Blood, sex and trust: the limits of the population-based risk management paradigm.

Keywords: Blood donation; HIV; risk-group; trust; MSM

#### Abstract

Blood screening is imperfect so Donor Health Check questionnaires (DHC) are used to defer those whose 'behaviour' suggests disproportionate risk of Blood Borne Infection (BBI). Taking the UK case, we compare deferment of three sub-populations with different HIV prevalence; Men-who-have-Sex-with-Men (4.7%), black-Africans (3.7%) and 'the-general-(heterosexual)-population' (c.0.09%) arguing that, with respect to STIs, DHCs assess risk based on broad population-level risk-groups not behaviour. This approach relies on an imaginative geography that distances heterosexual risk from the domestic population. Most DHCs knowingly commit the ecological fallacy allowing population-level statistics to obscure within-group diversity, identifying inadequately the risk posed by 'low-risk-groups'. The disjuncture between ontological risk phenomenon (diverse sexual practice) and the epistemological grid used to map risk (homogenized risk-groups) needs examination. Unpacking the category 'heterosexual' would both better differentiate risk within this group and change the relative-risk calculated for 'high-risk groups'. We call for practice-based DHCs that more accurately assess all potential donors.

#### 1. Introduction

During the HIV/AIDS crisis of the early 1980s bans preventing men-who-have-sex-with-men (MSM) donating blood were introduced in many parts of the world. However, as bloodscreening technologies have improved, so calls from activists, politicians and clinicians for the lifting of these bans have increased. Over the past decade, many countries have shifted from indefinite deferral of MSM to time-limited deferral: New Zealand now allows MSM to donate 5 years after their last same-sex contact; Australia, Brazil, Hungary, Japan, Argentina, and Sweden ask MSM to wait 12 months, while South Africa operates a 6 month deferment. In the United Kingdom (UK), a long campaign by Human Rights Organizations, the National Union of Students, and even the Royal College of Nursing, urged reconsideration of the blanket deferral of MSM. In 2009, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) was charged with reviewing MSM blood donor policy. In 2011 they recommended a change from indefinite to a 12-month deferral since last MSM contact<sup>1</sup>, and this proposal was subsequently adopted in England, Wales and Scotland (but rejected in Northern Ireland).

Despite this trend toward time-limited deferral, the logic applied to MSM remains little changed because of the way prevalence is calculated and risk is imagined. Drawing on the UK as an example of an internationally dominant paradigm this paper demonstrates the logical inconsistencies and scientific limits of current blood donor risk evaluation. The UK Blood Service claim their approach is based on 'the best available scientific data' (NHSBT 2013) but we believe there is a need to examine rigorously in what those data consist so as to explore the degree of fit between the epistemological frameworks of measurement and the ontological phenomena under investigation. This paper, therefore, interrogates the UK Blood Services' Donor Heath Check (DHC – a pre-donation questionnaire used to triage potential donors) as it selects for two sub-populations with elevated HIV prevalence (MSM and Black Africans)<sup>2</sup>, and their relation to a third group: 'the general heterosexual population'. As we will argue later, broad imaginative geographies about the location of HIV appear to inform the mapping of risk at the population level.

While some sections of the DHC assess *actual* risk to donor or recipient, risk from sexual activity is largely *assumed*. This requires re-thinking. Currently, risks posed by blood borne sexual infections are mapped onto broadly defined population categories (often described as 'risk-groups') and geographic regions – such as MSM vs. heterosexual, and domestic vs. foreign – rather than onto the ontologically relevant sexual acts through which HIV, Hepatitis and other infections diffuse. As a consequence the current approach knowingly commits the 'ecological fallacy' (Robinson 1950) – making inferences about individuals based on the groups to which they are said to belong (see Cascio and Yomtovian 2013). This

<sup>&</sup>lt;sup>1</sup> The definition of 'sexual contact' used by the UK blood service is "anal or oral sex (with or without a condom)".

<sup>&</sup>lt;sup>2</sup> 'Black African' is a category of the UK census that marks ethnicity (others include 'black Caribbean' and 'black other'). The category is also used by the UK Health protection agency to organize surveillance data on public and sexual health.

applies to those assumed to present a 'high-risk' but also to those believed to present 'lowrisk.'

Aligning pre-donation questionnaires to population profiles rather than to behaviors means that current procedures fail to capture the relevant risk profiles of *all* would-be donors. Furthermore, much of the epidemiological literature surrounding blood safety appears to assume a problematic division between blood donors and recipients (Galarneau 2010) – presenting the image of the blood donor as motivated by a fragile altruism that would not withstand more ontologically relevant questions about sexual risk taking. In contrast, we call for the piloting of a more practice-based pre-donation questionnaire that can identify the high-risk donors in all population groups, that can function as a more effective *self*-deferment tool and that will present 'donors-as-potential-recipients' with information that is consistent with programmes promoting sexual health. More broadly, in an era of enthusiasm for 'big data' (ESRC 2012: Kalil 2012), our analysis offers a timely reminder that data are only as good as the ontological assumptions and epistemological grids used to generate them.

# 2. The dominant paradigm of risk evaluation and continued controversy over deferment policy

Recent decades have witnessed advances in the clinical screening of blood and in the epidemiological modeling of risk, yet there remains a chance that blood will be donated during a 'window-period' where viral infections cannot be detected – e.g. it takes 9 days post exposure before Nucleic Acid Testing for HIV virus becomes effective (Wainberg et al., 2010). Because of this limitation, pre-donation questionnaires are used to manage risk by deselecting would-be donors whose gift is judged disproportionately risky – in particular, at risk of containing a Blood Borne Infection (BBI). As elsewhere, the UK's National Blood Service (NBS) use such a questionnaire to identify would-be donors whose 'lifestyle and medical history' suggests they may be more likely to have contracted a recent BBI. Potential donors are trusted to answer truthfully a range of questions, the answers to which may lead to their deferral (see table 1). Therefore, as Titmuss (1970: 163) observed more than 40 years ago, a core question for ensuring the safety of the blood supply is: "what particular set

of conditions and arrangements permits and encourages maximum truthfulness on the part of donors?" Consequently, trust and truth-telling remain central to the work of blood agencies around the world, because whichever questions are asked – they rely ultimately on donor honesty. The risk arising from blood transfusion must be communicated to the public in a simple-to-understand manner so that donors at higher risk, and with them a *proportion* of BBI infected blood, can be prevented from entering the supply in the first instance. Many DHCs are now online (see www.blood.co.uk/can-i-give-blood/donor-health-check/) meaning opportunities for stimulating efficacious self-deferral have increased.

