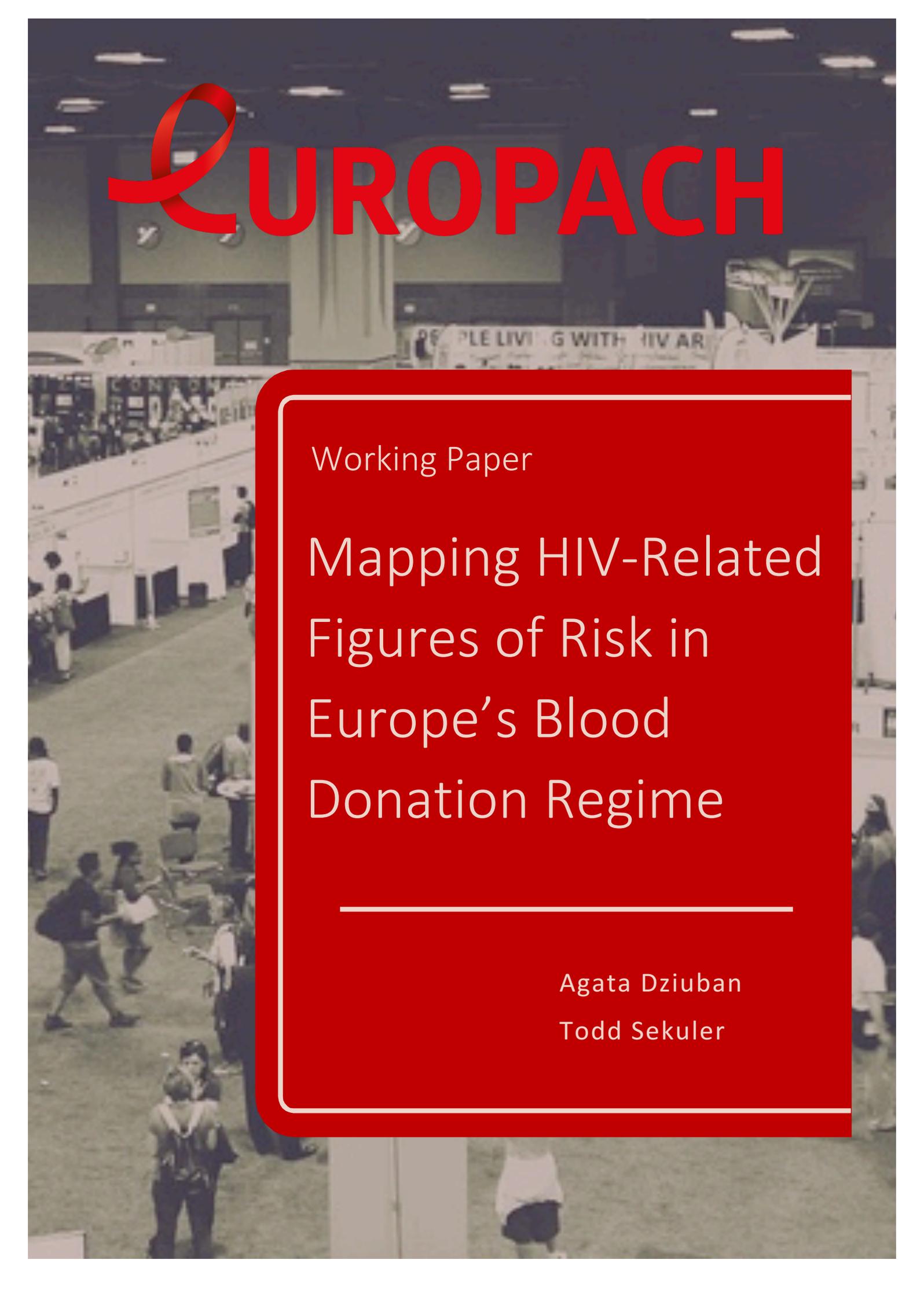




# EUROPACH



Working Paper

## Mapping HIV-Related Figures of Risk in Europe's Blood Donation Regime

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**Table of Contents**

<b>Introduction.....</b>	<b>4</b>
<b>The Europeanization of Blood Donation and Transfusion .....</b>	<b>7</b>
<b>HIV and Shifts in the Moral Economy of Blood Donation .....</b>	<b>10</b>
<b>The European Blood Donation Regime .....</b>	<b>13</b>
<b>Figures of Risk.....</b>	<b>16</b>
<b>Qualifications of Risk .....</b>	<b>24</b>
<b>Conclusion .....</b>	<b>27</b>
<b>Reference List.....</b>	<b>32</b>

## Introduction

In August of 2017, the German Medical Association, together with the German Federal Institute for Vaccines and Biomedicines, issued guidelines that made it newly possible for the following groups of persons to donate blood: “men who have sex with men”, “persons who provide sex for money or other benefits (ex. drugs)” and “heterosexual persons who engage in sexual risk behaviours, such as intercourse with frequently alternating partners” (Bundesärztekammer, 2017, 19-20).<sup>1</sup> No longer permanently deferred from donation as was mandated by the previously published set of guidelines, these groups were now able to donate blood if the listed behaviours did not occur within the twelve months prior to the date of attempted donation (Bundesärztekammer, 2010). The guidelines also introduced a new category of would-be donors, “transsexual persons with sexual risk behaviours” (ibid.)<sup>2</sup>, who were to be deferred under the same 12-month condition. In a 2016 report by a German working group on “blood donations from persons with sexual risk behaviours”, the findings of which provided a foundation for all of these changes, the authors referenced a collection of publications about the risk of becoming infected with HIV among “transgender women”, about the frequency of sex work among “transsexuals (male to female)” and about variously tabulated rates of HIV infection among “transsexuals who engage in sex work.” “Nowadays,” the authors concluded, “transsexuals are considered a risk group that for a long time was not acknowledged as such” (The Working Group Blutspende von Personen mit sexuellem Risikoverhalten, 2016). This incorporation of certain “transsexuals” into the list of groups at risk for infection with HIV and also of groups deferred from donation is just one example of how being named<sup>3</sup> and recognized as part of a community who is worthy of protection from illness can also translate into new forms of social exclusion.

With this case of Germany as an introductory example, we propose the notion “figures of risk” to refer to the various categories of persons who are implicated in the changing donor restriction policies as part of a given blood donation regime. The term “risk” here references the common-place notion of “risk group” in use in the field of public health, which groups individuals together based on criteria that are thought to put them at a particular risk of a

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<sup>1</sup> The wording in German read: “Männer, die Sexualverkehr mit Männern haben (MSM)”; “Personen, die Sexualverkehr gegen Geld oder andere Leistungen (z. B. Drogen) anbieten”; “heterosexuelle Personen mit sexuellem Risikoverhalten, z. B. Geschlechtsverkehr mit häufig wechselnden Partnern.”

<sup>2</sup> In German: “transsexuelle Personen mit sexuellem Risikoverhalten.”

<sup>3</sup> The terms “transgender women”, “transsexuals (male to female)”, “transsexuals who engage in sex work”, although dissimilar, are understood to provide information about the same underlying group of persons, who become the target of the adopted deferral policy: “transsexual persons with sexual risk behaviours”.

given illness. However, the concept “figures of risk” has also been selected to account for the fact that these groups of persons are further repurposed as they are thought to put others at risk of infection based solely on their previous behaviours – even when not necessarily engaging in behaviours that involve a possible route of infection – and regardless of their health status. As such, they become the perceived vector of possible illness by way of alleged risk rather than by way of a particular biological phenomenon. In the context of blood donor restrictions, behaviours of the past, it might be said, come to define the body of an individual even more than the biological impact of those behaviours. Wim De Kort et al. (2016, 106) thus refer to them as “risk carriers” rather than “pathogen carriers”. Given concern about the prejudices that these exclusionary policies are thought to be based on and to reproduce, one might read yet a third meaning of the notion “figures of risk” in the perceived risk of increased stigma that certain members of affected communities see to follow from their essentialised association by donation policy-making officials with risk, illness and especially with HIV.

