

# Regulatory Anatomy: How “Safety Logics” Structure European Transplant Medicine

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## Abstract

This article proposes the term “safety logics” to understand attempts within the European Union (EU) to harmonize member state legislation to ensure a safe and stable supply of human biological material for transplants and transfusions. With safety logics, I refer to assemblages of discourses, legal documents, technological devices, organizational structures, and work practices aimed at minimizing risk. I use this term to reorient the analytical attention with respect to safety regulation. Instead of evaluating whether safety is achieved, the point is to explore the types of “safety” produced through these logics as well as to consider the sometimes unintended consequences of such safety work. In fact, the EU rules have been giving rise to complaints from practitioners finding the directives problematic and inadequate. In this article, I explore the problems practitioners face and why they arise. In short, I expose the regulatory anatomy of the policy landscape.

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## Introduction

During the past decade, the European Union (EU) has sought with a number of directives to harmonize member state legislation to ensure a safe and stable supply of human biological material for transplants and transfusions (Swanson, Randell, and Freedman 2009). This harmonization of safety procedures has served as a vehicle for integration within the area of health policy, which is otherwise exempt from the Union's jurisdiction (Vollaard, van de Bovenkamp, and Vrangbæk 2013). Even a cursory glance at the directives passed during the past fifteen years reveals that this regulatory landscape draws on anatomical divisions but also that these divisions are not self-explanatory or mutually exclusive. There is an EU Tissues and Cells Directive (EUTCD) that covers *tissues and cells* used for therapeutic purposes.<sup>1</sup> *Organs and parts of organs* are covered by an organ directive, though of course organs are made of tissue.<sup>2</sup> *Blood* is medically speaking a tissue, but its exchange (except for cord blood) is governed by separate directives.<sup>3</sup> If a tissue or cell (other than blood) is seen as *enhanced into a product*, it falls under the Regulation of Advanced Therapy Medicinal Products (RATMP) or becomes regarded as a medical device.<sup>4</sup> The categorization not only divides practices, it also classifies quite different technologies as similar. For example, the use of gametes, bone, and bits of intestines now all fall under the rules of the EUTCD. With the EUTCD as its point of departure, this article sets out to explore the internal workings of this regulatory landscape. It is stimulated by two simple questions: Why these divisions? And What type of "safety" do they produce?

Though the anatomical mode of division is an interesting puzzle in its own right, there are more than academic reasons for understanding the regulatory landscape: the directives, in particular the EUTCD, are the cause of substantial frustration among practitioners. One cool and bright February afternoon, I am sitting with three tissue bankers in the offices of a tissue bank in the suburbs of a middle-sized European city asking them about their views on the European regulatory framework. They work every day to deliver human tissues for transplants to European hospitals and they passionately explain how the EU directives entail rocketing costs and nevertheless still implicate problematic safety breaches. One of them rises and says there

is this “great divide between policy people and practitioners.” Frustrated, he explains how “policy people” in ministries and the EU are “detached from reality.” He lifts his hands, as if holding two balls: “It is like two planets. We need to bring them together, but policy people don’t want to learn from practitioners.” Three days later, I am sitting with some members of the European Parliament who were part of developing the directives discussed so fervidly by the tissue bankers. They explain how the development of the concrete content of the directives was the result of close collaboration with the people “having the technical expertise” and “the people doing this work on an everyday basis.” As a matter of fact, the regulation was formulated drawing upon existing professional guidelines and in close dialog with some of the most prominent and esteemed practitioners (Tatarenko 2006).

The image of a divide between policy and practice articulated by the abovementioned tissue bankers is very common across policy fields. However, the most important problems in this field do not stem from lack of contact and I will argue that in fact they could not be solved with closer collaboration between experts, practitioners, and politicians. This collaboration is already in place. To understand the problems faced by practitioners, we need to understand instead how this regulatory framework is construed: its *regulatory anatomy*. I suggest regulatory anatomy as a deliberate pun: on one hand, the specific regulatory divisions outlined here draw on anatomical terminology; on the other hand, anatomy is a common metaphor for the “study of the structure or internal workings of something” (*Oxford Dictionary*). The “structure or internal workings” described in the following is influenced by a peculiar form of anatomical thinking which reflects a common-sense approach to the body rather than a medical risk analysis. The regulatory anatomy I uncover is not confined to legal documents. Rather, it can best be described as consisting of “safety logics” enacted through practice. With “safety logics,” I mean assemblages of discourses, legal documents, technological devices, organizational structures, and work practices intended to minimize risk. They are shaped by political mandates, but not determined by them. I have chosen the term “logics” because the assemblage takes the form of practical reasoning: “If you want more safety, then you need to . . .” Safety logics can be understood as constellations of solutions drawing upon available technologies and infrastructures. As solutions they travel and mould the type of problem that is addressed (cf. Spector and Kitsuse 2001).