Until the 2011 policy review, "men who had ever had oral or anal sex with another man, even if a condom was used" (NHSBT 2011a) were deferred indefinitely. This policy had its roots in the fog surrounding the emergence of HIV/AIDS. In March 1981 a cluster of young gay men in New York and California were diagnosed with Kaposi's Sarcoma (a rare cancer associated with much older men of Mediterranean origin) and Pneumocystis carinli pneumonia infection (a common fungal infection of the lung which seldom develops into pneumonia in those with a healthy immune system). By the end of 1981, these same symptoms had been found among gay men in Europe and among injecting drug users. In the early eighties what we now call AIDS was largely known as GRID (Gay Related Immune Deficiency) and its etiology and mechanisms of diffusion were unclear, with some early theories positing it was caused by an immune system compromised by the stresses of 'gay lifestyle'. The virus eventually called HIV was isolated in May 1983 but was not confirmed as the cause of AIDS by the US Center for Disease Control and Prevention for almost 12 months. By this time, media speculation had helped cement the idea that AIDS was a 'gay plague' and the 'inevitable consequence' of a 'gay lifestyle' (Treichler 1999). By 1989 some 1700 people had contracted HIV as a result of a contaminated blood transfusion in Britain alone (Weinberg et al., 2002) and the blood service was accused of using 'killer blood'. While there is now an understanding that HIV is not confined to the MSM population the association between HIV (and other sexually transmitted infections) and MSM has proved hard to change (it is rarely stated that 95.3% of MSM are not living with HIV).

However, since these early moments in the AIDS crisis blood screening has improved markedly – in the UK there have been no instances of HIV spread through blood transfusion

since 2002 and no recorded instances of any viral transmission since 2005 (DOH, 2011). These improved screening technologies have prompted a growing number of activists, clinicians and politicians in the UK and internationally to call for revision to donor selection policies, pointing out that they exclude MSM on the basis of their group membership rather than any specific high-risk sexual behaviours (see Tatchell, 2008; Kerry, 2010; Wainberg et al., 2010). Rights campaigner Peter Tatchell (2008) neatly summarised the prevailing critique:

...a total ban...lacks scientific credibility and medical justification...[it] is based on the ill-informed, homophobic presumption that all gay and bisexual men are "high-risk" for HIV, regardless of their individual sexual behaviour. This is nonsense. Most gay men do not have HIV and never [will].

Meanwhile, defenders of MSM deferral insist it is not, and never has been, homophobic because it rests "on specific sexual behaviour (such as oral or anal sex between men) rather than sexuality...[thus] there is... no exclusion of gay men who have never had sex with a man, nor of women who have sex with women...."(NHSBT 2010 ). Futhermore, epidemiological data consistently show heightened HIV prevalence within the MSM group. Nevertheless, as a result of mounting pressure a policy review was begun in 2009. Reporting in late 2011, it found that more sophisticated epidemiological modelling and improved BBI detection meant that the risk presented by MSM donors was insufficiently high to justify their continued indefinite deferral. Rather, MSM who meet the other donor criteria should be allowed to donate 12 months after last MSM contact (SaBTO 2011). This move from indefinite to time-limited MSM deferral follows similar changes elsewhere, and the prevailing consensus seems to be that while remaining a keenly debated issue, deferral policy is now more consistent across all 'high-risk groups' (e.g. Watkins et al. 2011, NHSBT 2011a).

We disagree. The 12-month deferral does not explicitly address the diversity of risk profiles and continues to exclude all sexually active MSM (see Brooks 2011) irrespective of their actual sexual practice (Cascio and Yomtovian 2013). However, while all science is situated within society and thus cannot be separated from questions of ethics and justice (see debates in *American Journal of Bioethics*, 2010, 10: part 2), and while aversion to *any* risk emerging from the MSM group is a legacy of the mistakes in the 1980s (Caplan 2010), we do not wish to present a 'rights-based' critique of deferral policy (see MCT, 2009; RCN, 2011). Indeed, legal scholars have shown there is no clear *right to donate*, whereas recipients of blood products *do* have a legal right not to be harmed by blood products (Franklin 2007; SaBTO 2011). These rights are firmly anchored in European law (Committee of Ministers 2008), and the UK Consumer Protection Act 1987 (UKBTTTS 2010). Moreover, the UK Equity Act (OPSI 2007) explicitly exempts those running blood donation facilities from the injunction against discrimination on the basis of sexual orientation (one of the very few such exceptions in the Act) *so long as such discrimination is based on reasonable scientific evidence*. Finally, key international legal test cases have found that despite 'detriment' to MSM, deferment policies are objectively 'reasonable' *when based on science and when they facilitate safety* (MCT 2009) (our emphais).

The critical ground for blood donor selection is not rights but science: It is the 'best scientific evidence' - on which donor selection is based (see NHSBT 2010, 2011a), on which selection criteria are reviewed (SaBTO 2010, 2011), on which third sector organization assent is secured (THT 2010), on which exceptions to the UK Equity Act explicitly depend (OPSI 2007), on which potential donors are asked to accept deferral, and most importantly, upon which recipients of blood products are asked to place their trust.

Given how much rests upon it, it is significant that the United States Advisory Committee on Blood Safety and Availability (ACBSA 2010) recently declined to change permanent MSM deferment, *not* because extant research provides sufficient evidence for existing policy, but because they provide an insufficient basis on which to revise it (ACBSA 2010). In fact the committee concluded that indefinite MSM deferral is "suboptimal in permitting some potentially high-risk donations [from heterosexuals] while preventing some potentially lowrisk donations [from MSM]" (ACBSA 2010) and called for more research to facilitate donor selection policies (see also MCT 2009). Certainly new data are needed in the UK as much as the US, but we argue that researchers must first interrogate *thoroughly* exactly what constitutes 'the best scientific evidence' and whether the population paradigm is sufficient to capture the risk posed by all potential donors; this is not an agenda that is made explicit by either ACBSA or the more recent SABTO review. The dominant epidemiological paradigm of risk evaluation needs to be unpacked because it fails to address adequately the degree of fit between its epistemology of group-based deferment – grounded on aggregate epidemiological data at the population level – and the ontology of actual risk – embedded in the heterogeneous complexity of individual practice.

#### 3. The limits of pre-donation questionnaires

Pre-donation questionnaires perform a reverse triage – attempting to prioritise the least risky to donate. Triage is necessary because testing, although improved, remains imperfect (e.g. mislabeling, handling and storage errors cause a small number of complications and even deaths annually – see Germain et al 2003; Murphy et al., 2009; Brooks 2011), and because blood services seldom have the budgets to adopt all new screening technologies (see Forsythe & Cardigan, 2009; Simmonds et al. 2002; Weinberg et al. 2002). Triage is context dependent; where supply is limited and demand great (as with rare blood types and organ donation), fewer donors are rejected and screening is supplemented by detailed review of individual medical histories. The remaining risk of 'window-period' donation is subordinated to recipients' desperate need (Forsythe & Cardigan, 2009). In situations of more reliable supply it is expedient to defer those whose donation is assumed more likely to test positive, as long as those categorised as 'lower-risk' provide sufficient blood to meet demand (Allain & Williamson 2007).