In Germany, the systematic exclusion of groups of persons who were thought to be at an elevated risk for HIV infection began in 1983, and individuals outside of those groups who might have engaged in so-called “risk behaviours” were encouraged to refrain on their own from donating as of 1987; this latter approach has been described as a system of self-exclusion (Flegel W.A. et al., 1996). The German Medical Council published the first official national guidelines regulating blood donation in 2005 (Bundesärztekammer, 2005); among those persons excluded from donation for life were “persons who consume drugs or abuse medication” and “persons whose sexual behaviours or life conditions bear an elevated risk for the transmission of severe blood-borne infections (HBV, HCV or HIV) compared with the general population.” A footnote specified the following examples: “homo- and bisexual men, drug addicts, male and female prostitutes, prisoners”. Persons who had “intimate contact” with members of those groups in the previous four months were also excluded, as were those who, in the same four-month time frame, had been imprisoned, or who had visited countries with an elevated risk of infection with HIV or a number of other viruses. Whereas the stigmatizing, identity-based language and temporal qualities of deferral policies have thus come to change in recent years for certain groups in Germany, the permanent exclusion of persons who use drugs and the time-dependent deferral based on travel and the behaviours of partners continue to be enforced in those guidelines currently in use.

The landscape of blood donation deferral has shifted in recent years in other areas of Europe as well. In Scotland and England, for example, men who have sex with men, sex workers, and

people who have sex with partners identified as “high-risk”, such as those who have been in overseas areas where HIV is thought to be common, are newly able to donate blood after abstaining from sex for just three months as of 2018 (Department of Health and Social Care, 2017). This change followed alterations to the deferral criteria within the England, Scotland and Wales Blood Services in 2011, and by The Northern Irish Blood Transfusion Service in 2016, both of which had adjusted the life-long deferral procedure for men who have sex with men to a twelve-month time frame. Although the Advisory Committee on the Safety of Blood, Tissues and Organs estimated that the most advanced tests are equipped to detect HIV in a sample of blood as early as one week after the moment of infection – an amount of time that varies based on the infectious agent and is widely described as a “window period” – they note that one can never fully eliminate the possibility of error in STI detection technologies and practices (SaBTO, 2017).<sup>4</sup> The UK government has also considered relaxing the deferral restrictions for those with a history of using injecting drugs that have not been medically prescribed, but such an adjustment, the blood service representatives have claimed, would necessitate a change to national and European legislation.

Against this backdrop of change in national blood donation regimes, which are also evident in an assortment of other European countries including Spain, Italy, and France, this paper seeks to identify several of the varied, unstable and shifting figures of risk that have emerged in relation to the HIV/AIDS epidemic as per blood donation policies issued on the European level. European countries such as Germany and the UK are expected to act under the guidance of the Council of Europe – created in the post-war period to enhance European unity, ideals and principles – which has increasingly come to act in conjunction with the European Union on the topic of blood donor restrictions. *The Guide to the preparation, use and quality assurance of blood components*, which has been revised and published on an almost annual basis by the Council of Europe starting in 1992, constitutes the core material for this analysis. Within the context of ongoing debate about the relevance and implications of deferral policies that target men who have sex with men specifically, special attention will be paid to this and other groups of persons who engage in behaviours that are thought to put them at elevated risk for HIV infection. Additional European-level blood donation policies and academic literature

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<sup>4</sup> They note the following reasons: “error in the process, poor assay sensitivity, and a donation collected from a donor in the infection ‘window period’” (pp. 44). However, according to their report, the Committee’s 2017 recommendations for updated deferral policies for these groups were no longer based on possible infection with HIV. Instead, they relied on the “window period” for syphilis, an all but curable bacterial infection that the authors argue can go undetected in blood components for up to 90 days (pp. 50-51). This relates to the de-exceptionalisation of HIV as elaborated below (pp. 21-22; 31-32).

that has emerged around debates about these figures will serve to further contextualize and elaborate them and their significance, as will brief discussion of the closely related figures of the ideal donor and of the potential donation recipient, both of which are co-produced in relation to them. Before we analyse these various implicated figures, however, let us first consider the meaning with which blood donation has been ascribed in the European context.

### **The Europeanization of Blood Donation and Transfusion**

In 1953, just three years after the creation of the Council of Europe, an assortment of broken dykes in the Netherlands provoked massive amounts of injury, and new awareness about the nation's limited and potentially insufficient supply of blood.<sup>5</sup> As a result, neighbouring countries sought to offer support by way of blood donation, but the linguistic and cultural illegibility of the packaging labels and other such obstacles exposed the absence of a reliable framework for enabling the safe and effective use of blood in one European country when it was collected according to the cultural codes and logics of another. If the newly constituted Council of Europe was created in part to reduce the barriers between European countries, the existing national and deficient transnational structures of blood donation appeared to be a threat to the aims of the Council. Bernard Genetet, a former member of the Council's Committee of Experts on Blood Transfusion and Immunohematology, has offered this episode as a seminal event in a narrative about what he describes as the council's "transfusion project" (2001). Even if, according to Genetet, "it resulted in an acknowledgement of impotence," he described it as "one of the first reactions of European solidarity," "a positive gesture, powerfully authentic and deeply appreciated in the first postwar decade." Hence, the first European Agreement by the Council, which sought to harmonize the technical and cultural practices involved in blood collection and storage and dates to 1958, opens by proclaiming, "it is most desirable that member countries, in a spirit of European solidarity, should assist one another in the supply of these therapeutic substances, should the need arise" (Council of Europe, 1958).

Not just a means to constitute and enact a form of European solidarity, however, Genetet pinpoints blood donation as a topic that helped to define and refine the function and identity of the Council. Borne in the aftermath of World War II, the founding instrument of the

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<sup>5</sup> This may have not been an isolated initiative at the time, indicating that social, political and/or technological changes of the post-war period might have helped to make imaginable such compassionate acts of solidarity. For example, people in Poland, and possibly other countries in the Eastern Bloc, organized mass blood donations for Hungarians who were wounded in the course of the Hungarian uprising that took place in 1956.

Council established that “human health was a prime concern of the new European structure.” Shortly thereafter, the establishment of a Committee of experts on public health occurred within the Council precisely as experts in the field were calling for “practical measures for the abolition of customs formalities in the case of therapeutic substances of human origin.” The Council then saw in blood donation policies, according to Genetet, an opportunity to “find and assert its identity and brand new legitimacy in a field which was considered something of a private preserve.” Blood donation offered a possibility to carve out space as an authority of health within a pre-existing landscape of international actors that already included the World Health Organisation, the League of Red Cross and Red Crescent Societies, and the International Society of Blood Transfusion, each with their own institutional character, function and purpose. Genetet used the term “transfusion Europe” to describe what was produced out of the 1958 and two subsequent (Council of Europe, 1962, 1974) blood-related<sup>6</sup> Council agreements.

Here it is worth highlighting that the field of blood transfusion in its modern form only became possible in 1901 with the identification of the first (ABO) blood group (Alboek, 2001). Until then, there was an assumption that all blood was the same, which left practitioners in confusion about the occasional disastrous consequences of blood transfusion, a practice that dates as far back as the 17th century. Without techniques to assess the presence of blood-borne infections at the time, such as of syphilis, malaria or hepatitis, early forms of donor assessment and interviews were introduced – precursors of the now elaborate donor guides and questionnaires – which relied primarily on visible symptoms and the truthfulness of donors about their medical histories. The 1958 agreement hence stated, “Donors must be in good health and, in particular, free of any communicable disease” (Council of Europe, 1958, 10) Within this context, it was quickly established that blood donation would need to be done solely on a voluntary basis. As Erik Alboek has written, “voluntary, non-remunerated donors who gave blood for altruistic reasons were regarded as more reliable than paid donors who had an economic incentive not to reveal their true health condition” (2001, 459). Based largely on this notion of altruism, Richard Titmuss (1997) famously applied the concept of the gift as developed by Marcel Mauss to describe the donation of blood, albeit with a particular set of attributes that distinguish it as a unique type of gift<sup>7</sup>. Infused with meaning about social life and connectedness, the “gift of blood” thus became a means for constituting a given

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<sup>6</sup> The 1962 and 1974 agreements sought, respectively, to regulate the exchange of blood grouping and tissue-typing reagents.

<sup>7</sup> These include qualities such as that blood is highly perishable or that only certain persons are allowed to donate.

subject (as healthy) and of that subject's (altruistic) relationship to others. Provoked by a growing world of policies on transfusion, as we have seen, that gift was also constructed within the European context as a way to enact one's sense of belonging to a national or even transnational community.