In brief, I argue that when practitioners are frustrated with the EU regulation, it reflects problems inherent to the regulatory anatomy, the safety logics, rather than some form of policy/practice divide. This is why we need

to understand how these divisions were established and the type of ‘safety’ they produce. It is well known that regulation often lags behind the technologies it is supposed to govern (Brownsword, Carnish, and Llewelyn 1998), but I argue that the problems experienced by the European tissue bankers primarily reflect (a) the limited mandate of the EU in relation to health and (b) issues of categorization. Concerning (a), *the EU mandate*, article 152 of the Treaty of Nice provides the Union with authority to act on cross-national public health safety concerns though health care delivery is otherwise a national concern. By focusing resources where the EU does hold a mandate to exert governance, some aspects of health governance receive more attention than others, irrespective of whether the same money could have had greater impact on health objectives if directed elsewhere. This is also the case at the national level. Concerning (b), *categorization*, policy makers make distinctions where there were previously no clear divisions and simultaneously subject different practitioners to similar rules by way of categorizing their work as equivalent. Policies need to construe “regulatory objects” to define an area of intervention (Kent 2012). Such objects emerge out of practices that have many other entanglements than those envisioned by policy makers. In relation to transplant and transfusion safety, the EU has constructed its regulatory objects based on anatomical notions rather than on assessment of the concrete safety issues in the respective forms of bodily transfers. The resulting safety logics mold financial and medical priorities in profound and sometimes detrimental ways to the extent that the pursuit of “safety” is itself, in some instances, a barrier to improved health outcomes for transfusion and transplant medicine in Europe.

## Regulatory Knowledge in the EU

The intensified regulatory focus on safety reflects societal concerns with risk (Beck 1999). One might see EU’s supranational emphasis on safety as a response to Ulrich Beck’s call for collective global reactions to shared risks (Beck 2006). This call for global reaction is indeed the *raison d’être* for the directives. On closer inspection, however, the rationality seems less stringent, and the relation between science and law propagated by the tissue bankers mentioned earlier is too simple: law is not a domain of its own which in varying degree draws upon presumably “unpolluted” science and skilled know-how (Jasanoff 1990). Regulatory knowledge is engrained in political and moral projects (Rothstein 2003), and safety regulation in particular exemplifies this because perceptions of risk reflect perceptions of desirability and fear (Jasanoff 1987).<sup>5</sup> Accordingly, there has been a lot

of emphasis in science and technology studies (STS) of regulatory science on differences in the “therapeutic cultures” (Daemmrich 2004) and the “civic epistemologies” (Jasanoff 2005) shaping scientific valuations. Horlick-Jones has argued that the actual work undertaken to reduce risk depends as much on culturally informed “practical reasoning” as on “information processing” (Horlick-Jones and Prades 2009), and that on the ground actors apply a “variety of logics,” some of them partly “habitual” (Horlick-Jones 2005). By introducing the concept of safety logics, I similarly focus on “habitual” forms of practical reasoning, but I depart from the implicit division between knowledge and practice in Horlick-Jones’ work. From my perspective, knowledge is as socially embedded as the practices on the ground. Safety logics should not be understood as a choice made by individuals. By focusing on mechanisms rather than individuals, I am in line with the classical work on safety in the nuclear industry by Charles Perrow (1981). I depart from Perrow, however, in my approach to “safety.” In Perrow’s work, it refers to absence of disaster. It is as such a well-defined and desirable state. In contrast, I do not think there is any clear state of total safety to aim for in transfusion and transplant medicine. Different policies generate different types of risk and priorities with different health outcomes. We therefore need to explore the *types of safety* that a given policy landscape generates.

The more specific study of tissue regulation in the EU has received a fair amount of STS attention already (Brown et al. 2006; Faulkner 2009; Faulkner and Kent 2001; Faulkner et al. 2008; Hoeyer 2010; Kent 2012; Kent and Faulkner 2002). This attention partly reflects how the EU has acquired a more dominant role in consumer protection vis-à-vis the United States during the past few decades (Vogel 2014). Alex Faulkner (2012) has discussed the taxonomic aspects of EU regulation by focusing on how definitions of regulatory objects involve commensuration understood as “a form of classificatory work that draws attention to the aligning of otherwise distinct cognitive or practical domains” (p. 169); that is, classifying different things as the same (cf. Espeland and Stevens 1998). I draw upon this work, but whereas Faulkner focused on the organizational implications of commensuration, I explore how commensuration generates a particular form of problematization by inviting transfers of “solutions” from one type of tissue or cell usage to another.

