Regulation in Practice:

Organising the Regulated Laboratory

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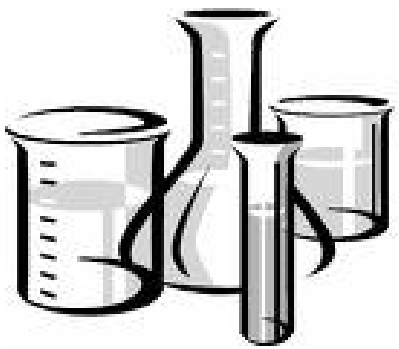
Overview of Paper

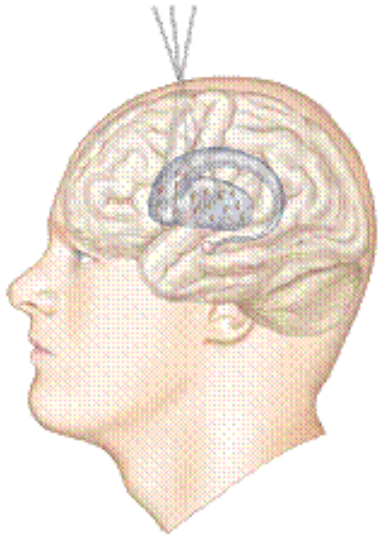
- Introduce the empirical setting
- Regulatory Regress: Experiences in the Laboratory
- Opening of the Regress
  - Interpretive Flexibility of Texts
  - Imagined Futures
- Closing of the Regress
  - External Consultants
  - Networks/Relationships
- Conclusion

Research Project

- 15-month CBAR Stem Cell Fellowship
- Interviews and observations at a laboratory conducting cellular work on HD and PD.
- Unique mixture of 25 clinicians, behavioural scientists and cell scientists.
- A leading centre translating basic science into clinical applications



HD Transplantation Project



‘As stem cell research moves towards clinical applications, negative perspectives may increase should problems arise in clinical trials’.

- HD neurodegenerative disease with no effective treatment.
- Clinical trials began in 2001.
- Primary tissue collected from aborted foetuses
- Category 2/3 safety laboratories

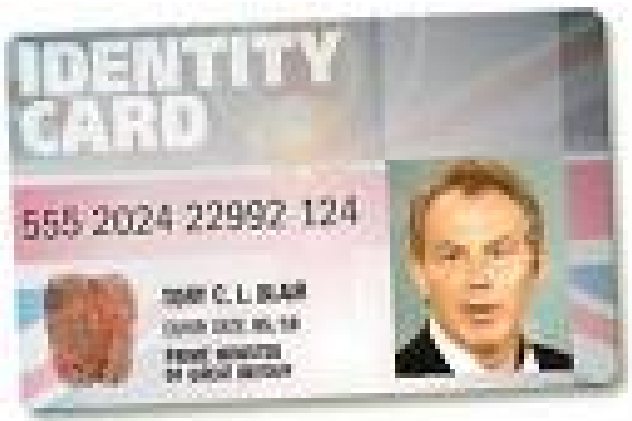
Problems of Building a GMP space

- The suite consists of **three rooms**.
- The first room is a semi-clean room where they will change out of street clothes into scrubs.
- In the second room they will gown up into 'Tyvek' Suits.
- The third room is the actual clean room itself which is where they will handle tissue. This contains the **Cat2 hood** within the room.
- All materials come in through a **transfer hatch** from the opposite side.

GMP Hood

GMP Technologies

- Intensive Documentation that inscribes a source of global stability.
- Cameras that video the dissection
- ID cards to trace who has entered the room



Regulatory uncertainty and confusion

'If I asked who your regulators are, who would you say?'

'I would say the Human Tissue Authority?'

'Do the MHRA get involved at all?'

'That's a very good question and I think it is still an area of confusion…we haven't had clear messages and it's been quite difficult to find out who exactly is regulating you and what is expected'

HTA
Human Tissue Authority

MHRA

Opening the Regress - Interpretive Flexibility of Texts

- **In an attempt to gain a fuller understanding of what is required of them, Headlab turned initially to existing regulatory texts – the Orange Guide.**

"It started by simply downloading off the web, EU tissue licenses…and then trying to get…hold of the Orange Guide for example. And then realising if you read it, it made no sense at all because it was all about just complying with acceptable standards; it doesn't tell you what you have to do. And that was where really it started becoming apparent that you needed a consultant because you'd need to have somebody who's worked with the system, who knows what the regulators want"

Opening the Regress - Interpretive Flexibility of Texts

- **Yet regulators do not necessarily know what they want themselves**

'It's equally apparent that [the HTA are] struggling with understanding their role and the extent of their remit and we get regular bulletins that are sort of updating their perspective'.

- Headlab find it difficult to interpret the various regulatory texts that are available to them. As such find it difficult to build the GMP suite there are no robust guidelines to lead their efforts.

"…To some extent a lot of what we do, I don't think there will be guidelines written down because it is academic work and you might be the only people doing it"

Opening the Regress

Imagined Futures 1

“No, they don't come under GMP because they're using a slightly different approach in that they use tissue pieces [of foetal brain tissue] as opposed to a cell suspension. So when they collect their human tissue, they just cut it into pieces and implant that directly [without subsequent manipulation as used in Headlab], so that doesn't come under GMP guidelines. There's no systematic study to prove either one being better or worse than the other. We've always worked towards a single cell suspension.”

“[Our use of] GMP was based on an effective long term strategy...The [other] group are going to have to come to GMP eventually if they’re going to work with stem cells or any other kind of cells”

Opening the Regress

Imagined Futures 2

"When estates built the room, they gave us the barometers on the wall outside, which was fine, until our external validators came in and tested the pressure in the room with independent equipment and said…'this isn't actually reading what your barometers say'. Then we discovered that you can make the barometer say whatever you want it to with a screwdriver…So we discussed getting access to the university's BEMS system, their environmental monitoring system which monitors the entire university campus, temperatures, pressures, whatever they want to do with it.

We bought a copy of BEMS and I have it loaded on my PC which means I can record information from the rooms. It can't be fiddled with. We can see what's going on."

Although regulatory structures are global, initial responsibility for regulatory control comes from within the group.

Beginnings of the Closing the Regress

- **Employing Independent GMP consultants**
- **Elements of self-regulation - SOPs**
- **Networking**

"The third area which I think has been the major source of information…has been the UK stem cell community…So right from the onset…both [the co-director] and I have been on the two committees; clinical users and the research user committees for the [UK] Stem Cell Bank. We have made a number of visits to the Bank. Increasingly now there are national meetings to do with establishing GMP standards in hospitals collecting stem cells. So attending those meetings and finding out the **latest interpretations** of what's required in upgrading the sourcing of cells for establishing GMP human tissue lines [is useful]".

Conclusion

- Shown some of the ways that regulation is experienced.

The Regress

- The group point to a lack of clarity in the regulation and clearly hampered by tensions similar to the UK Stem Cell Bank case.
  - The interpretive Flexibility of Texts
  - The importance of Imagined Futures

Closing the Regress

- Independent Consultants
- Networking, Informal Communication

- Social Science is important to demonstrate the real world anxieties, strategies and practices of regulating innovative bioscience.

Discussing Stem Cell Research in Context

Tuesday 19th May, 6 - 8pm.

Senedd Media Briefing Room, National Assembly for Wales, Cardiff Bay.

E-mail Mel Evans on cesagenevents@cardiff.ac.uk