These early practices of implicit rather than explicit deferral from blood donation, which rely on assumptions about the relationship between class, health and the social, constitute an ongoing point of contention within European health-governing bodies. "Paid blood is poor blood," wrote the economist Sherry Glied polemically as an intervention into these debates, "precisely because it is drawn from poor people" (Glied, 1999). Moreover, these practices anticipate other securitization strategies of the AIDS-era, which came to create healthful and abject potential blood donors, and which are based above all on sense of (self-)responsibility and a particular set of moral values rather than on technical capabilities, or on scientific evidence and precision. The moral investments embedded in this amalgam of blood donation logics – altruistic, voluntary, non-remunerated donation as an act of European solidarity – were also further mobilised in the construction and fortification of the burgeoning notion of European citizenship. In the words of one member of the European Parliament at a 2001 debate about their first blood-related directive, "Giving blood is a positive act of citizenship" (European Parliament, 2001).<sup>8</sup>

Any notion of citizenship that is embedded in the act of blood donation for members of the European Parliament should be differentiated from those most commonly referenced models that came to structure thought about European access to rights and recognition. Until the turn of the 21st century, Germany was long juxtaposed to France for its reliance on *jus sanguis* (right of blood) rather than *jus soli* (right of soil) as a path towards citizenship (Brubaker, 1992). The prospect of blood donation (versus blood relations) as enactment of citizenship enabled a more accessible type of belonging that would better conform with the European values of participation and solidarity. Moreover, this new configuration of citizenship (in terms of participation and solidarity rather than access to rights and state recognition) was in alignment with the unifying aspirations of European governmental institutions, such as the European Union and the Council of Europe, and the increasingly facilitated movement across EU member state borders. As presented above, however, new and shifting forms of exclusion took place through such a conceptualisation that relied on arguments about the threat of biological illness through blood donation, such as in relation to HIV. The fact that there is a

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<sup>8</sup> The quote was by Catherine Stihler, a British Labour Party politician who has been a member of the European Parliament for Scotland for almost 20 years.

so-called “window period” in the ability of a test to detect the presence of this and other viruses or bacteria in any batch of blood has provoked a practice of exclusion that is based on risk rather than just on illness. Indeed, as the next section will show, the emergence of the epidemic provoked a radical transformation in the moral economy that governs the logics of blood donor assessment, selection and exclusion. In practice, it has meant that a growing list of persons are excluded from the possibility to perform this act of solidarity.

### **HIV and Shifts in the Moral Economy of Blood Donation**

In 1983, the Council of Europe was the first governing European body to respond to the outbreak of AIDS in the form of policy. With its long-standing commitment to norm-setting in the field of blood transfusion and the management of blood supplies, it may come as no surprise that this response concerned the regulation of possible HIV transmission through the process of transfusion (Council of Europe, 1983). In particular, the Council's Committee of Ministers issued a formal recommendation that warned Member States about the emergence of “a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that may be caused by an infectious agent transmissible by blood and blood products” (ibid., 1-2). As a result, it advised the implementation of measures to prevent the possible transmission of AIDS from “affected blood donors to patients receiving blood or blood products”. Alongside recommendations urging member states to avoid the importation of plasma products from paid donors and from countries with “risk populations” (at the time, likely referring to the USA), and to inform physicians and selected blood product recipients about any transfusion-associated risks, the Council of Europe called on governments to provide blood donors “in risk groups” with pertinent information about AIDS so that they could “refrain from donating”. Based on the brief genealogy presented above, and in the absence of an effective HIV-test, this call to self-deferral was in some ways consistent with earlier strategies for managing the possibilities of infection with illness through blood donation.

While examples of the “risk groups” in question were not provided directly in the body of the recommendation, they were identified in the exemplary leaflet for donors that was added as an appendix to the document. Initially developed by the American Red Cross, the notice defined several groups of persons who were thought to constitute a threat to the safety of blood donation recipients, and who were asked, as a result, to consider refraining from donation (ibid., 2). However, with little effort made to conform to the dynamics of the epidemic as it was emerging in western Europe at the time, the list included – in addition to “persons with symptoms and signs suggestive of AIDS”, “sexually active homosexual or bisexual men with

multiple sexual partners”, “present or past abusers of intravenous drugs”, and “sexual partners of persons at increased risk of AIDS” – “recent Haitian entrants into the United States”. By targeting Haitians, “homosexual and bisexual men”, and drug “abusers”, the flyer appended to the first AIDS-related policy recommendation of the Council of Europe thus largely reflected the imagery of risk groups as had been depicted in the United States, which became the vehicle through which some of the very first HIV-related figures of risk were introduced into European-level policy and debates on the safety of donation.<sup>9</sup> From the logic of this norm-setting institution, of course, it might be said that this first policy followed from a heightened sense of responsibility to public health in the context of an emerging threat rather than from an obligation to achieve or preserve equality across society. Whatever the intentions, the logics and language of the flyer reflected certain prejudices that existed in discourses on health of the time, and led to the creation of an initial set of moralistic and stigmatizing “figures of risk” in European level policy that targeted people based on their race, sexuality and national origin. “They were created, *qua* groups,” wrote Oppenheimer of these early epidemiological groupings, “to signify their potential status as carriers of tainted blood and as contaminators” (1988, 283). Analysing the social consequences of these early risk-group constructs and the revocation of their ability to donate blood, the anthropologist Paul Farmer thus describes HIV as an epidemic of discrimination (Farmer, 1992).

Despite these efforts, highly-mediatized narratives emerged throughout and beyond Europe during the 1980s and 1990s about incidents of HIV transmission through the transfusion of blood and blood products. Such cases were reported in a number of European countries, including France, Germany, the Netherlands, Switzerland and the UK, and provoked outcry from transfusion recipients, established haemophilia societies, and also from the general population as it meant that they too were at risk of acquiring the virus (Farrell, 2012; Feldman & Bayer, 1999; Tylor & Power, 2016; Bovens, ‘t Hart & Guy, 2001). However, with no stigmatised behaviours to blame for their (possible) infection, the state became the target of criticism in its failures to protect the so-called “innocent victims” – marking a moral shift that has been widely described as a loss of trust in the structures that regulate the transfusion of blood and blood products (Farrell, 2012). These various blood “scandals”, as they quickly came to be known, provoked varied consequences ranging from compensation for impacted individuals to the impeachment of implicated political figures. Related analyses by social scientists have further amplified a sense of crisis, employing terms such as “blood collection catastrophe” (Bennett, 2009, 57) and “international iatrogenic catastrophe” (Bayer &

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<sup>9</sup> The same is true in other European countries, such as in Switzerland and the UK.

Feldman, 1999) to describe the factors motivating this diminished dynamic of trust in the broader economy of emotions, values, norms and obligations – or what has been called the “moral economy” (Fassin, 2012) – around the transfusion of blood.<sup>10</sup>

Anne-Maree Farrell has suggested that the adverse public response that followed from these blood contamination episodes, and the implicated growing mistrust in governments' abilities to ensure the safety of national blood supplies, led to the adoption of the so-called “precautionary principle” as the guiding logic of blood donation governance (Farrell, 1997). Initially applied to environmental and food policies, this variously defined strategy is meant to provide a guide for responding to a perceived but unquantifiable risk to health by, especially, taking preventive action in the face of uncertainty, and shifting the burden of proof of non-harm to the advocates of a particular activity (ibid., 168). As such, it can be seen to justify the application of exclusionary measures that might be considered discriminatory in the name of the greater good of society, and to enable the continuity of such exclusions until the conditions of their inclusion have been established to be harmless. European policy-makers - on the national level but also within the Council of Europe - thus turned to the precautionary principle due to the initial lack of effective blood testing or purification technologies, and given the sense of crisis that came to undermine trust in politicians and created a need for political action. In practice, however, applications of the principle were all but reduced to the fortification of donor screening, selection and deferral policies (ibid., 166-197).