In her book *Regenerating Bodies*, Julie Kent explores links in EU regulation between the domains of regulation, technology, and body with particular emphasis on how tissue technologies “are socially shaped and what their transformative capacity is in terms of reshaping relationships between

our bodies, our selves and others” (Kent 2012, 4). Whereas she focuses on how technology and governance mould perceptions of body and self, I turn the gaze around and explore the influence of anatomical notions of body on the regulation. Considering the great differences between the regulated technologies, it is striking that the regulation builds on categories such as blood, cells, tissue, and organs. Such bodily categories do not reflect ontologically preexisting divisions; rather, it is an analytical achievement to construe something as “a whole” or “a part,” not a matter of observing reality (Strathern 2004). This article unpacks what such constructs produce as elements of a regulatory anatomy.

## Entering a Policy Field

Where should you go when you wish to explore the logics of a given policy field? The fieldwork on which this article builds involves moving between texts and people. I have moved back and forth among those formulating, translating, and using the European regulation which structures the procurement of bodily material as well as the people expected to deliver and use the material as registered donors and future patients. Part of this work was conducted within the context of the project *Body and Person: Governing exchange in 21st Century Biomedicine*, where I collaborate with scholars studying different forms of exchange of human biological material for therapeutic purposes, namely, Anja M. B. Jensen (organs and cornea), Sebastian Mohr (sperm), Maria Olejaz (cadavers), and Zainab Sheikh and Ida Deleuran (blood and blood products). They explore donors’ and recipients’ hopes and concerns as well as the everyday practices of blood, organ, tissue, and cell therapies. My own interests revolve around the policies uniting and separating these fields. In this article, I take point of departure in the EUTCD and contrast and compare it to the other directives to identify the safety logics driving this area of EU integration. I do not claim that the specific points I make about the EUTCD necessarily apply to the other directives.

I build my analysis on interviews with politicians, representatives from multi- and monotype biobanks engaged in inter-European tissue exchange, and fieldwork and committee work among health professionals working with organ and tissue retrieval in Denmark and in Europe. I also draw upon an earlier study of bone banking in Denmark (Hoeyer 2010). I have visited and interviewed members of the European Parliament and tissue bankers in Denmark, The Netherlands, Belgium, Spain, and France and related their

perceptions of safety to the ones expressed in legal documents and academic journals. Interviews were conducted either in Danish or in English.

Most politicians demanded strict confidentiality. Given their prominent public role, it is difficult to provide without silencing also their precise function. Only one tissue banker and only one politician wanted to be mentioned by name. Tissue banking is a small world, and it is difficult to provide contextual information such as type of tissue bank and country without revealing also the name of bank and banker. For the sake of symmetry and to respect their wish for confidentiality, I have chosen to present the material without such identifying markers throughout.

Previous research has pointed out how the EUTCD builds upon existing guidelines from the Council of Europe and the European Health Committee (Cox and Walmar 2007; Tatarenko 2006), and my aim in the following is not to do a history of EUTDC or the other directives. Rather, I provide an analysis of why practitioners get frustrated with the safety rules by way of outlining the “structure and internal function” of the regulatory landscape—that is, the safety logics that make up the regulatory anatomy. I do this in two sections each seeking to answer one of the simple questions I posed at the outset: (1) Why these divisions? (2) What type of “safety” do they produce? As shown subsequently, many of the concerns with “safety” described in the second section reflect the nature of the divisions and commensurations described in the first section.

## **Defining Parts and Wholes: Establishing a Regulatory Landscape**

As noted earlier, it is common to identify conflicting objectives as the source of frustration when regulation is criticized (Carroll 2014; Mesman 2012). In the case of the EUTCD, however, both practitioners and policy makers talk about their goals as ensuring a safe, stable, and cost-effective supply of human biological material. The preamble of the EUTCD states “The quality and safety of [tissues and cells] should be ensured, particularly in order to prevent the transmission of diseases.” Similarly, the directive covering organ transplants states in its second preamble that the objective is to “minimise any risks associated with the transmission of diseases.” The preamble also mentions cost-effectiveness. Practitioners fully endorse these objectives to the extent that one tissue banker laconically mentioned the preambles laying out the objectives as “the best part” of the directives. Hence, conflicting objectives are not the source of practitioner frustration with the safety framework delivered by the EU. It is of much greater

importance, I argue, that the division between directives is modeled on divisions of the body. The divisions could have been based on, for example, technologies involved or forms of risks involved, but the directives divide their regulatory objects by dividing the body up into blood, tissues, cells, and organs. I term this body-based approach part-and-whole thinking.