Triage is a vital tool to manage (because it cannot eliminate) relative risk, but central to its utility are the questions and categories used to rank potential donors. Some questions in the UK DHC positively select *for* good donors (e.g. age, absence of illness etc.): Others, which concern us here, attempt to manage risk by *excluding* donors thought more likely to carry a BBI (e.g. recent tattoo, intravenous drug-use, sex with an HIV positive person). However, both kinds of question are under-utilised with respect to gathering relevant information about the risk posed by blood borne Sexually Transmitted Infections (STIs). Ontologically, risk of acquiring any particular STI emerges from three connected, practice-related variables: (1) the likelihood that one's sexual partner(s) are carriers; (2) the type of sexual activity undertaken; and (3) the frequency of exposure. Thus to assess accurately the risk presented by an individual donor one would need to know some tangible information about

their actual sexual practice *and that of their partner(s)*: Has either had a large and diverse number of partners, or have both been monogamous for a period? Has either engaged in a higher risk sexual activity (e.g. unprotected receptive anal intercourse – which carries a higher risk of HIV infection than similar vaginal intercourse), or has the donor consistently pursued safer-sex (e.g. condoms reduce risk by 80-90% while oral sex is very unlikely to transmit HIV infection – MCT, 2009: 176)?<sup>3</sup>

On closer inspection, it is clear that the UK DHC (like most pre-donation questionnaires) does little to capture the interaction of these variables because it asks few ontologically relevant questions about *practice*. Instead, questions are primarily designed to assign individuals into population *risk-groups* that are more or less associated with BBI risk (see also Cascio and Yomtovian 2013). It is membership of a high-risk or low-risk group (e.g. practicing MSM/non-practicing MSM/heterosexual) and not practice *per se* that determines whether a donor is deferred.<sup>4</sup> However, the language of 'practices and lifestyles' so often used to explain deferral policy to the public obfuscates the issue. Rather than identify the absolute risk presented by an individual, the DHC as triage focuses on assigning a donor to a risk-group (e.g. practicing MSM, commercial sex worker, migrant).

# 4. The limits of epidemiological modelling

The operationalization of risk behaviours, groups and contexts remains overly simplistic and leads to sub-optimal policy. To illustrate, we compare two subsections of the UK population with similar HIV prevalence; MSM (4.7%) and black-Africans (3.7%), and consider how judgements of relative risk are reliant on a third group - 'the-general-(heterosexual)-population' (c.0.09%) (HPA 2012, 2010a – all prevelance rates include estimates of those living with undiagnosed HIV).

<sup>&</sup>lt;sup>3</sup> The qualities of the anal environment, such as concentration of CD4 cells that are targeted by HIV, and the proximity of the anal site to the gut where initial invasion and replication occurs, explain why anal sex is more risky (Baggaley et al 2010: Beyrer et al 2012). In HIV discordant couples the peract risk of anal sex is 18-times higher than for vaginal sex for the receptive partner. The infectivity risk of unprotected *receptive* anal sex is estimated to be 1.4% per-act and 40.4% per-partner. The risk of *insertive only* unprotected anal sex is estimated to be 21% per-partner, while that for unprotected receptive oral sex is 0.04% per-act (Baggaley et al 2010: Beyrer et al 2012). <sup>4</sup> The question used to identify men as MSM conflates oral and anal sex, and ignores condom use, monogamy and multiple partnering.

Despite both MSM activity and black-African ethnicity being markers of significantly higher HIV risk, the deferment policy toward each group has been markedly different. Before MSM deferment was reduced to 12 months, African migrants were already allowed to donate after 12 months UK residence/last sexual contact with someone from a high HIV prevalence region. While elevated HIV prevalence attaches to the entire category the greater tolerance to the risk presented by black-Africans (a group excluded from the recent review - SaBTO 2011: 9), can in part be explained by low supply and high demand for rare blood types: black-Africans are courted as "VIP donors" because they are more likely to have type Bblood and, along with others of African genetic heritage, are the only source of type Unegative blood (NHSBT, 2011b). By comparison, the genetically diverse MSM group has no correlation with rare blood types at a population level and so the risk/benefit calculation behind past permanent deferral was that MSM "donor loss can be tolerated" (Allain & Williamson, 2007). This said, type B-blood is common in the more numerous and lower-risk Asian population, and donations from black-Africans are not restricted to those with type B or U-negative blood (c.1 in 400), or to men (twice as many black-African women are newly diagnosed with HIV - HPA 2012). To explain fully the past and present differential deferral policies, one must understand the role that context plays in the constitution of 'risk-groups'.

Because in the UK most black-Africans present late, and therefore at a more advanced clinical stage of HIV infection (Erwin & Peters, 1999), it was assumed (until recently) that seroconversion is predominately historical; with perhaps 68% of black-African HIV transmission occurring outside the UK (HPA, 2008b, 2010a; SaBTO 2011). Consequently, a 12-month deferral after traveling from a region of high HIV prevalence (or sex with a partner who has so travelled), has been deemed reasonable to avoid window-period donations. This assessment cannot be based on any impact that assimilation into the UK milieu may have on sexual practices *per se* because, we re-emphasise, the DHC does not ask questions about actual sexual practice. Instead, the DHC simply determines whether a donor can be connected to a risk-group or a geographic region of risk via a sexual partner (*inter alia* commercial sex worker, BBI carrier, MSM, recent migrant from high-risk area). Thus, the 12-month deferral of black-Africans appears to be based on the assumption that (unless stated

otherwise in response to DHC questions), migrants of 12-month residence draw partners from the lower-prevalence UK 'general (heterosexual) population'.

By contrast the model *still* applied to all MSM is endemic and proximate: 82% of MSM transmission is estimated to occur within the UK and when diagnosed, is more likely to indicate a comparatively recent seroconversion (HPA, 2009 - although a compressed time between exposure and diagnosis also reflects the positive uptake of STI screening by many MSM). The contextual assumption is that, regardless of specific practice, *any* MSM activity constitutes a high-risk because MSM draw partners from within a high-prevalence population (and condoms are only 80-90% effective and infidelity is always possible – see MCT, 2009). Consequently, population-based statistical calculi predict sexually active MSM as at disproportionate risk of making a window-period donation. Post-2011 deferral rules require MSM to remove themselves entirely from the context of MSM sexual relations for 12 months.

These assumptions would appear to rest on simplistic and unequal understandings of social milieu and on a particular imaginative geography or risk. Analysis of the assumptions underlying risk categories have not always been rigorous as Galarneau's (2010) examination of deferral policy deliberations in the US suggests. In the UK the DHC imagines sexual networking to only one degree of separation, leaving questions about partners' partners unasked. In the case of MSM, entanglement in complex sexual networks is assumed; the presence within 12 months of a single partner from the same population category indicates high-risk. No questions are asked to determine an individual's specific sexual history, and the pursuit of safer-sex (e.g. condom use) is an irrelevance. By comparison, there is no deferral of black-Africans who are sexually active (oral, vaginal or anal; even if a condom was used) with other black Africans.<sup>5</sup> Rather the category is subdivided along geographical lines (practice remains irrelevant): risk and complexity attaches to high prevalence regions and to those who have recently travelled from them; amongst the remainder of black Africans, complexity beyond immediate partners, and the elevated prevalence associated

<sup>&</sup>lt;sup>5</sup> While this would be consistent with MSM deferral it might be regarded as racist to assess people on the basis of *ethnic* categories, the eventual fate in 1991 of the permanent US deferral of Haitians immigrants (Galarneau 2010).

with group as a whole, is ignored. The unstated 'imaginative geography' informing current deferral policy toward 'black Africans' is that the risk of transmission and window-period donation can be distanced 'over there' to the African continent, whilst 'over here', the sexual networks of heterosexual black Africans are indistinguishable from those of the 'general population'. This fails to account for the ethnically segregated geography of contemporary Britain (see Stillwell & Van Ham, 2010) and the probability that many people draw partners from their immediate locality/'community'. Furthermore, it has not been adjusted in response to the most recent surveillance reports which use "a new method of assigning probable country of infection", and estimate that 52% of new heterosexual HIV infections (57% of which were among black Africans) occurred *inside* the UK (HPA 2012: 7). Policy would appear to be inconsistent, and to rest on overly simplistic geographic/risk-group categories that explicitly elide ontologically relevant behaviours and willfully homogenises a broad range of complex sexual networks and practices.