The very early critical response of gay rights activists to applications of the principle - claiming that such policies violate their rights to non-discrimination, privacy and equality (Belavusau, 2016; Bennett, 2009; Krip, 1999) - did little to sway the politicians and donation governing officials who needed to demonstrate to the public that they were vigorously responding to their sense of threat and possible exposure to infection. Indeed, this clash reveals a moral tension that exists in liberal democracies between the liberal ideal of individual rights and freedoms and a democratic investment in public health as means for securing the greater good of society.<sup>11</sup> Moreover, even when testing and other techniques for

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<sup>10</sup> The political and moral tenor of these events continues to be so profound that as recently as June 2017, Prime Minister Theresa May ordered a renewed investigation into the conditions that led to the early infection of thousands with HIV and hepatitis C. See, for example: <https://www.theguardian.com/society/2017/jul/11/contaminated-blood-scandal-theresa-may-orders-inquiry> [Accessed at 01 Nov. 2017].

<sup>11</sup> The UK advisory Committee on the Safety of Blood, Tissues and Organs, alternatively, locates the moral dilemma in terms of discrimination and protection: “The moral justification for discriminating

preventing transmission via transfusion became available, the logics of precaution that provided a framework for selective donor deferral have been remarkably slow to adjust. Hence, although the most recent testing technologies enable the detection of HIV in the blood of an individual who has been infected up to one week before the date of the test, even the newly updated deferral criteria in Germany, as we have seen, imposes a deferral for individuals based on behaviours that occurred within the twelve months prior to donation. Before we examine this closer using the deferral recommendations on the European level, and consider the reasons for these continued exclusions, let us first show how the Council of Europe's *Guide to the preparation, use and quality assurance of blood components* has become a tool at the heart of the entanglement of the Pan-European health governing institutions that collectively constitute what we describe as the European blood donation regime.

### **The European Blood Donation Regime**

Although the terms for regulating European health systems are largely left to the sovereignty of Member States, the governance of blood and blood products has been one of the few health-related realms to provoke considerable attention, political cooperation and regulatory oversight on the part of the ever-growing number of implicated pan-European advisory and governing bodies. Over the last three decades, both the Council of Europe and the European Union (also in its previous incarnation as the 'European Communities') have been increasingly engaged in the development and subsequent alignment of regulatory frameworks for the management of blood and its derivatives in their respective (and partially overlapping) Member States. It has been said that the impression of crisis that came to circulate around the emergence and spread of HIV within the context of the donation and transfusion of blood and blood products has contributed to a "noticeable upsurge in the adoption of norms, standards, guidelines, recommendations and regulations" (Farrell, 2012, 24) at the regional level, and in the gradual development of a complex web of supranational policies that are embedded in the shifting European landscape of donation regulation.

Starting with the aforementioned policy document to first engage with AIDS on the European level, the Council of Europe (1984, 1985, 1987, 1988) has adopted numerous recommendations and resolutions on blood and plasma sourcing and supply, which established increasingly stringent standards with regards to the responsibilities of health

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against a potential donor is based on the moral obligation to protect others (or indeed the donor) from harm" (SaBTO, 2017, 23).

authorities in the field of blood transfusion, in the protection of the health of recipients and donors, in the screening of blood donors using relevant testing technologies (when HIV antibody tests were made available in 1985) and, most importantly, in the selection criteria for people donating blood. One of the most instrumental but rarely acknowledged milestones in this field was the development of the comprehensive *Guide on the preparation, use and quality assurance of blood components* (henceforth referred to as “the Guide”), prepared by the Council’s Selected Committee of Experts on Quality Assurance in Blood Transfusion Services. Although, as has been stated, the first version of the Guide was published in 1992, it has been revised nearly annually, and has been officially adopted as a technical appendix to a 1995 recommendation by the Council’s Committee of Ministers (Council of Europe, 1995), thus affording it an enhanced legal foundation and status. Moreover, it has been regularly verified, updated and re-published by the Council’s Directorate for the Quality of Medicines and Health Care (EDQM) as of 2008, and henceforth played an increasingly crucial role in informing the standards and regulations of blood donation and, in particular, of donor screening, selection and deferral as implemented in the member states of both the Council and the European Union (Farrell, 2012, 45-49).

Functioning primarily as an economic union, and hence deprived of the ability to develop policies in the field of public health, the European Community/Communities was much slower than the Council of Europe in its regulatory response to the epidemic in general, and in particular to any related threats to the quality and safety of the supply of European blood and blood components. A catalyst for action occurred with the adoption of the Maastricht Treaty in 1993, which established the European Union as such, and at last granted it with the authority to act in matters of public health (Alternsetter, 1994; Flear, 2015; Steffen, 2004, 2012). This shift in identity and in scope of authority, together with the political fallout that followed from the highly-mediatised transfusion of so-called “tainted blood” in several Member States, contributed to the introduction of the first program for action in relation to blood safety and quality by the Commission of the European Communities in the mid-1990s (Commission of the European Communities, 1994; Commission of the European Union, 1996), and several resolutions in the field adopted by the Council of the European Communities (1993, 1995, 1996, 1998) and the European Parliament (1993, 1995, 1996). The Amsterdam Treaty (which came into force in 1999) further reinforced the European Commission’s competences over public health, and laid down the foundations for the development of a first blood-related Directive of the European Parliament and Council

(European Parliament, 2002), thus establishing the earliest signs of a harmonised blood donation regime across European institutions.

This Directive, a legally binding document that is commonly referred to as the 'Blood Directive,' set the minimum standards for ensuring quality and safety in relation to the use of blood and blood components in the European Union. These standards – including the deferral criteria for prospective donors, permanently or temporarily suspending the eligibility of an individual to donate blood or blood components – largely conforms to the recommendations that were laid down in the seventh edition of the Guide by the Council of Europe (2001), and as were further elaborated in a series of blood-related Directives that were subsequently adopted by the European Commission. These included a 2004 Directive (Commission of the European Communities, 2004), which identified various behaviours that were thought to jeopardize transfusion safety and which we return to below, as well as a 2005 Directive setting Community standards and specifications relating to a quality system for blood establishments (Commission of the European Communities, 2005).

Despite this tendency towards harmonisation, the prerogatives, political powers and legal competences of the two main political actors that were engaged in managing HIV-related risks to the European blood system differ considerably. While the Council of Europe, which is known to be deprived of any legally binding power, must resort to “informal or soft governance mechanisms such as guidelines, standards and recommendations” (Farrell, 2012, 54), the European Union is able to introduce and enforce binding regulatory frameworks that establish the minimum legal standards to be expected of Member States. This landscape of pan-regional governance appears even more complex if we add to the equation national health structures and governments, representatives of which make up both the Committee of Ministers and the Parliamentary Assembly of the Council of Europe, as well as other stakeholders who are in different ways invested in shaping regional blood systems, such as the World Health Organisation (WHO), the European Blood Alliance (EBA), the European Haemophilia Consortium (EHC), the Red Cross and Red Crescent Societies, plasma producers and other pharmaceutical companies. Thus, understandably, one of the main goals of the European-level blood governance has been “a drive towards greater technical harmonisation and cooperation” (ibid., 25).

One expression of the varied efforts made to achieve this goal has been the increased alignment of a blood regulatory framework that has been proposed by the Council of Europe, and blood-related legislation that has been adopted by the European Union. Thus, for

example, the Council's Guide has been supplemented not only with a Standards section in recent years (since 2009), which closely follows the minimum standards for blood establishments and blood banks that have been set by 2004 and 2005 EU Directives, but also with the Good Practice Guidelines (since 2013) that were elaborated as per a direct collaboration between the EDQM and the Commission of the EU. Indeed, calls for future changes to the powers of the European blood donation regime point to the likelihood of an even stronger collaboration between European-level governing bodies. Moreover, actors on the national level have begun to turn to European authorities to intervene in the local practices of donor exclusion. A 2016 decision by the European Court of Justice, for example, ruled against a plaintiff who claimed that the ban on donation for men who have sex with men in France was a violation of their rights to private life, equality and non-discrimination (Belavusau, 2016). Despite that ruling, the emergence of this case and in the fortification and harmonization of European standards underscores how citizens of Europe have come to increasingly challenge the sovereignty of nation-states in the regulation of health issues, especially in the areas of the collection and transfusion of blood and blood supplies.

The fact that these different policy frameworks have increasingly become aligned over time – with the European Union and the European Blood Alliance now explicitly referencing and relying on the Council's *Guide* in their own policy documents and deferral recommendations – has led to a refinement and harmonisation in the terms that are used, which further reinforces and solidifies the figures of risk that circulate within the imaginary of European institutions.