### *Part and Whole: Basing the Regulatory Distinctions on Notions of Body*

Each directive lists a “definition” of the terms used that are supposed to outline the intended area of competence. In practice, however, these definitions are of little help when determining what falls under which set of rules. The EUTCD, for example, uses this definition [article 3(b)]: “‘tissue’ means all constituent parts of the human body formed by cells” and defines cells as “individual human cells or a collection of human cells when not bound by any form of connective tissue” [article 3(a)]. Such formulations look like medical definitions, but they are more like common-sense understandings drawing on medical terms. If taken literally, the directive would cover also blood, hearts, livers, kidneys, and lungs, etc., but as I have already explained, these body parts are covered by other directives. The organ directive is a little more precise when employing the following definition:

Article 3(g): ‘organ’ means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy.

Still, if simply reading the text, one should expect skin and bone marrow, normally regarded as organs, to fall under this definition, but everybody interviewed for this study treated them as falling under the EUTCD. Rather than communicating medical insights, these definitions pretend to create regulatory objects by way of describing bodily divisions.

That we are dealing with a form of part-and-whole thinking, which is not derived from medical evidence, becomes clear when practitioners are asked how they interpret the division between directives. One tissue banker, for example, stated, “In my opinion, skin as an organ is the entire skin and skin as a tissue is a part of this organ”; but he also said that it was confusing because liver *parts* fall under the organ directive and he continued “it’s always difficult when you have to define the things in the human body,



because there're always connections along with separation and division." It gets a little less confusing, however, if one sees this form of part-and-whole thinking, not as a matter of definition but as reflecting material work practices and moral hierarchies.

### *Work Practices and Moral Hierarchies*

Practitioners usually substantiate their interpretation of the division between organs, tissues, and cells by describing differences in work practices: most "organs" need to be transplanted within a very short time frame, whereas most "tissues and cells" can be stored in banks (though, again, there are exceptions such as pancreatic islets which are considered organs but stored in banks). The temporality of work practices is explained by a tissue banker as he responds to a question concerning his opinion about having a separate directive for organs:

You can put them all together, organs, tissues and cells, but you can also do two laws. Maybe there is some logic to [the division] you know, because the work dynamic for organs and tissue transplantation is different. Why? When you have to transplant the organs you will do the control of your donor once. (...) And then when you take the tissues you have more time to do the processing, to preserve those tissues, to store them (...) it will take a few weeks before you are ready to send those tissues for implantation.

The different work practices made several informants working with cadaveric material talk about "organ people" versus "tissue people" ("cell people" and "blood people" were not part of their landscape). One tissue banker explained the difference like this: "The first thing you need to understand is that organs and tissue are two separate worlds, and people in the organ world always think they are better and more important." Note how the difference in work practices is accompanied with a moral difference (they think they are better). A couple of tissue bankers explained that tissue donation is not seen as having the same moral appeal as organ donation, and some organ people thus fear that donors are deterred from organ donation if hearing that also tissue will be procured. Several organ people have expressed exactly this concern to me too, and procurement staff often explain that larger parts are seen as more "life saving" than smaller parts. The division into two directives (organs and tissue) thus interacts with a form of epistemic culture involving a moral hierarchy according to which "larger parts" removed under great urgency take precedence over

“smaller parts” subject to less stringent time pressures. Note also that this form of boundary work serves to separate stake holders procuring material from the same source (cadavers), but makes no mention of the blood within the same corpses. Blood is an epistemologically and organizationally separate issue.

Further indication of a moral hierarchy might be discerned in the way the degree of restrictions on commercialization of bodily products follows a similar part-and-whole hierarchy, so that blood component products are subject to EU laws on tender (though whole blood is to be “donated”; see Farrell 2012); there are fewer restrictions on commercial engagement with cells (donors are allowed “compensation”) than tissue; and fewer restrictions on tissue than organs (stored tissue is packaged and advertised with price tags unlike organs, which are keenly guarded as public resources). Following this logic of upscaling into “wholes,” it makes sense that cadavers, the primary source of most of these bodily products, have so far escaped EU regulation. In principle, a cadaver can only traverse borders for transplant purposes when divided into parts. Cadavers per se are apparently too close to “whole” human beings. Policies on commercialization furthermore follow logics of “added” work, so that enhanced bodily products fall under the RATMP (Kent 2012) and can be sold in ways plain body parts cannot (Kent 2012; Parry and Gere 2006; Waldby and Mitchell 2006). Policy logics thus express both a sort of horizontal differentiation of parts and whole and a vertical distinction between body parts and enhanced body parts (also discernible in the distinction between blood and blood products). As the vertical axis (and its implications for commercialization) has been dealt with in detail elsewhere, I continue here with reflection on how the moral hierarchy of parts and wholes can be discerned also in the sequencing of the directives.

