



the social science stem cell initiative

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Quality Assured Science The Role of Standards in Stem Cell Research

In this project, we examine a new and emerging scientific discipline in which standards have yet to be created and established. Social scientists and bio-scientists work together to track and understand the function and meaning of standards that are currently being developed and agreed on in the field of stem cell research. The research focuses particularly on standards being developed for human embryonic stem cell (hESC) lines and we take a specific interest in how the lines are being characterised, that is to examine what biological criteria are set up for a stem cell line to be called a hESC line. This work is done empirically by studying the standardisation- and characterisation processes from the point of view of the laboratory and key intermediary institutions, such as the UK Stem Cell Bank.

To most of us, 'standards' is a fairly abstract concept that we rarely have cause to consider. It might make us think of general expectations ('high standards'), codes of conduct or lack thereof (double standards), specific quality controls (ISO9000) or mainstream formats (a standard A4 page). Yet, we are constantly surrounded by standards and deal with them on an everyday basis. Successful standards are invisible and we tend not to notice them until we run in to a problem, often caused by competing standards, for example having bought a bayonet cap light bulb when the lamp required a screw cap. Once a standard is firmly established it will have the power to set the parameters for and shape activities and objects. A lamp designer will have to accommodate either of the two standard bulb fittings or face angry customers who feel cheated. Standards are a necessity for our modern lives to run smoothly and can be enabling as well as constricting.

A wealth of material has been obtained from in-depth interviews with key stakeholders in the field, internationally and nationally. Our analytical emphasis on characterisation standards has proven fruitful, however technological and procedural standards have also been included. Currently we are examining the tension inherent in the simultaneous tendency to move towards embracing a heterogeneity - previously perceived to be problematic - and an ambition in many quarters to scale up the production of cell lines. An increasingly heavy workload on technicians, together with the suspicion that some differences between cell lines are in fact

confounded with differences in laboratory practices, opens a potential market for automation technologies to be introduced into hESC labs. We explore how the imprecise nature of manual lab work by necessity is being built into machines, how green fingers are being exchanged for grey ones and whether the identity of hESC lines is being negotiated in an automation practice.

We are also interested in the peculiar materiality and temporality of the pluripotent stem cell how it is nothing yet, but could be anything. Pluripotency is generally described as the ability of a single stem cell to give rise to all of the various cell types that make up the body, and in that sense hESCs are defined by their future. Standardisation involves judgments on sameness and difference and as pluripotency is the main characterising marker of hESCs, differences, or promises of difference, lie in the future. Standards are being developed in (any) field to enable work on practicable, doable futures and the key site around which doable futures are being built in hESC research relates to the meaning attributed to pluripotency. The current definition of an essentialised pluripotency serves perhaps better as a demarcation criteria against somatic stem cells than as a practicable definition of a hESC and we are in the process of mapping a move towards what might be called hESC heterogeneity.

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