### **Figures of Risk**

Although its name has remained remarkably stable, the form, content and structure of the *Guide to the preparation, use and quality assurance of blood components* have shifted significantly over time. The very first Guide, published in 1992, was made up of five parts, which were labelled “Introduction”, “Blood Collection”, “Blood Components”, “Laboratory Procedures” and “Transfusion Practices”. These were further broken down into 24 chapters, amounting to a total of 129 pages. The 2017 Guide, as a contrast, devoted the first twenty pages entirely to the presentation of the book's table of content. The “Good Practice Guidelines” referenced above amount to eleven chapters of the Guide with a total of over 70 pages. They are followed by a section presenting the “Principles” of blood donation (11 chapters, 114 pages), the aforementioned “Standards” section (10 chapters, 205 pages), and then five appendixes that take up a total of 69 pages. The concluding 26 pages are made up of

an elaborate presentation of the definitions, abbreviations and references used in the document. In total, the 2017 Guide uses 545 pages to offer a how-to manual for the various actors of the European blood donation regime. While this contrast of versions underscores the sheer and massive increase in size of the Guide over the last 25 years, it also points to how its scope has drastically expanded and its technical precision has been enhanced. Among the key issues that have been gradually augmented with each new version are the donor selection and deferral criteria - which collectively amount to the norm-setting information that gives shape to what we call the European figures of risk.

Prior to the publication of the first Guide, the language of several Council of Europe policy documents exemplified some of the moralising labels that were in circulation to describe persons thought to be at an elevated risk of contracting HIV. The Council's 1983 Recommendation, for example, was already mentioned above, which simply replicated the listed figures of risk that emerged out of the United States (including Haitians, "homosexual and bisexual men", and "drug abusers"). Although not concerned exclusively with the donation or transfusion of blood or blood products, a 1987 Recommendation by the Council on a Common European Health Policy to Fight AIDS (Council of the Europe, 1987), on the other hand, depicts a locally-produced set of figures that group people into homogenising categories that are not sensitive to differences in their life experiences, health status and efforts taken to reduce any risk of infection: "intravenous drug users, men with homosexual contacts, prostitutes, customers of prostitutes, 'sex-tourists', haemophiliacs, the prison population, adolescents, people staying in or traveling to areas with a high prevalence of AIDS" (ibid., 4).

The first Guides of the Council of Europe, alternatively, might be seen as part of a widely observable shift as was promoted by the World Health Organization - and which has become largely associated with Jonathan Mann (Mann et al., 1994) - from "risk groups" to an at-first diffuse emphasis on behaviours that are thought to pose a risk of infection. Given the ongoing shifts in the epidemiology of and general knowledge about the epidemic in Europe at the time, the authors of the earliest Guides were fairly restrained in delineating concrete figures of risk. As such, in the first Guide, a subsection of the chapter "selection of donors" devoted to "Acquired Immune Deficiency Syndrome (AIDS)" explains, "All blood donors should be provided with accurate and updated information on AIDS so that those with unsafe sex practices or other risk behaviours exposing them to potential infectious sources will refrain from donating" (Council of Europe, 1992, 14).

Imposed deferrals within the context of AIDS were thus not yet mandated, relying instead on a system of self-deferral that was consistent with the earlier blood donation standards as described above. In “Seeing like a survey,” John Law (2009) works to uncover the performative function of surveys - in their assumptions and messages, how they work to create and not just reproduce the reality that they seek to describe. “Seeing like a Guide” here might mean understanding this expectation of self-deferral as productive of a particular type of citizen, one who is expected to be informed, self-aware, compliant and responsible for the protection of the health of fellow citizens. For example, a sample donor selection questionnaire included as an appendix to the first edition of the *Guide* asks, “Have you read and understood the information on AIDS given to you?” It then continues, “Have you been involved within the last twelve months in any of the risk behaviours defined (e.g unsafe sex, intravenous drug-abuse)” (Council of Europe, 1992, 20)? This question thus produces a certain concept of “risk” that does not yet have a particular gender, sexuality or occupational relevance (i.e. men who have sex with men and sex work are not targeted explicitly), but it does have a time frame that was thought to last a period of just twelve months. Although reference in the question is only to intravenous drugs – and the vague and morally-laden word “abuse” implies debatable assumptions about the meaning and moment of harm – an additional subsection of the chapter implicates a much broader range of drugs in the criteria for deferral by stating, “illicit drug taking if admitted or suspected should debar” (Council of Europe, 1992, 16).

It is remarkable that this first and most subsequent Guides encouraged deferral only for persons who engaged in these behaviours in the twelve months prior to the date of attempted donation. As of 1994, the World Health Organization had issued its “Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives”, which mandated the permanent exclusion of “past or present intravenous drug abusers”; “men who have had a sexual relationship with another man”; “men and women who have engaged in prostitution”; and “sexual partners of any of the above” (World Health Organisation, 1994). Although and perhaps precisely because the Guide of the Council of Europe pre-dates the WHO publication, the time-frame for deferral in the Guide continues to deviate from the norms suggested by the WHO for an unexpectedly long stretch of time over the following years. The decision to defer only based on the 12-month time frame is, in retrospect, particularly significant given that the publication of this first Guide took place in the aftermath of a whirlwind of scandalized reports about infection with HIV through blood donation, as the spread of the epidemic had taken up speed across Europe, and also at a time

when antiretroviral therapy had only just begun to show signs of prolonging life for persons living with the virus. Given that the “window period” of the earliest HIV test was estimated to be between three and six months, this discrepancy between the 12-month and permanent deferral practices demonstrates that the application of the precautionary principle varied based on the convictions of policy-making bodies, which were likely influenced by the degree of influence of their policies, the political pressures that they faced about their positions, and the amount of residual risk of infecting blood donation recipients that they were willing to accept.

Although effective antiretroviral therapy became available around this time, the 1995,<sup>12</sup> 1996, 1997<sup>13</sup> and 1998 Guides were only slightly modified. Only in 1999 was it stated in the subsection on AIDS that “the information provided may vary between countries according to the local epidemiological data” (Council of Europe, 1999, 28). While this statement might be read to suggest that so-called “risk groups” or “risk behaviours,” and thus also figures of risk, should vary across the region in conjunction with available epidemiological data, an enhanced variety of figures became decipherable on the European level for the first time in the same Guide as the sample questionnaire was expanded and rendered more categorical. In particular, the newly formulated questions read:

Have you read and understood the information on AIDS and hepatitis?

Have you ever injected drugs?

Have you ever accepted payment for sex, in money or drugs?

For men:

Have you ever had sex with another man?

For women:

To the best of your knowledge has any man with whom you have had sex during the past 12 months had sex with another man?

During the past 12 months:

Have you had sexual contact with:

a partner who is HIV positive or has hepatitis?

a partner who has injected drugs?

a partner who receives payment for sex, in money or drugs?

These questions presented to donors are designed to elicit the history of unsafe sexual practices. A positive response will in general lead to a deferral for 12 months, but each case must be considered on merit (*ibid.*, 39-40).

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<sup>12</sup> Instead of writing “those with unsafe sex practices” in the section about AIDS, which otherwise remained the same, the authors wrote “those indulging in unsafe sex practices,” thus injecting a religious character and another level of moral judgement. This wording continued until the Guide of 2004. No sample questionnaire was included in 1995 and 1996.

<sup>13</sup> It was recommended for the first time that potential donors receive information about hepatitis B in addition to AIDS.

“Unsafe sex” thus became, specifically, the act of sex between men, or sex with (1) a person living with HIV or with (2) persons engaging in any of the listed behaviours. Targeted citizens are no longer expected to assess their own risk themselves and then refrain from donation on their own; instead they are introduced and guided through the world of risk by the authors and administrators of the questionnaire, and are denied or awarded the right to donate by an external authority. We are thus talking about a passive (responsibilised) rather than active (responsible) citizen. Moreover, the previously introduced 12-month time frame persisted for “unsafe sexual practices” despite the fact that a 1998 Council of the European Union recommendation (which is different from the Council of Europe) called for the permanent deferral for prospective donors who have a history of “sexual behaviour which places them at a high risk of transmitting infectious diseases, including persons who have had sex in return for money or drugs” (Council of the European Union, 1998, 22). In addition, therefore, this Council of the European Union recommendation might help to explain why being paid for sex came to be explicitly articulated as a practice of risk on the European level as of the afore quoted 1999 Guide. Finally, with regards to the concluding sentence, one is left to wonder about the exceptional narratives that might “merit” an ability to donate, a wording that persists in the subsequent Guides up until 2002 and underscores the moral tenor ascribed to such an outcome.