### *The Policy Process: Sequencing and Windows of Opportunity*

The EU has dealt with safety concerns following a sequence similar to the described moral hierarchy: from smaller to larger “parts.” First came regulation covering blood and blood products, then tissues and cells, and finally organs. Numerous other factors have influenced this sequencing, the most important of which is the political structure of the EU with the limited mandate in the area of health. The directive on blood reflected a political situation marked by the risk of HIV transmission combined with a well-developed international market in blood products (Farrell 2012). The widely publicized scandals of infected

blood created an impetus for the EU to regulate according to the subsidiarity principle implying that the EU acts on that which cannot be handled adequately by nation-states. The blood scandal also institutionalized a particular set of donor-screening procedures focused on detection of HIV contamination later imported into the safety logics of the subsequent directives, as described subsequently.

Several members of the European parliament had wanted to include organs in the tissues and cells directive, or as one member explains:

Some colleagues [put forward] amendments to include organs already [at the time of the tissue directive] . . . but there was big resistance from the council, from member states . . . the scarcity is much more obvious in organs than in parts of tissues.

Observe how he points to a political consideration of scarcity, rather than a medical point about safety procedures. His point is that in case of higher safety standards, there might be fewer organs. Tissues and cells could become regulated because they did not have the same lure of urgency and therefore not the same prominence in national politics. Another member, from a former Eastern European country, thought that harmonization was seen as a threat by the Western countries fearing that they would have to send organs to Eastern Europe. It is a general trend, he claims, that “former Western countries fear attacks on their health systems. The newer countries are more eager for cooperation, the old ones are protective.”<sup>6</sup> All in all, it is about finding what he called the “political window of opportunity” for passing a directive: “This is how the legislative process goes . . . new situations are created when people are willing to enter new areas of cooperation.” This experienced politician thus reminds us that directives reflect political and not only medical needs.

The vague definitions and unclear reasons for divisions leave member states and individual agencies with room for interpretation (see also Faulkner 2012; Pirnay et al. 2013). I will now show how such ambiguities lead to practice variation with unfortunate implications for the ability to exchange material across borders. Equally important, the anatomical mode of constructing the regulatory objects has quite unfortunate implications for the medical outcome of all the “safety work.” The commensuration achieved with anatomical part-and-whole reasoning might have some moral and political validity, as we have seen, but it does a poor job of enhancing the health outcome of transplant and transfusion medicine in a cost-effective manner.

## **Safety: Commensuration, Evidence, and Cost**

As described in the Introduction section, practitioners are not content with the directives. When, for example, I asked a group of tissue bankers who they regarded as the most important regulator in the area, I was asked to clarify whether I meant: “Who we look to when seeking clever advice or who sets up rules that we consider a pain in the ass?!” The EU was considered a pain, and professional societies were seen as delivering clever advice. So why are the EU rules so frustrating? Paradoxically, the problems described by tissue bankers relate to the regulation being both too detailed and too vague.<sup>7</sup> To a large extent, this complaint reflects problems of commensuration: regulating different practices as if they were the same. Again I take point of departure in the EUTCD in my exploration of the safety logics and thereby what the directives—with all the ambiguities outlined earlier—produce in practice.

### *Commensuration: Focusing All Attention on One Form of Contamination Risk*

Due to commensuration of tissues and cells in the EUTCD and the tendency to model the directive on the rules from the blood directives, practices as diverse as bone grafting, skin transplants, and assisted reproduction now involve similar test practices and donor screening using more or less the same questions about sexual behavior, tattoos, and so on. Bone bankers explained to me that the bureaucracy of the EUTCD implied that they simply handed over the safety monitoring to the blood bank staff “already having the competence.” Unsurprisingly, it implied that the screening of bone came to resemble screening of blood. It also implied that the added safety work never came to address bacterial infections though they are the most commonly transmitted disease in bone transplants. Similarly, having rats as pets involves particular risks of skin infection (Miranda et al. 2009), but such questions have not been included in the screening of skin donors. Following the EUTCD, gamete donors are more stringently tested for HIV and other viral risks, but the EUTCD posed no demands for genetic testing even though sperm donation has a history of transmission of genetic diseases (Maron et al. 2009; Wirojanan et al. 2008). Commensuration thus implies that the options for strengthening screening efforts for well-known but tissue- or cell-specific risks have not been pursued.

