibited costs of RCTs and the potential of poor outcomes are furtively addressed when talking about money raising events and publishing strategies. Overall, references to courage, risk-taking and institutional challenges emphasise the perilous path of the endeavour. In this context, our data illustrate how one area of translational medicine allow for turning what has been traditionally perceived in sociological literature as a potential threat to professional autonomy into an opportunity to fine-tune the clinician-scientists' research credibility and record, and strengthen their position.

Despite persistent attempts to enforce SCR clinical practice through collaborative work, and a presentation of united efforts on the side of clinician-scientists, there is an epic sense of solitary battle to convince other actors and agencies of one's group position and point of view, as evidenced above in descriptions of institutional settings and practicalities of organising the trials. This captures the tensions in modernising health care systems in terms of both cutting-edge research, legitimating the spending on stem cell treatments and establishing a new interdisciplinary profile that combines scientific and medical expertise (Nettleton et al. 2008).

Finally, as entry to professions is typically regulated at a national level, sociological literature has traditionally framed its analyses in a national context often comparing European state-regulated professions to Anglo-American privately regulated ones (Abbott 2005, Neal and Morgan 2000). Although the present discussion focuses primarily on the UK, the German clinician-scientists we interviewed used similar rhetorical devices to legitimise treatments with autologous stem cells for heart repair and engaged in strategic professional adaptations and negotiations of expertise that replicate those of their UK counterparts. Our observations of the professional alliances, dependencies and hierarchies formed in SCR in both countries, tentatively suggest that these do not simply mirror national regulatory and economic frameworks but reflect the tensions present in the consolidation of a clinical research elite across national boundaries, a finding supported in the wider medical literature on the challenges of translational research and the position of the clinician-scientist across various specialisms (Lander et al. 2010, Lemoine 2008, Ley and Rosenberg 2005, Zerhouni 2005).

Conclusion

The recent onus on biomedical technologies and translational research has brought the figure of the clinician-scientist to renewed prominence. This article attempted to address a gap in social science research between studies of the clinical aspects of medicine and the emergent professional dynamics associated with new health technologies, through a case study that illustrates discursive strategies employed by clinician-scientists in SCR to reflect on their status. We framed our investigation within wider discourses concerning the decline of academic medicine, on one hand, and translational research and clinical SCR initiatives on the other. We showed how SCR represents one instance of biomedical innovation that offers clinician-scientists a platform to delineate and consolidate what has been traditionally perceived by

medical commentators as an uncertain position, and to reaffirm their place within a broader professional hierarchy. We outlined how clinician-scientists in SCR perceive themselves in an advantageous yet vulnerable place and crystallise economic and scientific rationales around a specific area of research and clinical trial strategy to accomplish widespread professional recognition. The discussion aimed to increase the understanding of how RCTs are involved in consolidating clinician-scientists' individual status and collective standing as leaders of change in translational medicine.

This exploration of professional dynamics documents the diversification and specialisation of medical workforce and shows clinician-scientists' efforts to establish distinct fields of expertise, maintain professional jurisdictions, and justify research positions at the top of a knowledge hierarchy. The present case study is too narrow to make any broader claims regarding professional hierarchies in SCR, and more generally translational research nationally and cross-nationally, but the importance of examining in greater depth occupational configurations in the creation of new therapies becomes apparent. Such a focus is needed to understand better the changing professional landscape of translational research and explore the strategies through which authority is established in this increasingly prominent domain.

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