In an attempt to make the chapter on “Selection of Donors” more “user-friendly”, a new structure was implemented in the 2001 Guide that relied on a three-tiered time-based deferral scheme, each depicted in its own page-size box. These included: “conditions leading to permanent deferral (rejection)”; “conditions leading to temporary deferrals (suspension)” and “conditions requiring individual assessment.” Consistent with the previous Guides, “Any history of injectable drug abuse” was grouped as a condition for permanent rejection (Council of Europe, 2001, 33). The other groupings of interest to us, however, which were all entirely excluded from the scheme, were presented as before in the information about AIDS and in the suggested questionnaire – both of which remained largely unaltered. With the introduction of a section entitled “Questions related to HIV/HBV/HCV infection risk,” the authors began to think about HIV together with hepatitis B and hepatitis C, and indeed they came to equate the recommended questions to ask in relation to each virus, and thus also their routes of transmission and perceived figures of risk. This shift followed a recommendation in the 1997 *Guide* that potential donors receive information about hepatitis B in addition to AIDS. With both of these changes, we see a gradual de-exceptionalisation of HIV as the primary factor structuring donor deferral (Smith & Whiteside, 2010). Given that both hepatitis B and

hepatitis C had pre-existed AIDS, and donation authorities of the time did not see a need to adopt this expansive screening and deferral policy to attempt their elimination from transfused blood components – which Farrell labels a “zero-risk mindset” (2012, 176) – one might also describe this shift as one in which hepatitis B and hepatitis C became newly exceptionalised.

Under a new heading, “Questions related to lifestyle risk,” the following question appeared in the 2001 guide, which had previously (since 1997) been posed in the questionnaire as part of a general medical history assessment: “Have you had a sexually transmitted disease” (Council of Europe, 2001, 47)? As of 2004, this question was moved to the section bringing together “Questions related to HIV/HBV/HCV infection risk” (ibid., 51-52), and the notion of “lifestyle risk” was forever eliminated from the Guide. The fact that this occurrence was temporarily categorized under the rubric of “lifestyle” before it was incorporated in with the other factors of risk for HIV/HBV/HCV reveals how viral infections like HIV were linked, not just with behaviours, but also how – likely assumed but unspoken in the framings of previous authors – they and their associated behaviours of risk were equated with what were understood to be forms of life and ways of living.

In 2006, the temporally-bound figures of risk as per the Guide of the Council of Europe underwent a noteworthy transformation with impact that continues through to today. For the first time integrated into the group of conditions leading to permanent deferral were now “Persons, whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood,” a change that runs contrary to the more recent shifts described at the start of this text and also to the continued development of HIV tests with ever more precision, such as the NAT test, which was introduced into European countries starting in 1999 (Laperche, 2005; Rekha & Neelam, 2014). While this change put the Council of Europe in line with the aforementioned 1994 WHO policy, it was likely more influenced by the 2004 Directive of the Commission of the European Union, which stipulated how to implement a preceding EU document on the standards and specifications relating to quality systems for blood establishments. According to the implementation directive, which was a binding document unlike the policy and Guides of the Council of Europe, “Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood” (the exact same wording as in the 2006 Guide) are among the conditions that demand permanent deferral (Commission of the European Communities, 2004, 32). Importantly, the behaviours implied in this statement again become clear in the sample questionnaire of the Guide, which remains largely unchanged, whereas the EU

Directive makes ongoing reference to a needed questionnaire but provides no corresponding model.

One can trace in the transition from the 2007 to 2008 Guides the shifting tensions between rights, health and financial burden (of the newest testing technologies of the time, but also of possible legal fees in the case of iatrogenic infection) that emerged with interventions by activists and scholars concerning the blanket exclusion of men who have sex with men from the possibility to give blood, and the resistance with which they were faced by blood donor authorities. For example, a new text was introduced to the 2007 chapter on the selection of donors which read, "Since blood establishments are ultimately responsible for the quality and safety of the blood components collected, blood establishments must be entitled to decide on the final acceptance or deferral of a donor or a prospective donor, considering that giving blood shall not be considered as 'a human right'" (Council of Europe, 2007, 14). In the 2008 Guide, alternatively, which was for the first time published by the European Directorate for the Quality of Medicines, the final part of the sentence was adjusted to conclude, "considering that the right of blood recipients to the protection of their health and the resulting obligation to minimise the risk of transmission of infectious diseases override any other consideration including individual's willingness to donate blood" (EDQM, 2008, 57-58) a formulation that was laid down by a 2008 Council of Europe Resolution on donor responsibility and on limitations to donation of blood and blood components (Council of Europe, 2008). In its social dimension, the assertion that blood donation was not a "human right" was not aligned with its earlier portrayal by the Council of Europe as an expression of solidarity. Indeed, this tension might explain its reformulation in the language of "individual will" rather than "human rights." Likely influenced by the still expanding human rights framework in Europe at the time, the political focus explicitly shifted away from arguing against the rights of the donor to protecting the rights of the recipient. In this way, the recipients of donation are constructed as a group worthy of rights, whereas the donors are conceived to be individuals who act out of will and not out of obligation to the community of whom they are a part.

In 2009, the bulk of the information that had been presented in the previous Guides were re-imagined and presented as "Principles," referring to "background information that has been considered in forming policy decisions as well as educational aspects; it provides information on 'why and how'". Putting the Guide in alignment with the European Pharmacopeia and European Commission Directives, however, the aforementioned "Standards Section" appeared for the first time in 2009, which supplemented the "Principles Section" and was said to define "what must be done." In other words, this section was meant to provide, as it was

described in the Guide, “minimum standards”, and was offered as a policy framing to be transposed into the legislation of individual EU Member States. While the three-tiered deferral boxes were moved into the “Standards Section” – including the permanent deferral of “Persons, whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood” – the sample questionnaire, largely unmodified, remained in the section on “Principles”, and thus continued as a suggested but not mandatory, minimum tool.

Starting in 2010, the Guides were published every two to three years rather than annually. A final shift took place in the 2015 publication with the introduction of yet another section called the “Good Practice Guidelines,” developed in 2013 by the European Commission and the Council of Europe. The questionnaire is moved from the section on “Principles” to the appendices section to become Appendix 1: “Key Criteria for Donor Eligibility.” While the authors of the Guide acknowledge that it “is not possible to provide a generic questionnaire in this Guide” and “blood establishments should develop a questionnaire that is appropriate for local circumstances”, they nevertheless propose (and provide reasons for the) “key eligibility topics for donor inclusion”, which are also translated into questions to be brought up in the donor selection process (EDQM, 2015, 450). The lengthy quote below illustrates some of the key evaluative topics for donor eligibility along with their justification, and core sample questions that have been designed to determine if a person should be deferred from donating blood:

**BLOOD-BORNE RISKS - intravenous use of drugs** → Intent of question: Injecting drug use is an important route of transmission for blood-borne infections including HIV, hepatitis B and C. → Core sample question: Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?

**SEXUAL ACTIVITY - sex worker** → Intent of question: In many countries, sex workers have a significantly higher prevalence of blood-borne and sexually transmitted infections than the general population. → Core sample question: Have you ever received payment (gifts, money or drugs) for sex?

**SEXUAL ACTIVITY - male to male sex** → Intent of question: Male to male sex is associated with a higher risk of HIV. This group also has a higher risk of syphilis, gonorrhoea, as well as infection by hepatitis B and hepatitis A viruses. → Core sample question: For men: have you had male to male sex in the (specified time period)? (For the purpose of this question, sex is defined as oral or anal intercourse with or without a condom.)

**SEXUAL ACTIVITY - female partner of man who has sex with men** → Intent of question: Men who have sex with men have a higher risk of HIV infection and other sexually transmitted diseases. Therefore, women who have sexual contact with men in this group have a higher risk of such diseases than other women. → Core sample question: For women: to the best of your knowledge, has any man with whom you have had sex in the (specified time

period) ever had sex with another man? (For the purpose of this question, sex is defined as oral, vaginal or anal intercourse with or without a condom.)

