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KCL, May2014, Models of Biomedical Innovation and Consumer Demand

Patient, Consumer or Subject in Power

I The Arts of Translational Research in cell therapy biomedicine.

UK NIHR Biomedical Research Centres (BRC 2014) stresses that projects and project leaders must have a track record '*in translating advances in basic biomedical research into clinical research, and pulling through basic biomedical research findings into benefits for patients, the public and the NHS'.*

But there are problems with the *Imperative of Translation* from bench to bedside and the dual-way information pathways between clinic and lab.

SSK: Science as Social Practice: Scientists and clinicians balance conflicting expectations of what is an achievement from funding organisations, the scientific community, publics, patients, industries and policy makers.

Clinical vs. scientific validity: Ethnography *British Cardiovascular Collaborative for Stem Cell Repair of the Heart* (2004-2011):

> *"All agreed that clinical researchers had first to define which problems they would attempt to treat with transplanted cells (e.g. heart failure, dilated cardiomyopathy, or myocardial infarction) and by what route (e.g. intravenous, percutaneous, or surgical). Then the groups working on animal models would adapt their models to that clinical need [...] The group working on cells and gene transfer to cells would define the best cells to transplant, or the best way of stimulating endogenous cells to activity."*[1]

The scientists should service the clinic with the biological knowledge and cells to aid heart repair. From the clinical point of view understanding of the mechanisms of cell regeneration is secondary to clinical safety and long-term efficacy.

Non-Profit clinical SC therapies: Patient acceptance, scientific doubts, no investments. Established cells in new application – endpoint death

Case: BAMI Trial. 11 country international trial on 3000 patients with autologous bone marrow for very severe AMI - http://www.bami-fp7.eu

Re-covering the many hurdles raised by culturally, politically, regulatory and professionally different practices in the clinic on the implementation of the same EMEA and Voluntary Harmonization Procedure approved protocol. WP7.

Trial underfunded – all labour is free. 2 years from start to first patient recruitment Problems from SC therapy regulation implementation and monitoring requirements

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[1] References*: Harrington and Hauskeller, Translational Research: An Imperative Shaping the Spaces in Biomedicine, Technoszientia June 2014; Wilson-Kovacs, Weber, Hauskeller, Regulation as Practical Accomplishment, Sociology of Health and Illness 2010.*

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II The Patient as Consumer: Direct-to-Consumer Genetic Testing

4 main reasons why regulators say they need to control DTCGT:

- Non-exerts are not able to understand the information they provide properly
- The tests do not comply to best scientific standards in terms of quality and clinical utility.
- Consumers cannot make good sense of the findings and might cause unnecessary burdens on the HC system
- The data collection and management practices in private DTCGT companies are ethically doubtful and user data used for research.

Problems:

DTCGT are traded globally via the internet and regulation cannot be properly implemented without policing tools.

The ethical use and scientific credibility of genetic tests generally is not well standardized, and might benefit from proper oversight

The selection of DTCGT from among the arsenal of publicly available health innovations is somewhat random. The attitude of the regulatory agencies toward consumers and publics is patronizing and not confirmed in social sciences studies on DTCGT.

The whole issue seems more one of experts among themselves defending the territory of their status and importance and their power to intervene in markets and product provisions on a national and international scale.

Possible solutions:

1) Global Industrial Standard Procedures and Certificates for scientific quality and validity of genetic tests should be introduced, ideally through an independent organisation such as ISO

2) General education (online) should include qualified knowledge and give individuals with the ability to understand health issues in context and make considered decisions.

3) Need to re-evaluate the relation between the individual and epistemic (science) and political authorities (institutions) given governmentality and regulation creep affecting personal and private decisions with seemingly limited if any harm for others.[2]

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[2] *See C Hauskeller BMJ 2011 and Knowing New Biotechnologies 2014 in press.*

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III Patient, Consumer, Client, Person or Subject in Power

Justifications for denying individuals the right to decide which treatment or product they buy? The buying is the problem in part, because the conflict includes individuals (free and best treatments), politics (control over domain), markets (revenue) and epistemic authorities (expert status).

Principles and the life-style creep of biomedicine

Medical Ethics built son the notion of patients as helpless beings in the competent hands of physicians. The four principles in medical ethics demand that good professional conduct is guided by beneficence, non-maleficence and justice, and, foremost, respect for the patient as a person. There is a contra-factually assumption of her autonomy, and treatment aims to recover her as a competent person.

For the routine care of coma patients that seems to make sense – but not in the case of most novel biomedical innovations, in genetics or cell therapy research.

If a person is fit enough to fly abroad for treatment, why can it not be assumed she has assessed her options and made an informed choice? We deem her a free agent if she books an overpriced holiday with excessive clubbing provisions, yet when her life and health are threatened she is deemed incapable of weighing options and deciding for herself. Stakeholders who control niche expertise and profitable market interests take the right to offset the assumed everyday competence of legal persons.

Re-Framing the patient: Language and its implications on how we see the individuals to whom Health Care innovation is addressed

There is not much decision space in routine practices: symptoms are diagnosed (blood test, scans, MRI) and lack of expertise enforces patient subjection. Yet, the suffering individual is involved in every clinical innovation and increasingly treatment choices exist in which she remains the final decision-maker.

Client/Consumer evoke economic ability, not ethical self-competence

Person stresses legal/moral status, denies dependency/vulnerability

Subject in Power stresses the situational relationship between two or more actors involved in offering, producing, wanting and needing HC.

Agent may be the best word, without the ill person as an agent with needs and demands medical innovation does not occur and is useless.