We do not deny that the 'MSM population', as currently constituted in epidemiological surveillance data, suffers from disproportionately higher levels of HIV and other BBI's: as series of epidemiological studies across a range of national settings have shown (Beyrer et al 2012). But our question relates precisely to the way data are constituted. We argue that the 'best science' too often relies on some circular reasoning whereby design, methods and analysis are all structured by the logic of risk-groups. This results in a failure to collect or to analyse key data, pre-determining that the significance of risk-groups will be confirmed. For example, an often-cited study (Sanchez et al., 2005) defended US deferral policy using data from a post-donation survey of 52,650 respondents linked to screening results. The findings showed that 569 donors (1.2% of 25,168 males) were MSM who should have self-deferred. Of these, 6% subsequently had a reactive screening compared to only 1.7% of heterosexual men surveyed (Sanchez et al., 2005: 407-9). However, no data were collected from MSM that distinguished between oral or anal sex, or condom use. Moreover, data on partner numbers was confused by a failure to properly correlate 'last MSM contact' with 'total lifetime partners', making it impossible to estimate partner numbers within any given widow period. Meanwhile, data for heterosexual men did not indicate either partner number or sexual practice. Finally, evidence that the crude BBI prevalence for the heterosexual group was higher than for some MSM cohorts was ignored in favour of an

overriding focused on the risk presented by the 'MSM group'. For all their sophistication, statistical models "[designed to provide]... quantitative tool(s) for blood banks to estimate the impact of certain HIV risk behaviours on the blood supply" (Musto et al., 2008: 52, see also Germain et al., 2003) tend to be characterized by an absence of detailed about actual sexual activities (e.g. for Musto et al. 2008 'MSM' is taken as synonymous with anal sex while heterosexual sex is imagined as exclusively vaginal).

Even in studies where diversity within MSM is recognised the relevance of condom use is marginalised and ultimately, diversity is subsumed in favour of reconfirming the category 'MSM' as high-risk (see Pathela et al 2011: Beyrer et al 2012). Furthermore, assessments of MSM risk are always relational to those calculated for the 'general [heterosexual] population'. This population is too rarely disaggregated, or is disaggregated in ways that primarily reconfirm 'MSM' as a high-risk group. For example, a recent study from New York City (Pathela et al. 2011) reports a headline statistic that MSM face a 140-fold higher risk of newly diagnosed HIV than do heterosexual men. Valid though this statistic may be, we note it is constituted in a particular way: (1) it is geographically specific (relating to a city at the epicenter of the disease - and not necessarily relevant elsewhere): (2) it is based upon diagnoses of HIV rather than prevalence - and while the authors acknowledge that heterosexuals are much less likely to seek HIV screening and therefore more likely remain undiagnosed, no weighting is applied to the calculation to attempt to control for this: (3) It is based on a comparison between MSM and heterosexual men – rather than between MSM and heterosexual women; the fraction of heterosexuals biologically at higher risk via unprotected receptive sex.

Modelled estimations of "risk associated with a particular practice" (Musto et al., 2008: 50) emerge as rather imprecise statistical associations between risk and membership of a broad population group. Like other devices used to map coherent sub-groups onto diverse populations, the category MSM facilitates the search for significant patterns within large data sets, only by simultaneously obscuring multiple other dimensions of experience and behaviour. Whilst simplification is a necessary and reasonable component of science (see

MCT, 2009), in *this* case, simplification obscures practices *directly* relevant to the phenomenon in question.

The tendency in surveillance data to disaggregate inadequately broad population-level categories produces deferral policy that over-emphasises certain variables at the expense of others. Just because identity markers like 'gay' and 'bisexual' are now eschewed, does not mean 'MSM' identifies: "...precisely the [specific] behaviour that leads to an increase in risk..." [Emphasis added] (see Franklin, 2007: 161, NHSBT, 2010, 2011a). Rather MSM emerges as a variable primarily denoting partner choice and says little about type of sex or frequency of exposure (Sothern and Kesby 2011: see also Young & Meyer, 2005: 1147). The grid of risk-groups obscures actual patterns of risk within complex and diverse human sexual practice. Explicit discussion of practice is avoided and practices with very different risk profiles are conflated (e.g. "oral or anal sex... even if a condom was used") (Cascio and Yomtovian, 2013). Individual MSM, even those engaged in low-risker activities (e.g. monogamy and/or condom-use) remain assessed on the basis of the aggregate risk for the MSM group as a whole.

This said, if one drills down into the recent SaBTO review, a greater appreciation of ontological complexity is evident: it is noted (1) MSM practice can be disaggregated – e.g. 50% have only non-penetrative experience, 44.7% only one sexual partner, and only 22% have had penetrative sex in the last 12 months (of which less than half changed partner more than twice – SaBTO 2011: 29), and (2) "societal changes" mean "gay men are...[now] less willing to accept being 'lumped together' as a single risk category irrespective of their own sexual behavior" (*ibid* : 43). Nevertheless, the paradigm for risk calculation remains unchanged: epidemiological modeling studies remain the primary tool (*ibid*: 45-48), and few see an alternative to these "complex [statistical] assessments of risk" (NHSBT 2011a). We are less convinced. To develop our critique further we depart from the usual focus on MSM, and focus instead on the group which sits at the "center of the circle" of risk calculation (Fisher and Schonfeld 2010; 41) but which is so rarely discussed except as the category against which other subgroups are deemed too risky to donate.