Some of these effects can be explained with path dependency from the initial regulation of blood, and it is worth noticing how the focus on

contamination has similar contemporary implications for transfusion medicine (Farrell 2012, 18). Today, it is well known that most fatal outcomes of blood transfusions relate to inadequate monitoring of blood component compositions during operations along with inadequate blood management systems—such as grabbing the wrong bag of blood from the rack (Gudmandsen 2013). These aspects of transfusion medicine lie beyond the EU mandate, however, and fall under national jurisdiction. In consequence, the directive has sustained the continued focus on dangers residing *inside* the blood and the other bodily products at the expense of a range of other factors influencing health outcomes (cf. Deleuran, Sheikh, and Hoeyer 2015; Farrell 2013, 214). Similarly, EUTCD has focused on potential pathogens infecting the material.

Another concern with the commensuration implied by the EU rules, which was raised in all interviews with tissue bankers, was the ability to make individual risk/benefit calculations. Some forms of material are so rare that it is deemed reasonable to overlook a risk factor to get them. For example, the risks associated with not having a rare twenty-eight millimeter aortic heart valve on store might be bigger for the potential recipient needing it than the risk of the donor having contracted HIV within the last eleven days before his death—even when the donor is identified as a so-called Man who has Sex with Men (MSM; see also Schweitzer et al. 2007). Eleven days correspond to the so-called “serological window” marking the incubation of HIV. Such concerns about the written rules turned out to be rather theoretical however, since in practice tissue bankers often simply ignore the standards they dislike and make their own risk/benefit calculations. This is what we might call secreted practice variation.

### *Harmonization and Practice Variation*

Harmonization is aimed at minimizing practice variation, but it is well known from the literature that neither secret nor open variation can be fully eliminated (Dunn 2005; Hogle 1995; Timmermans and Berg 1998; Winthereik, van der Ploeg, and Berg 2007). Indeed, I have come across many examples of both forms of practice variation in safety standards relating to differences between nations, agencies, and tissue types. They are all part of the “internal workings” of the regulatory anatomy.

The EUTCD’s demand for physical examination of the donor can serve as a first example, as it has been discussed also in the literature as representing a demand with too many interpretive possibilities (Beele et al. 2009). When a tissue bank receives a full cadaver for multiple tissue recovery it

might seem a straightforward matter to conduct a “physical examination,” but what should you look for? It has been suggested to search bodies for tattoos, recent piercings, or signs of anal intercourse, even though identification of the latter lacks established criteria (Van Wijk et al. 2012). It gets more complicated when, for example, bone is harvested from *living* donors, which is the case of patients undergoing a prosthetic device operation. As the prosthetic device goes in, the bone goes out. Here, however, we find surgeons who oppose asking their patients to undress for a “physical examination” to find signs of “tattoos, recent piercings, or anal intercourse” (Hoeyer 2010). In most instances, they do not even ask the obligatory questions about risk behavior introduced through the transposition of the EUTCD because they wish to preserve the clinical confidence needed to proceed with an operation. They have only ten minutes for the entire pre-operation consultation during which the screening is also supposed to take place, and they refuse spending them on anal inspections and questions about sexual behavior. Similarly, physical examinations are often avoided when corneas are harvested from cadavers in mortuaries. Here, a cultural variance in mortuary practices across Europe conflicts with the demand for a physical examination because it is custom in some places to dress the cadaver before placing it in the mortuary, which makes undressing seem like desecration of the dead for the involved practitioners, as two tissue bankers explained to me.

Behavioral contraindications for donation are looked upon very differently in different procurement agencies. Some make exceptions for male homosexuality when tissues are particularly needed, as in the case of unusually big heart valves mentioned earlier, whereas others uphold a total ban on gay men while making exceptions for recent tattoos “if they look as if they were made a decent place.” The procurement agency with this practice explained that “even though not all homosexuals are dangerous (...) it’s just that you never know for sure. They might have had a prostitute coming by the hospital just before they died. You have to be absolutely sure.”<sup>8</sup> Practice variation is thus partly a reflection of personal assessments of relative danger (cf. Horlick-Jones 2005).

There are also technical variations in how to perform tests (e.g., charts for hemodilution calculations) and organizational variations in health systems as when a directive demands questioning of next of kin in countries where there is a tradition for posing these questions to the general practitioner instead. And, finally, there are variations stemming from what is seen as stubbornness: “People follow their own processes and opinions, ‘I’ve always done it like this’.” This is seen as particularly annoying for the tissue

bankers engaged in research to enhance the evidence base for safety standards. The tissue banker complaining about stubbornness gave an example:

Some add antibiotics when the materials are cooled, but studies have shown that it does not kill the bacteria. You need to do it at 37°. But they don't listen. It's a general problem that people don't read the literature and don't publish their results.

This, along with all the other forms of practice variation, ironically implies that often materials cannot be exchanged as a consequence of incompatible safety procedures installed *in order to* achieve EU harmonization. Previously, tissue bankers would make an individual assessment and send the material; now the audit systems preclude this practice. Our tissue banker's concern about professionals who "don't read the literature" is pertinent also for a wider discussion of the role of evidence in the setting of safety standards.