#### SEXUAL ACTIVITY - **at-risk sexual partner** →

Intent of questions: A donor with a known history of sexual contact with persons in these risk groups has a higher risk of infection by HIV and/or hepatitis. Core sample questions: In the past (specified time period) have you had sexual contact with someone who: - is HIV positive or has hepatitis? - has ever used needles to take drugs, steroids, or anything not prescribed by his/her doctor? - receives or has received payment (gifts, money or drugs) for sex?

Intent of question: Donors who have had sex with a new sexual partner may be at higher risk of infection by HIV and other sexually transmitted diseases. Optional sample question: Have you had sex with a new partner within the past 4 months?

Intent of question: Some countries have a high prevalence of HIV. Sexual contact with residents or former residents of those countries is a risk factor for HIV exposure. Optional sample question: Since your last donation (or, if a new donor, in the last 12 months) have you had sex with a new partner who currently lives or previously lived in another country? [...]

OTHER BLOOD-BORNE RISKS - **positive infectious disease testing** → Intent of question: HIV, hepatitis B, hepatitis C and HTLV are transfusion-transmissible infectious agents, and all may be transmitted between partners by sexual or blood contact. Core sample question: Are you or is your partner positive for HIV, hepatitis B, hepatitis C or HTLV (ibid., 465)?

As we see, the Council of Europe has come to add an elaborated justification for the exclusion of certain groups, and thus for the various imagined figures of risk. As rights-based arguments have escalated with regards to the blanket exclusion of groups of persons from donation, especially concerning the exclusion of men who have sex with men, and given that various anti-discrimination laws were implemented on the European level starting at the turn of the century (Council of the European Union, 2000a, 2000b, 2004; European Parliament, 2006), one might read these detailed elaborations as efforts at precision so as to avoid criticism or legal pursuit.

Importantly, no changes were made to the donor deferral criteria in the subsequent 2017 Guide(s). This is because the 2015 version followed from an important set of meetings and a written report and subsequent resolution, which we turn to in the next section. A close analysis of these documents will serve to provide a context for understanding and analysing the most recent Guide as exemplified in the extended excerpt presented above, and will help to further unearth and critically interrogate the guiding precautionary logics that have accompanied the preceding versions of the Guide as well.

### **Qualifications of Risk**

In 2010, the Council of Europe Steering Committee on Blood Transfusion created an ad hoc Working Group to provide a “harmonised interpretation of temporary versus permanent

deferral and, based on evidence, evaluate a possible differentiation of high risk behaviours” (Ad hoc Subordinate Group of Experts TS057 to the European Committee on Blood Transfusion of the Council of Europe, 2012). Provoking its creation was the mounting pressure from, especially, gay-rights activist groups, and contradicting interpretations of the aforementioned 2004 EU Directive. According to reports on the matter, confusion emerged because the document demanded permanent deferral for “Persons whose sexual behaviour puts them at *high risk* of acquiring severe infectious diseases that can be transmitted by blood” but only temporary deferral for “Persons whose behaviour or activity places them at *risk* of acquiring infectious diseases that may be transmitted by blood” (italics added to both) (Commission of the European Communities, 2004, 32-33). The goal was thus to determine whether a select number of sexual practices put individuals at “high risk” and not just “risk” for contracting HIV, and then to formulate a Resolution and adapt the subsequent version of the Guide by the Council of Europe accordingly. Over the course of four meetings, which were held from early 2010 to 2011, the group evaluated epidemiological and behavioural data, assessed available research on adherence to donor selection criteria, and reviewed the results of existing modelling studies on residual risk and on the spread of sexually transmitted infections.

Although they concluded that “It is impossible to differentiate between ‘high risk’ and ‘risk’ for individual sexual behaviours,” they made the recommendation that permanent deferral should continue for men who have sex with men and for sex workers, the only figures of risk to be considered in the consequent Technical Memorandum (Ad hoc Subordinate Group of Experts TS057 to the European Committee on Blood Transfusion of the Council of Europe, 2012). that summarised their findings. Risk among “heterosexual individuals” was addressed as well, but more as a comparative group than as a possible group to consider for deferral. The resulting Resolution of the Council of Europe concludes that “persons engaging in male-to-male sexual acts and sex workers in many European countries are at the upper end of the risk scale for acquiring HIV and other sexually transmitted transfusion-relevant infections, with the risk classification being totally independent of sexual orientation per se” and “that there appears to be a high risk of acquiring severe transfusion-relevant infections for persons engaging in male-to-male sexual acts and sex workers” (Council of Europe, 2013). It is against this backdrop that one is to understand the quoted formulations in the 2015 Guide, such as “Male to male sex is associated with a higher risk of HIV,” and according to which the term sex might be defined as “oral or anal intercourse with or without a condom” (EDQM, 2015, 458).

The conclusions of the Technical Memorandum, and their translation into the Resolution and the 2015 Guide, take for granted that “male to male sex” and “sex worker” – an uneven pair of descriptors that are based on a behaviour and occupation respectively – constitute essential and cohesive groupings. At the same time, however, the authors note:

the attribution of risk factors to certain ‘at risk groups’ is difficult since risks are not equally distributed among the members of a group. For example, a person who is forced to exchange sex for money or drugs (CSW) on the street in a foreign country has a different risk of acquiring an STI than a person who selects clients themselves and only has 2-3 clients per week and can insist on condom use. Therefore, epidemiological research is increasingly focused on settings, networks or communities. However, for the purpose of donor selection, the term ‘at risk groups’ is still used in this document (Ad hoc Subordinate Group of Experts TS057 to the European Committee on Blood Transfusion of the Council of Europe, 2012, 7).

Interestingly, while the authors of this document acknowledge that risk is not equally distributed in populations classified here as “at risk groups” – thus recognising internal diversity within these populations with respect to their behaviours and HIV vulnerabilities – they still decide to uphold their permanent recommendations about deferral from donation. In this way, they not only capture sex workers and men who have sex with men in the essentialising and homogenising notion of “(at) risk group,” but they also distinguish them from the “heterosexual” population, whose heterogeneity is seen to be a potentially injurious but irreconcilable reality of life that should not inhibit their inclusion into this performative act of citizenship. The authors make apparent here a tension in the translation of research into norm-setting language, and in the individualising logics of human rights or person-centred risk with the need to study the spread of illness and set global benchmarks in the name of public health: How to acknowledge the complexity of real life experience, and yet also set transnational standards about which groups or persons and ways of life pose a risk to the larger society?

In addition, the authors make the basic assumption that sexual “risk” should be defined by the number of sexual partners only, which, over the course of the related meetings and publications, became a stand-in for “sex work” and “male to male sex” *per se*. Indeed, as per the wording in the Guide, the authors of these documents decided to explicitly not define risk based on the type of sexual behaviours that are practiced (such as anal or oral, with or without a condom). While such an approach may be defensible for certain other sexually transmitted infections, research has shown that a number of techniques are in use by sex workers and by men who have sex with men – as well as by a great many other persons – to reduce the risk of contracting or transmitting HIV, such as the use of condoms, or only engaging in condom-less sex with individuals who are of the same sero-status or with a single, monogamous confirmed

HIV negative partner. Although it is true that these various strategies have been shown to be more or less effective at reducing risk of infection, one might point out that they might all introduce new groupings of persons, or new figures of risk, who might rightly be compared with the baseline group of heterosexual individuals to determine if they are at an elevated risk for contracting HIV or other conditions. Rather than to make such a suggestion, however, we intend this exercise to make apparent the underlying logics that serve to imagine the creation of categories of persons in the first place – a fundamentally political pursuit – and to underscore the facility with which select characteristics become stuck to certain of these groupings rather than to others, and are further used to essentialise their distinction and coherence.<sup>14</sup>

### **Conclusion**

Blood, a necessity for human existence, is a deeply symbolic bodily fluid. As part of the broader landscape of that symbolism, we have demonstrated how the development and negotiation of blood donation policies have served to establish a blood donation regime on the European level, which has been inscribed with the name “transfusion Europe” in the political imaginary. Indeed, as we have shown, it might be said that policies regulating the donation of blood have contributed to the fortification of the European project. While this is perhaps especially visible in the strengthening and scope of influence of the Council of Europe, for whom recommendations about blood donation became a way to establish a form of institutional authority in the field of health enhancement and protection, this text demonstrates how the different European institutions ultimately came to cooperate on the regulation of donation.

