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Bioethics and power: Informed consent procedures in post-socialist Latvia

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ABSTRACT

This paper explores two lines of development in the donor consent procedures in post-Soviet Latvia. The paper is based on secondary analysis of interview, focus group discussion data, and media and legal text material collected throughout three previously conducted research projects on organ transplantation, population genome project and xenotransplantation focusing on the historical development of the issues of donor consent across these three fields of medical technologies. The paper argues that the quality of consent depends not as much on political and legal change *per se* as on the strengthening of the position of both medical specialists and donors, facilitating bonds between the two.

Introduction

The introduction of consent procedures in cell and tissue donation can be regarded as one of the most remarkable points of transition in health care between the socialist and post-socialist political regimes, shedding light on changes both in politics and medical practice. The informed consent doctrine is the product of specific political events in Western democratic societies which followed the outrage at Nazi medical experiments after the Second World War (Nuremberg Code) and the Helsinki Declaration in 1964 (Boulton & Parker, 2007; Hoeyer, Dahlager, & Lynöe, 2005; Miller & Boulton, 2007). Current European legislation (Directive 2004/23/EC) sets donor consent as mandatory and specifies timing, quality and scope of information exchanged. Requirement of obtaining the consent from deceased donors is less specific and depends upon the legislation of member states.

The debate by-passed Soviet Latvia, but its results reached Latvia after the country regained political independence. Latvia as an EU member state has harmonized its legislation incorporating the relevant EU directives. Despite the legal surface regulating tissue donation legal specialists (Dupate & Olsena, 2008; Olsena 2010) point at fragmentary and incomplete implementation of the legislation. The tissue removal scandal and parliamentary debates I describe later in the paper show that political freedom and legislation on tissue donation have not been sufficient tools to attain donor's rights.

Increasing awareness in the literature on consent has been paid to cultural diversity and difference. It allowed for the problematizing informed consent procedures (e.g. Harper, 2007; Miller & Boulton, 2007; Mills, 2002) and explored the embeddedness of such crucial concepts as patient literacy and autonomy (Alderson, 2007; Dein & Bhui, 2005) – the backbone of the informed consent model. They also allow for the view of donor participation as a broader issue than just a mere understanding of research (Dixon-Woods et al., 2007). These perspectives seek solutions that will improve the processes of communication (Dixon-Woods et al., 2007; Mattingly, 2005; Sankar, 2004) and translation (Hunt & de Voogd, 2007). In this perspective the Soviet background would have contributed to specific models of communication in the hospital ward that would prevent from direct transferring of consent procedures. The different developments of informed consent in two Latvian cases allow for reexamining the cultural background argument and look for deeper factors determining influencing consent procedures.

Hoeyer (2009: 273-4) argues that informed consent regulations did not stem from medical practice and were even at odds with established doctor and patient relationships. Rather, he sees emerging litigation processes based upon not observing informed consent as tools of changing power balance in medical practice. Informed consent thus can be seen as a procedure through which concepts of autonomy and human dignity are framed and used to define medical practice.

Looking at the relationship between politics and medicine, Miller and Boulton (2007: 2203) suggest that the Helsinki Declaration (1964) marks the move from internal ethical regulation and

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responsibility of the researcher to external regulation. The Declaration requires the formal documentation of consent to have an ethical committee which represents the interests of the participants in research and thus renders the decision making transparent. Later years witnessed a diminishing trust in researchers and attempts to standardize the ethical review procedure and institutional structure, putting an emphasis on regulating informed consent (Boulton & Parker, 2007: 2188; Miller & Boulton, 2007: 2203). Miller and Boulton (2007: 2004) draw a parallel of the strengthening of the informed consent procedure with increasing consumerism in society – which gives voice to patients and their representatives. Patients began to speak back through measurements of satisfaction, feedback and lay expertise. Miller and Boulton (2004) also note the change of naming research participants from "research subjects" to "research participants" and later to "partners" (also Hoeyer, 2009), which points to the changing dynamics of the researcher–donor relationship. This allows Miller and Boulton (2007: 2009) to advocate for a shift from a "static audit and accountability model" to a more "democratic, process-sensitive support forum" seeing the solution not in improving the model but using it for negotiating interests.