### *"Evidence": A Troubled Trope*

Thomas Schlich has pointed out that dependence on surgical handicraft is somewhat at odds with the demands for evidence to be achieved through randomized clinical trials (RCTs) (Schlich 2007), but there are other problems with the notion of evidence in relation to the EU "safety" ambition. To create statistical evidence, you need high numbers. Mostly, contamination cases are rare and insufficient for that. Furthermore, they need to be recorded: to generate anything like "evidence," there is a need for traceability.

Interestingly, traceability is one of the cornerstones of the EUTCD and one tissue banker thus remarked that *thanks to* the directive we might now finally know whether the directive was actually needed. Another tissue banker explained that "unless we have good measures of traceability . . . we don't even know whether there is a problem that should be treated." Before the EUTCD, there was often no way of knowing the incidence rate of graft-induced contaminations (Najjar 2005). The directive has also facilitated funding of several EU projects to develop technical standards, teaching modules, and monitoring of implementation. Rather than building on "evidence" (Pirnay et al. 2013, 544), the regulation thus serves to generate new forms of "evidence." Unfortunately, however, traceability is one of the areas in which the implementation of the EUTCD is most flawed: all tissue bankers face problems with surgeons who do not report back on even the most basic parameters.

Even though it is difficult to generate “evidence,” evidence is a trope with strong performative effects. A case from the field of Assisted Reproductive Technologies (ART) may serve as an example. ART practitioners with long-standing personal experience were strongly opposed when the Commission during a meeting in 2009 clarified that the 2006/17/EC requirements for serological testing (for, among other things, HIV) also applied to men in long-term relationships with women: their semen had to be tested before it could be used in treatment of their partners. The Chair of the European Society for Human Reproduction and Embryology (ESHRE) pointed out that he knew of no examples of disease transmission between partners through ART (Satkunarahaj 2009). Other prominent members of ESHRE added in material released by ESHRE that “there has been no single documented report of viral transmission” (Dr Ziebe) and suggested that “the ART field should have a separate specific Directive given that ART is different in its specifications compared to tissue or organs” (Professor Guérin; European Society for Human Reproduction and Embryology 2009). The real concern for these doctors was the cost issue. However, this sort of argumentation based on clinical experience and common sense (partners hoping for pregnancy are likely to have unprotected sex anyway) had no impact on the Commission. It did make a difference, however, when members of ESHRE initiated a research project showing that out of 79,291 tests performed in over 12,500 patients no infections were reported (Hughes et al. 2011). The study also confirmed the fear of increased expenditure. At a European level, the cost of continuous testing was estimated at around €240 million annually. If tests could be reduced to once a year, it would be possible to save €160 million. In response to the “new evidence,” the EU changed the rules in 2012.

### *Cost Reconsidered: Tacit Prioritization*

The fixation of the regulatory gaze on contamination risk produces a tacit form of prioritization. There is no way to accurately determine the “real costs” of this area of EU regulation. There are calculable costs associated with carrying out the tests, as with the abovementioned ART example, but without knowing whether the directives bring down infection rates, we do not know how much is saved elsewhere. Still, it is clear that the directives direct attention toward contamination risks at the expense of other forms of risk. It concentrates resources where the EU has a mandate, at the expense of improvements falling under national jurisdiction. The money cannot be spent twice.



Though tissue bankers generally receive more funding thanks to the EUTCD, they struggle to finance basic things such as clean rooms, which they deem absolutely essential for high quality. Instead, the money goes to screening. The emphasis on screening influences also the prioritization among groups of potential disease bearers. For example, the Danish government lowered the budget for HIV prevention work among identified high-risk groups (MSM) from eight to six million DKK concomitantly with increasing the expenditure related to the transposition of the EUTCD with well above fifty million DKK annually and a similar amount to screen the blood supply with refined methods. Note, however, that no one explicitly decided to transfer money from areas of high risk to areas with low risk: the prioritization came about through tacit safety logics.

Considering the significant increases in expenditure stimulated by the directives, I naively asked one of the members of parliament whether they had considered the costs associated with the new regulation. He rightly pointed out that the Parliament leave such calculations to the Council: “We’re looking more to principles, for example safety, that it is unpaid and voluntary, traceability, etc. The cost is not my job. Others in the council will look into that because it relates to national interests.” In this way, the division of labor between the various bodies of governance in the EU sustains the implicit form of prioritizing expenditure.