For some European Parliamentarians, the act of donation has come to embody an act of European citizenship, it serves to (re-)create an altruistic European subject, and assisting in the protection of recipients of blood components has become a responsibility of European and not just of national or local policy makers. Herein lies a first moral dilemma of blood donor

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<sup>14</sup> To be sure, the Memorandum is interesting for what has been excluded as much as for what has been included in its analysis. Although its focus becomes about risk via sexual behaviours, the Directive to which it makes reference also addresses any “behaviour or activity” that can place one at risk of acquiring infectious diseases. Similarly, the authors present a table of diagnosed HIV infections among persons who use injecting drugs in Europe, but then never return to that particular figure again throughout the text, and they entirely neglect questions of deferral based on the migration from, or travel to, so-called high prevalence countries. Moreover, there is an absence of discussion about the actual number of cases of HIV transmission through transfusion in each context, and of the amount of time since a given episode of exposure according to which the most recent testing technologies are able to detect a possible infection. One would think that these figures would be essential to understanding the role of time in the assessment of transfusion-related risk.

regulation: the need to both protect the public from illness and to protect the individual from discrimination. In that this dilemma concerns a tension between individualistic freedom (liberalism) and the public good (democracy), we propose that this may be a fundamental tension that lies, not only in the centre of public health policy, but also of contemporary liberal democracy.

While blood donation officials may have always taken up efforts to limit the risk of illness by way of donation, widely mediated infections in relation to the emergence of the HIV epidemic sparked a new type of societal fear. Generally labelled a “crisis”, as we have shown, these developments destabilised trust in the governing of donation, thus provoking a shift in its moral economy. In their responses, authorities turned to the precautionary principle, an approach to managing uncertainty that came to favour donor restriction in the name of protecting public health. When one considers the terminology that was used and the indiscriminate exclusions that it provoked – especially given the artificially constructed groups that were impacted, and their remarkably dissimilar practices – it may have been inevitable that this zone of action was based on moral values and not just on technical know-how. This is the second moral dilemma that we identify, which might instead be called a “dilemma of morals” in that the dilemma concerns the very presence of morals rather than competing moral investments.

Recent activist efforts have provoked transformations in national donor restriction policies. As some groups of persons are newly able to donate under certain conditions, other groups are newly deferred from the prospect of donation. The term “figures of risk” was offered to describe those groups of persons who have been denied the possibility to donate due to their national origin, identity, profession or behaviours that are seen to somehow pose a risk to the safety of the blood supply in European countries. In the shifting terms that are used to dictate their deferral, we argue, these figures are continually brought into existence. Concomitant with these national and local changes have been shifts in the norms and recommendations of the European blood donation regime. Through a collaboration between the EDQM and the Commission of the EU, this regime has come to be centred around a set of EU Directives and Good Practice Guidelines, both of which make reference to the regularly updated *Guide to the preparation, use and quality assurance of blood components* (the Guide) by the Council of Europe.

Four important shifts concerning the “figures of risk” in the Guide were decipherable. The first concerns shifts in the temporal quality of these figures, which has been in a direction that

runs contrary to the increasing precision that was made possible by improved testing capabilities. The shift from a 12-month to permanent deferral for certain groups of persons may be due to pressures from other transnational health governing bodies, but a more precise explanation remains to be identified. This is especially noteworthy given the current maintenance of a permanent deferral for certain groups of persons even as select European countries begin to shift to a 12-month (or less) time frame. This holding onto the past despite the possibilities of change might be a particular translation of the precautionary principle. However, it might be said that the amount of uncertainty about donation has decreased with a growing body of research showing that a reduction in deferral time does not increase the risk of transmission, which could come to undermine the legitimacy of the precautionary principle and thus the current European blood donation regime.

Secondly, the Guide came into existence in relation to the exceptional status of HIV, and yet it also documents the progressive de-exceptionalisation of the virus. The shifting figures of risk that were imagined in relation to the HIV epidemic became gradually blurred together with those groups of person who were thought to be at an elevated risk of other blood-borne illnesses - first with hepatitis B and hepatitis C, and then also with HTLV, the Human T-lymphotropic virus. In the context of European blood donation regulation, the HIV-related figures of risk thus came to apply to each of the viruses indiscriminately. This process - of developing a particularly robust health-governing structure in response to HIV, and then expanding that structure to other, also previously-existing illnesses - can be observed in other contexts of health promotion in Europe as well.

What becomes apparent in the context of blood donation policies is that these expansions have been dissimilar across contexts - as select guidelines include data about Syphilis or *Treponema pallidum* in the tabulation of an acceptable "window period" for the figures of risk that were borne out of the early HIV era - and create the impression that the variously grouped together health conditions somehow pose the same risk to the safety of donation. Are curable and incurable conditions equivalent in this regard? And given the message and underlying evidence of the recent U=U campaign,<sup>15</sup> to what extent does an undetectable HIV infection still indicate a risk of infection through transfusion? In short, how do the levels of acceptable

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<sup>15</sup> 'Undetectable = Untransmittable (U=U)' is an advocacy campaign initiated in 2016 by the Prevention Access Campaign (Prevention Access Campaign, 2016a) with the publication of a consensus statement entitled, 'The Risk of Sexual Transmission of HIV from a Person Living with HIV who has an Undetectable Viral Load' (Prevention Access Campaign, 2016b). The campaign brings together advocates, activists, researchers, and over 525 Community Partners from 70 countries mobilised around the message that people living with HIV on effective treatment do not sexually transmit HIV.

risk change based on the futurity of an illness? And how do the moral economies of the past continue to influence our understanding, not just of HIV, but also of the illnesses that have become associated with it in the context of donation?

Thirdly, we observe a shift in the type of citizen that these figures represent, and thus also come to constitute: from an active (responsible) citizen who is compelled to self-defer, to a passive (responsibilised) citizen who is obligated to deferral. In both instances, information plays a key role, but in the former it is intended to provide a would-be donor with the knowledge, agency and responsibility to defer on one's own, whereas in the latter it is used to justify deferral due to the possibility of critique or legal pursuit, but also out of a growing expectation that health governing bodies take responsibility for their own actions as much as for public safety. This responsibilisation of the European "state" might also be seen as a reflection of the precautionary principle in action. Moreover, as anti-discrimination law and human rights discourses have gained authority in Europe, the justifications offered in the Guide for deferral have become increasingly precise and elaborated.

Finally, our analysis of the succession of Council of Europe Guides demonstrates the progressive expansion of the types and precision of behaviours that came to be targeted by blood donation authorities. Taking on an almost confessional character, the questionnaire is used to identify and enquire about particular (largely stigmatised, sometimes even criminalised) behaviours in which people engage, and it thus enables a particular type of "epidemiological profiling" in the donor screening process. Those persons who come to be subsumed within these figures of risk, in other words, become perceived vectors of possible illness due to their membership within a progressively elaborated range of social groups, which are defined by an ever more detailed set of behaviours. As a result, the associated figures of risk became increasingly varied, solidified and provided with particular form. However, despite this heightened variability and precision, groups of deferred donors remain constrained by the homogenising and essentialising logics as have been mapped out above.

To conclude, the privileging of precaution and of protecting health over equality has created a particular blood donation regime that centres around the constitution and exclusion of "figures of risk." Critical discussion about the limitations of ongoing donor restriction practices have been largely limited to a focus on gay and other men who have sex with men, and they tend to focus on the issue of discrimination and on national level policies exclusively. This paper has made clear that these figures concern a much more vast collection of persons - including migrants, sex workers, persons who use drugs and persons living with

HIV - and that deferral in the form of any time frame might not only be grasped through the individualising logics of discrimination, but that it also concerns the possibility to enact solidarity and participate in the (European) community. It has thus been our intention to render more complex and further re-invigorate these conversations as they concern the European context. Moreover, we hope that the above analysis underscores how dynamics of the past continue to shape both the blood deferral policies of the present and the imaginings of the future that such policies entail.

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