# 5. Unpacking heterosexuality

Reviewing numerous studies we were struck by how infrequently authors acknowledge explicitly the contribution that 'low-risk' groups make to over-all incidence of BBIs. A careful reading of Sanchez et al., (2005), reveals that MSM who failed to defer resulted in c.17 infected donations, whereas heterosexual donors made in excess of 400. Yet the authors make no comment about the absolute risk presented by heterosexuals, and offer no suggestion that deferment on the basis of some heterosexual practices might be appropriate. The circular logic of risk-groups stands as the self-evident justification for the paper's focus on the minority MSM group and the argument for their continued indefinite deferral in the USA. Similarly, while the study by Grenfell et al., (2011) disaggregates MSM experience, it too fails to collect or compare data on risk behavior within the heterosexual population. Meanwhile, UK statistics clearly show the greater absolute risk posed by groups conferred 'low risk' status; for example: there are more heterosexuals than MSM living with HIV (51,500 and 40,000 respectively - HPA 2012):<sup>6</sup> in 2009 heterosexuals comprised 63% of all new Hepatitis B cases and 54% of new HIV cases (SaBTO 2011: 20): over 70% of the 23 HIV infected blood donations detected in 2009 (England and Wales) came from heterosexuals (HPA, 2010b). Between 1996 and 2008, of donated blood that tested positive for any marker of infection, 44% came from donors who reported heterosexual sex as the likely source (as opposed to 29% from MSM); crucially, 38.4% of heterosexuals that tested positive for HIV did not report a partner that fell into any 'high-risk' category (SaBTO 2011: 26). Therefore, in discussions of deferral we think it important to acknowledge explicitly Roses' classic observation that: "a large number of people at a small risk may give rise to more cases of disease than the small number who are a high risk [original emphasis]" (Rose, 2001 [original 1984]: 431).

However, our point is not simply that significant residual risk remains even after some of the total risk is eliminated via the exclusion of active MSM. Rather, it is also that the existing practice insufficiently emphasizes that accurate and efficacious measures of prevalence and incidence are entirely reliant on the parameters used to define 'the population' under investigation. As geographers with an appreciation of the 'modifiable areal unit problem' (Openshaw, 1984), we are acutely aware that quantitative data can yield very different

<sup>&</sup>lt;sup>6</sup> Although in 2011 new diagnosis were higher among MSM than heterosexuals for the first time since 1999 and have remained at 2,300-2,500 per year for a decade (HPA 2012).

results depending on what spatial units and/or social categories are used to organize and analyze it. In our view deferral policy not only knowingly commits an 'ecological fallacy' (Robinson, 1950) with respect to practicing MSM it also does so in relation to the general [heterosexual] population: again risk is calculated in terms of the group as whole – except in the latter case large group size greatly reduces an individual's risk when expressed as a percentage. Thus while it is too simplistic to suggest that deferral criteria construct all MSM as 'infected' and others as 'risk free' (see Cascio and Yomtovian 2013), recognition of absolute risk within the majority group is seldom made explicit.

The heterosexual population and heterosexual practice is in fact diverse, but it is too rarely measured in ways that reveal this. Let us take one example to illustrate the point: anal sex is undeniably part of the contemporary heterosexual repertoire, with c40% reporting at least one experience, and 10% (in both UK and US studies) reporting anal sex within the last three months (Javanbakht et al., 2010) to a year (McBride & Fortenberry, 2010). There are indications that prevalence is increasing (Gindi et al., 2008; McBride & Fortenberry, 2010). Meanwhile, condom usage among heterosexuals reporting anal sex tends to be low (c.60% never use), while the same individuals are also more likely to report a history of STIs (Hensel et al., 2010; Javanbakht et al., 2010; McBride & Fortenberry, 2010). Studies in New York found only 38.3% of heterosexual men reported condom use at last sex compared to 62.9% of MSM (Pathela et al 2011) while only 23% of heterosexuals used condoms during anal sex, compared to 61% of MSM (The Body, 2010). This raises the possibility that more heterosexuals practice un-protected anal sex (and within the last 12 months) than do MSM; Halperin (1999 in Baggaley et al 2010) suggested a ~7-fold higher figure in the US. And yet as previously noted, many influential models used to "estimate the impact of certain HIV risk behaviours" (Musto et al., 2008: 52) make no assessment of such practice, conflating heterosexual sex (including that which is transactional or involves people from high-risk regions) with exclusively vaginal sex. Others mention the issue but offer no calculus of the risk (Beyrer et al 2012) despite studies which have suggested that undeclared acts of unprotected receptive anal sex may "explain why no vaginal microbicide has been proven effective in preventing or reducing HIV acquisition" in trials among heterosexuals in sub-Saharan Africa (McGowan and Taylor 2010: 636).

In our teaching we are at pains to critique the ontology of population-based risk-groups, encouraging students to deconstruct the category 'heterosexual' and recognise the diversity of practices subsumed within this label (e.g. multiple and co-partnering, casual sex, anal sex, unprotected sex, and combinations thereof - see Bell et al., 2010; Javanbakht et al., 2010; McBride & Fortenberry, 2010). We urge our (predominately middleclass, white and heterosexual) students to reflect on their sexual histories and connections to local/global networks of known and unknown others. Situated as they are in an internationally diverse community that revels in its title as 'Britain's top match-making university', and which enjoys a vigorous social scene, we suggest that like other young people, their sexual networks are probably complex (see Berman et al., 2004; Vivancos et al., 2008), and sexualhealth risk more proximate than they assume. We remain surprised, therefore, when mobile blood collection units visiting campus fail to encourage any real reflection on actual practice. Both practitioners and donors trust the notion that membership of an undifferentiated 'heterosexual' group indicates low-risk: heterosexuals who pursue highrisk practices (e.g. unprotected anal sex with multiple partners) continue to donate immediately without question. Because these arrangements provide no explicit space for an individual who falls outside an already constituted risk group to reflect on the risk their donation of blood may pose they cannot "encourage maximum truthfulness on the part of donors" (cf. Titmuss 1970: 163).

So long as analysis of generalised patterns across populations remain the primary means to assess the risk of a would-be donor, blood services should **not** claim to be doing all they can to "minimize the risk of a blood transfusion transmitting an infection to patients" (NHSBT, 2010). By comparison, attending to diversity within heterosexual practice: may change the relative-risk calculated for current 'high-risk groups' like MSM: would more appropriately recognise the risks present within the majority heterosexual group: and will speak directly to Blood Service's insistence on vigilance to the emergence of previously unidentified infectious agents (e.g. SaBTO 2011: 22), by recognising that the source of future threats may not be the risks-groups mapped out by past crises.

One response to ontological diversity would be to produce more complex risk-profiles for sub-populations of heterosexuals: so for example: HIV is geographically concentrated in

metropolitan areas (in the UK, particularly London – HPA 2012); the economically deprived are more likely to contract HIV and other STI's (HPA 2012 - HIV prevelence is 2.8% in some poor urban areas in the US - CDC 2012); it is likely that housing insecurity has a negative influence on STI rates (Buffardi et al., 2008); level of educational attainment is a key indicator in heterosexual risk-taking (Leichliter et al., 2010); cohort studies suggest correlation between excess alcohol consumption, number of sexual partners and STIs (Standerwick et al., 2007); travel may be associated with sexual risk-taking (Bellis et al., 2004; Mercer et al., 2007); and of course we could go on... But we are not arguing for a finer taxonomy of 'risk-groups' as proxies for practice – as if only rich, white, suburban homeowners, who have a degree, drink moderately and avoid holidays on the Costa-del-Sol should be allowed to donate blood. Our point is that findings about relative prevalence rates rest upon the epistemological choices we make about how to collect and categorize STI surveillance data; these result from the questions we choose to ask, they do not have firm ontological existence. If we chose to map STI prevalence onto populations engaging in anal sex, or multiple partnering within a relevant 'window-period', we might produce very different risk-profiles. Deferral is always about eliminating a proportion of the total risk the issue is whether or not existing cognitive maps of risk drawn the right lines, and whether science can devise new means to exclude a greater proportion of the total risk - whilst continuing to exclude the most risky fraction of currently recognized 'high-risk' groups?<sup>7</sup>

### 6. Reforming Pre-Donation Questionnaires

We have asserted elsewhere (Sothern and Kesby 2011) that the NBS could better assess individual risk, stimulate more effective *self*-deferral, *and* (potentially) improve available data, if it utilised a more ontologically relevant pre-donation questionnaire that explicitly addressed sexual practice. Longstanding aversion to practice-based assessments sheds light on the pervasiveness of the dominant population paradigm and the limits it places on scientific understanding. In a revealingly hetero-normative statement, the Strategy Director of the Scottish Blood Service suggested:

<sup>&</sup>lt;sup>7</sup> An un-named reviewer suggested that practiced-based questions might also be applicable to nonsexual practices (e.g. have you abstained from IV drug use/only pursued safe injection - in the last 12 months). We welcome debate on this issue – though it is beyond the scope of the current paper.