These are context-specific developments which could not be directly transported to Latvia but set a comparative background for Latvian cases. There are parallel developments in Latvia, for example, concerning the role of ethics commissions or public opinion pools but as pointed out in Hansson et al. (2011: 635), those tools seem to have the effect of excluding the public from the debate rather than including it.

I argue, following Hoeyer (2009), Miller and Boulton (2007), that consent procedures should be viewed as a process where consent is one the tools for reaching consensus. The Latvian case allows for critically addressing consent and examination of alternative informal forms of obtaining agreement against legally binding informed consent regulation. It demonstrates that informed consent can be reached in cases where the flow of information is based upon mutual trust and flexibility of arrangement rather that fixed in law. As Humphrey (2002: 107-8) claims, the Soviet state used the law as a political instrument to meet certain ends rather than practice. Taking this into account, there is the risk that the law and informed consent solution steals rather that grants donors rights. Emerging civic society, media coverage, public funding of medical research, and international regulations are essential factors that promote informed consent procedure but its internal dynamics can be altered only by addressing the participants of the donation process – donors and medical specialists.

Data and methodology

In order to map the historical developments of consent I look at legal documents and public discussions concerning tissue and cell donation. Data on implementation of donor consent comes from three broader research projects on medical technologies in Latvia (see Table 1). The xenotransplantation case study offers material for uncovering some of the medical practice and reasoning during the Soviet period in the 1970s and 1980s. Xeno research ceased after the Soviet period when state support was withdrawn (Hanson, Lundin, Kaleja, Putnina, & Idvall, 2011). The routine kidney transplantation procedure was introduced roughly around the same time and has continued up through today. This case study offers insight into the interpretation and practical management of donor consent. Population genome research is a new project which took off in this new millennium by attracting public attention through the offering of new practices of legislating and managing donor consent.

All of these project proposals considered ethical dimensions of research and were submitted to external reviewers. As there were no institutions dealing with ethical approval in social science research in Latvia at that time, each individual research participant was informed about research obtaining consent. The data of all three research projects was coded using Atlas.ti. Here I use material clustered around codes of "informed consent" or "consent" dealing with the description or actual practice of consent. During this secondary analysis I realized that I had taken the consent procedure for granted by coding those passages of text where consent had to present according current standards. It became an opening passage for addressing the emergence of donor consent in this paper.

For the convenience of the reader I will briefly sum up an empirically constructed historical timeline (Table 2), which points to the legalization and spreading of donor consent in my case studies. Below I explain how and why the donor's rights and consent, as an important political benchmark, was so unevenly implemented in different fields of medical practice.

Table 2
Timeline of organizing informed consent in collection of biomaterial.

Timeline	Organ and tissue procurement	Biomaterial for genetic research
1970–1990	State support, no legal regulation of informed consent	
1990–2000	Legislation of organ and tissue donation in 1992, presumed consent established	No legal regulation or practice of informed consent
2000–2010	Debates on legislation and support for loose regulation	Debates on legislation and support for tight regulation
	Practicing negotiations informally	Designing return of results and science communication

Soviet period: clean ground

Research documents from the Soviet period do not contain information on donor involvement. Graham (1990:10) argues that Soviet Marxism lacked a developed ethical theory. While rejecting "bourgeois" ethics developed in Western countries it did not

Table 1
Data sources.

Organ transplantation	Population genome project	Xenotransplantation
EC 6th Framework Programme "Science and Society" project "Challenges of biomedicine" (2005–2007)	UNESCO funded project "Societal aspects of Latvian Human Genome Project" (2008)	EC 7th Framework project "Citizen participation in decision-making in knowledge intensive policy field" (2009–2011), SSH-CT-2008-225327
• 9 interviews with patients and specialists, • 2 focus group discussions' • text analysis of major policy documents, policy debates and media texts (1990–2005)	• donor survey, 104 questionnaires; • 23 interviews with donors and experts and 1 interview with a patient who refused to become a donor. • 4 focus group discussions with patient groups organizations	• 6 expert interviews, 4 interviews with patients with animal origin transplant, • one focus group discussion with a patient organization, • media articles (1997–2010)