## **Conclusion: “Safety” Reconsidered**

With this article, I have described the regulatory anatomy characterizing European transfusion and transplant medicine. I have suggested thinking of this anatomy as a set of safety logics understood as assemblages of discourses (part-and-whole reasoning), legal documents (directives and their transpositions), technological devices (available tests and facilities), organizational structures (divisions between sectors and agencies), and work practices (divided according to temporal demands) aimed at minimizing risk. With this perspective, I have moved beyond the understanding otherwise prevalent among the practitioners who find themselves subject to the EU rules, namely that unwanted consequences stem from insufficient guidance by “those in the know.” The problems associated with the directives do not stem from “lack of science.” They stem from a set of safety logics commensurating very different practices and focusing the regulatory gaze on particular forms of contamination risk. The safety logics are shaped partly by a form of part-and-whole reasoning with moral and political (rather than medical) appeal as well as the way in which the EU mandate is limited to particular aspects of the

health services. With the concept of safety logics, our understanding of policy making need not be reduced to matters of political institutions, recorded “opinions” or human ingenuity or inadequacy. Safety logics draw attention to the ways in which available test kits and other material actors serve as “solutions” that contribute to the definition of problems by conjuring an action-oriented form of practical reasoning taking the form of “*If you want more safety, then you need to. . .*” Safety logics are not employed *by* people; they conjure people and things in specific assemblages through which available solutions come to frame the “safety problems” that policies can address.

By focusing on the mechanisms rather than individuals, I am in line with the classical work on safety by Charles Perrow (1981), but I have throughout this article shown how we need to explore notions of “safety” at a more basic level than the classical scholarship. We must interrogate the processes through which some practices come to be seen as relevant for “safety,” while others never make it onto the table. What is “safe” and for whom? “Safety” sounds so laudable that few people oppose policies enacted in its name. However, procedures executed in the name of safety do not eliminate risk and might even increase some risks; just as preambles mentioning cost-effectiveness as reason for new rules, need not produce cost-effective expenditure.

This study illustrates how the regulatory framework produces a number of problems. The ART field, for example, has had to conduct partnership testing to comply with rules for tissue transplants while rules addressing specific risks, such as genetic testing in sperm donation, have been omitted. Legal commensuration produces organizational proliferation and accompanying practice variation, and the desired harmonization process is therefore intertwined with production of exchange incompatibility. Most importantly, the directives direct funding and attention toward selected forms of risks with limited health impact. Such findings underline the need for continued STS analysis aimed at deconstructing the safety logics shaping transfusion and transplant medicine in the EU and beyond.

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## **Notes**

1. EU Tissue and Cells Directive 2004/23/EC, which is a so-called mother directive developed further by two technical directives 2006/17/EC and 2006/86/EC, to be fully transposed into national law by 2007.
2. Directive on standards of quality and safety of human organs intended for transplantation 2010/45/EU.
3. Blood and blood products are regulated by Directives 2001/83/EC and 2000/70/EC(5), Recommendation 98/463/EC(6), and Directive 2002/98/EC(7).
4. Directives set goals that member states should achieve through transposition whereas regulations are binding legislative acts applicable throughout the European Union (EU). Medicinal products fall directly under EU jurisdiction with respect to market regulation and therefore subject to a Regulation, whereas the directives relate to matters otherwise falling under national authority (Kent 2012). For explication of the institutional background for EU governance of health, see Martinsen and Vrangbæk (2008).
5. By pointing to the interdependence of social values and regulatory science, science, technology, and society has opened important avenues for exploring the political implications of epistemic claims in relation to the use of human material for therapeutic purposes. For example, scholars have discussed how identification of “dangerous individuals” in blood-donor screening can imply racial and sexual discrimination (Martucci 2010). Others have pointed to the multiplicity of actors in safety work and thereby to the potential for conflicting objectives and priorities between them (Carroll 2014; Mesman 2012). I draw upon this work, but seek to show how safety logics are not divided into “social” and “medical” aspects: they are social all the way to the bottom (see also Deleuran, Sheikh, and Hoeyer 2015).
6. With the term “newer,” he refers to the Eastern European countries joining the European Union in the enlargement in 2004 (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia) and in 2007 (Romania and Bulgaria). He did not seem to consider the two Mediterranean countries (Malta and Cyprus) “newer” though they also joined in 2004.

7. The technical directives, in particular, are criticized by the tissue bankers for being “too weak and too elastic” (especially 2006/17/EC, articles 3 and 25-28).
8. The tissue banker making this statement would probably not have said that gay men were more likely to invite prostitutes to their deathbed unless I had asked her to explain why she made exceptions in one area and not another. It is nevertheless interesting that she justifies her risk assessment by adding a second form of danger (prostitution) to the first (homosexuality) both within the realm of promiscuity.

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