"...I think healthy, happy couples [also] have unprotected sex, [but] I think we would have very few blood donors if we had to go into [a] detailed sexual history with everyone who volunteered" (BBC, 2008).

We do not believe that the history of relevant practice would need to be detailed (see below), and doubt all who fall outside existing high-risk groups should be described as "happy-healthy-couples". We also reject the underlying assumption that dominant heterosexual practice presents no threat to the blood supply. Meanwhile, SaBTO defends population-based deferment because:

"...there is insufficient evidence... to determine the impact on blood safety of... a system [that assesses every individual's behaviour]. It is also not certain that all people could objectively assess their own level of risk. Based on published data, the review... concluded that the introduction of extensive donor questions regarding sexual behaviour could lead to a loss of existing donors who may find the process intrusive" (NHSBT 2011a).

All three parts of this statement are problematic: first more evidence exists than SaBTO seems willing to admit. Since 2001 Italy has operated deferment criteria based on sexual practices, and like the UK, processes c.2.5 million donations annually from a similarly sized national population (SaBTO 2011: 49, 67). Extrapolating figures from a 20% sample, it seems c.650 infected donations were made in Italy 1997-2005, most from heterosexuals (ibid: 49). By comparison, 747 infected donations were made in the UK 1996-2008 by people who should have deferred (ibid: 28). This figure *excludes* infected donations from heterosexuals with no connection to a 'high-risk' category and therefore no requirement to defer. When included, a figure of 335 infected donations was recorded in 2009 alone (ibid: 335). However, rather than explore the implications of these data, SaBTO talks down the significance of the Italian example on the basis of the relative lack of data (ibid: 49).

Second, we agree that it is difficult to objectively assess one's own level of risk, and that some MSM, resentful that overly simplistic risk-group deferral categories inadequately describe their own complex practice and circumstances, have made ineligible donations believing themselves to be low-risk, only to test positive for BBIs (Grenfell et al. 2011). However, the point would be that these MSM donations, and those of a *much larger* number of heterosexuals who also test positive for BBIs, are made in the absence of any detailed questioning that might stimulate more realistic reflection and self-deferral that would remove a greater proportion of the total risk.

Third, beyond cross referencing each other, the Blood Service (NHSBT 2011a), SaBTO (2011), Grenfell et al., (2011) and Watkins (et al., 2011) cite only the postal questionnaire study of Canadian blood donors by Goldman et al., (2011) as evidence for the contention that assessing the actual behaviours of all donors would cause donation rates to fall. However, these reports misread this study: while respondents voluntarily answered several somewhat more detailed questions, and (males only) indicated preference level for detailed questions on sexual behaviour, no respondents were asked directly if such questions would actually deter donation, or whether deferral should be based on actual sexual practice. Questions focused explicitly on MSM risk while reference to risks within the heterosexual group was muted. Data generated were broad and consisted of uncorrelated descriptive statistics with only limited fit to ontologies of transmission risk and BBI detection. Therefore, the papers' conclusion that practice-based questions are "unfeasible due to large donor loss" (ibid 2011: 1834) is not informed by rigorous analysis of donor opinion; instead the paper concludes that were data on sexual behaviour of all donors collected (using similarly unrefined questions), whole new gross population categories of 'high-risk' would be identifiable, leading (under existing protocols) to many more potential donors being deferred by blood services themselves. Thus while the paradigmatic model offers an expedient means to exclude a proportion of total risk by indefinitely deferring minorities like practicing MSM, poorly differentiated population-based deferral would generate intolerable donor loss if applied equally to broad swathes of the heterosexual population.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Brooks (2011) cites a further study of attitudes towards practice-based donor assessment (Go et al., 2011) as evidence that people "find probing questions unacceptable". However, the study is inconclusive since it failed to ascertain meanings behind responses (measured on a 1-7 Likert scale). To us (and possibly respondents) the questions tested seem poorly worded and inadequately focused on window periods or relevant risk: e.g. *In the last 10 years* have you... "had two or more sexual partners *in a short period of time*/had a first sexual encounter with any... partners immediately after meeting them?" [no reference to anal sex or condoms] Go et al., 2011; 743 [emphasis added]). The finding that behaviour-based questionnaires are "no more acceptable... than

Behavioural science and psychological studies point to blood donation as a benevolent prosocial act in which donors gain from a sense of doing good, of social inclusion and the knowledge that *they or their loved ones* may be dependent on the blood of others (Ferguson et al., 2008; Sojka & Sojka, 2003). Indeed, thinking beyond the binary categories of 'donor' and 'recipient', it seems sensible that 'donors-as-potential-recipients' would *want* others to be asked about risky behaviour. Indeed the study of MSM by Grenfell et al., (2011) notes (with supporting evidence) a widespread preference for individual assessment. However, the authors ignore the voices of their research participants and instead choose to ventriloquize the paradigmatic position, stating without statistics or quotation: "[however respondents]... acknowledged [that] more in-depth questioning... would be costly, complex, and a potential deterrent to the wider donor population" (ibid 2011: 4 see also SaBTO 2011: 50).

Rather than speaking for prospective donors, we would prefer to speak with them. Therefore we call (since SaBTO has not), for appropriately qualified social scientists to assess public opinion toward practice-based pre-donation questionnaires rigorously, and to devise and test bespoke questions that are brief, pertinent and not overly invasive. These need not be complex - attempting to identify *all* possible risk, nor irrevocably compromised by the inevitability of self-reporting errors - since their role would be to promote efficacious self-deferral and exclude a proportion of total risk - leaving lab tests to identify the residual risk - just as at present. Questions should focus on the practices most strongly associated with STI transmission (we offer some provisional examples in table 2). It would seem sensible to test alternative formats since questions focused on stimulating self-deferral rather than generating useful epidemiological data might be more acceptable to the public (again see provisional examples in table 3). It is probable that computer-based questionnaires would generate more reliable responses than paper-based surveys or face-to-face interviews (see Katz et al., 2007; Locke et al., 1992; O'Brien et al., 2006) and certainly, online materails

the current... questionnaire" (ibid; 750) might say as much about respondent's views on the study's methodology as it does about opinions on practice-based assessments.

could be better used to prepare donors for personal questions and to encourage effective reflection before presenting at donation centres.

Furthermore, while we think the time has come to pilot practice-based questions we see no reason why the strengths of this approach should not be combined with those of the existing epidemiology and biological science, to produce a reformed DHC and deferral process based on a broader and more robust combination of the best methods available to science. Questions designed to correlate the most risky forms of (1) exposure (e.g. unprotected anal sex), (2) frequency (number of partners within a given window period) and (3) partner (derived from bio-epidemiological data) could be used to exclude a greater proportion of the total risk across all population groups. Thus while no person would be deferred simply on the basis of group membership, the evolving epidemiological data (augmented with data emerging from the new DHC and, we hope, a more critically informed approach to data categorisation) could be used to adjust practice-based deferral periods for different categories of donor (see table 2).

Finally, we return to Titmuss's observation that ultimately the safety of the blood supply rests on establishing conditions and arrangements that best encourage truthfulness on the part of all donors. Whichever questions are asked, blood services have little choice but to trust donors to speak truthfully. Presently UK donors are trusted only to assign themselves to population categories – but the statistics on donations testing positive for BBIs across the full range of donors (HPA, 2010b, SaBTO 2011) suggests that this approach communicates a deceptively simple model of risk to the public and fails to encourage adequate reflection on actual risk behaviours thus exposing the blood supply to unnecessary risk. Furthermore, current deferral policy drives a wedge between blood collection and broader efforts to facilitate sexual-health education across the population as a whole (Cascio and Yomtovian 2013). This neglects that the best way to "control the determinants of incidence...[and] lower the mean level of risk factors, [and] shift the whole distribution of exposure in a favourable direction [ultimately is to] alter...society's norms of behaviour" (Rose, 2001: 431).

# Conclusion

This paper compared differential deferral policy towards three sub-groups of the UK population as a means to expose the limits of the international paradigm of populationbased blood donor risk assessment. While screening has improved the persistence of window periods means that pre-donation questionnaires remain an important tool in the management of the risk of sexually transmitted Blood Borne Infections (BBI) in transfused blood. It is important therefore that those questionnaires be evidence-based and effectively identify the risk posed by individual donors. The paper evaluated critically what constitutes 'the best scientific evidence' within the existing paradigm, and found it wanting. At its heart lies a too little acknowledged disjuncture between the ontological complexity, dynamism and unboundedness of actual sexual practice and the epistemological simplicity and rigidity of the categories used to estimate donor risk. Deferral policy is explained to the public in terms of 'lifestyles' and 'specific behaviours', and yet both pre-donation questionnaires and epidemiological models often fail to interrogate actual sexual risk-taking, doing little more than sort donors by partner choice and divide them using simplistic imaginative geographies that distance heterosexual risk taking. There is insufficient recognition that accurate and efficacious measures of incidence are entirely reliant on the parameters used to define 'the population' under investigation. Findings about relative BBI prevalence rates that justify the on-going exclusion of all sexually active MSM and the acceptance of most domestic heterosexual donors (including those form higher prevalence groups like 'black Africans') irrespective of their specific sexual practices, rest upon epistemological choices about how surveillance data are collected and categorized; they do not have firm ontological existence.

In an era of enthusiasm for 'big data' this paper therefore raises what we hope is a timely question: *In what* do we place our trust? At present we have a system that trusts too easily on aggregate population categories, and in donors' willingness to assign themselves to these despite (or without) recognition that their sexual histories are complex and individual. Statistics show that existing deferral policy allows a significant number of infected donations to be made annually – with heterosexuals being the major source – a practice that introduces unnecessary risk *and* undermines efforts to educate the public about Sexual health. To be authoritative, 'the best science' must be honest and open about its methods, and relentlessly self-critical about the nature and limits of its claims. If there were greater honesty about the limitations of blood screening, and specifically about the impossibility of

filtering out all risk using population-based selection criteria, and about the likelihood of intolerable donor loss were such aggregate deferrals applied more equally, then perhaps the public would be more willing to trust in deferral criteria more tightly focused on the mechanisms through which BBIs diffuse and on the test window periods that thwart detection.

Not only is a practice-based selection policy the *only* way in which it is possible to treat all potential donors equally based on probable risk, but blood-donors-as-potential-recipients have the right to expect candour from other donors, and therefore an obligation to provide it themselves. Rather than being a unilateral exercise in donor selection, pre-donation questionnaires should be a bilateral opportunity for all would-be donors to reflect on the risk their gift may pose to its recipient, and on the need to protect their own sexual health. Taking blood from one body and injecting it into another will always carry a risk, but using pre-donation questionnaires as a more effective tool for reflexive self-deferral, would contribute to the public health strategy of reducing STI levels in the population as a whole, further increasing the safety of blood transfusion.

We believe that blood donors can be trusted to see the logic of this, and despite more relevant questioning, can be trusted to remain motivated to donate. Rather than lament the insufficiency of data to support this view, we call for social scientists to develop questions that are brief, pertinent and not overly intrusive, and then to test public tolerance to them thereby informing an alternative paradigm of practice-based donor risk assessment.

#### References

- ACBSA (Advisory Committee on Blood Safety and Availability). (2010). Recommendations, June 2010. US Department of Health and Human Services.
- Allain, J.P., & Williamson, L.M. (2007). Reflections about Blood Donation. *Transfusion Medicine*, 17, 149-149.
- Baggaley, R. White, R. and Boily, M. (2010) HIV transmission risk through anal intercourse systematic review, meta-analysis and implications for HIV prevention. *International Journal of Epidemiology*. 39:1048-6.
- BBC. (2008). Fight to allow gay blood donors. BBC News Channel: BBC News Channel.
- Bell, M., Roode, T., Dickson, N., Jiang, Z., & Paul, C. (2010). Consistency and Reliability of Self-reported Lifetime Number of Heterosexual Partners by Gender and Age in a Cohort Study. Sexually Transmitted Diseases, 37, 425-431.

Bellis, M., Hughes, K., & Thomson, R. (2004). Sexual behavior of young people in international tourists resorts. *Sexually Transmitted Infections*, 80, 43-47.

- Berman, P., Moody, J., & Stovel, K. (2004). Chains of Affection: The Structure of Adolescent Romantic and Sexual Networks. *American Journal of Sociology*, 110, 44-91.
- Beyrer, C., Baral, S., van Griensven, F., Goodreau, S., Chariyalertsak, S., Wirtz, A. and Ron Brookmeyer, R. (2012) Global epidemiology of HIV infection in men who have sex with men. *Lancet*. 380: 367-377.
- Buffardi, A., Thomas, K., Homes, K., & Manhart, L. (2008). Moving Upstream: Ecosocial Correlates of Sexually Transmitted Infections Among Young Adults in the United States. *American Jounal of Public Health*, 98, 1128-1136.
- Brooks, J., (2011). Blood donation in men who have sex with men. *British Medical Journal*, 343, 648-649
- Caplan, A. (2010) Blood stains why an absurd policy banning gay men as blood donors has not been changed. *The American Journal of Bioethics*, 10 (2) 1-2.
- Cascio, M., & Yomtovian, R., (2013). Sex, Risk and Education in Donor Education Materials. Transfusion Medicine Reviews, 27: 50-55
- CDC (Centre for Disease control and Prevention) (2013) HIV Infection Among Heterosexuals at Increased Risk — United States, 2010. March 15, 2013 / 62(10): 183-188 (CDC website).
- Committee of Ministers. (2008). Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components. Council of Europe.
- DOH (Department of Health) (2011) Lifetime blood donation ban lifted for men who have had sex with men http://mediacentre.dh.gov.uk/2011/09/08/lifetime-blooddonation-ban-lifted-for-men-who-have-had-sex-with-men/ (accessed 15/06/2012)
- Erwin, J., & Peters, B. (1999). Treatment issues for HIV+ Africans in London. *Social Science & Medicine*, 49, 1519-1528.
- ESRC (Economic and Social Research Council) (2012) The 'big data' debate. ESRC web site (accessed 25.01.13).
- Ferguson, E., Farrell, K., & Lawrence, C. (2008). Blood donation is an Act of Benevolence Rather than Alturism. *Health Psychology*, 27, 327-336.
- Fisher, C., & Schonfeld, T., (2010) Sex and Blood: A Deeper Exploration of Discrimination in the FDA Blood Donor Policy. *The American Journal of Bioethics*, 10 (2) 40-42.
- Forsythe, J., & Cardigan, R. (2009). Advisory Committee on the Safety of Blood, Tissues and Organs. *Transfusion Medicine*, 19, 57-58.
- Franklin, I.M. (2007). Is there a right to donate blood? Patient rights; donor responsibilities. *Transfusion Medicine*, 17, 161-168.
- Galarneau, C., (2010) Blood Donation, deferral, & Discrimination: FDA Donor Deferral Policy for Men who have Sex with Men. *The American Journal of Bioethics*, 10 (2) 29-39.
- Germain, M., Remis, R., & Delage, G. (2003). The risks and benefits of accepting men who have had sex with men as blood donors. *Transfusion*, 43, 25-33.
- Gindi, R.M., Ghanem, K.G., & Erbelding, E.J. (2008). Increases in Oral and Anal Sexual Exposure Among Youth Attending Sexually Transmitted Diseases Clinics in Baltimore, Maryland. *Journal of Adolescent Health*, 42, 307-308.
- Go, S., Lam, C. Lin, Y. Wong, D., Lazo-Langner, A. and Chin-Yee, I. (2011) The attitude of Canadian university students toward a behavior-based blood donor health assessment questionnaire. *Transfusion*, 51:742-752.

- Goldman, M., Yi, Q., Ye, X., Tessier, L. and O'Brien, S. (2011) Donor understanding and attitudes about current and potential deferral criteria for high-risk sexual behavior *Transfusion*, 51, (8), 1829–1834
- Grenfell, P., Nutland, W., McManus, S., Datta, J., Soldan, K. & Wellings, K. (2011) Views and experiences of men who have sex with men on the ban on blood donation: a cross sectional survey with qualitative interviews. *British Medical Journal*, 343, d5604.
- Hensel, D., Fortenberry, D., & Orr, D. (2010). Factors Associated with Event Level Anal Sex and Condom Use During Anal Sex Among Adolescent Women. *Journal of Adolescent Health*, 46 232-237.
- HPA (Health Protection Agency). (2008a). Sexually transmitted infections and men who have sex with men in the UK: 2008 report. Health Protection Agency.
- (2008b). Sexually transmitted infections in black African and black Caribbean communities in the UK: 2008 report. Health Protection Agency
- \_\_\_\_\_ (2009). MPES Model-Based Estimates of HIV Prevalence in the UK in 2009.
- \_\_\_\_\_ (2010a). HIV in the United Kingdom: 2010 Report.
- \_\_\_\_\_ (2010b). Infection Reports. *Health Protection Report: Weekly Report,* 4, 1-26.
- \_\_\_\_\_ (2012). HIV in the United Kingdom: 2012 Report.
- Javanbakht, M., Guerry, S., Horbach, P., Stirland, A., Chien, M., Anton, P., et al. (2010).
   Prevalence and Correlates of Heterosexual Anal Intercourse Among Clients Attending
   Public Sexually Transmitted Disease Clinics in Los Angeles County. Sexually
   Transmitted Diseases, 37, 639-376.
- Katz, L., Cummings, P., & Wallace, E. (2007). Computer-Based Blood Donor Screening. *Transfus Medicine Reviews*, 22, 12-25.
- Kalil, T. (2012). Big data is a big deal. Office of Science and Technology Policy. The White House website (accessed 25.01.13).
- Kerry, J. (2010). Kerry Fights To End Ban On Gay Men Donating Blood. John Kerry US Senator for Massachusetts website: John Kerry US Senator for Massachusetts website.
- Leichliter, J., Chesson, H., Sternbery, M., & Aral, S. (2010). The concentration of sexual behaviours in the USA: a closer examination of subpopulations. *Sexually Transmitted Infections*, 86, iii45-iii51.
- Locke, S., Kowaloff, H., Hoff, R., Safran, C., Popovsky, M., Cotton, D., et al. (1992). Computer-Based Interview for Screening Blood Donors for Risk of HIV Transmission. *JAMA*, 268, 1301-1305.
- McBride, K., & Fortenberry, J. (2010). Heterosexual Anal Sexuality and Anal Sex Behaviours: A Review. *Journal of Sex Research*, 47, 123-126.
- McGowan, I., and Taylor, D. (2010) Heterosexual Anal Intercourse Has the Potential to Cause a Significant Loss of Power in Vaginal Microbicide Effectiveness Studies. Sexually Transmitted Diseases. 37(6):361-364.
- MCT (Magistrates Court of Tasmania). (2009). Anti-discrimination Decisions Cain v the Australian Red Cross. Magistrates court of Tasmania web page
- Mercer, C., Fenton, K., Wellings, K., Copas, A., Erens, B., & Johnson, A. (2007). Sex partner acquisition while overseas: results from a British national probability survey. *Sexually Transmitted Infections*, 83, 517-522.
- Murphy, M., Allard, S., & Newland, A. (2009). Modernizing hospital transfusion laboratory services. *Transfusion Medicine*, 19, 153-155.

- Musto, J., Seed, C., Law, M., Keller, A., & Kaldor, J. (2008). Estimating the risk of blood donation associated with HIV risk behaviours. *Transfusion Medicine*, 18, 49-54.
- NHSBT (NHS Blood and transplant). (2010). Exclusion of Men who have Sex with Men from Blood Donation: Frequently asked questions. NHS Blood and transplant website.
- (2011a). Why men who have sex with men are deferred from blood donation for 12 months Position Statement: November 2011. NHS Blood and transplant website.
   (2011b). What is the VIP appeal. NHS Blood and transplant website.
  - (2013) Who Can't Give Blood? NHS Blood and transplant website.
- O'Brien, S., Fan, W., Ram, S., Goldman, M., Nair, R., Chiavetta, J., et al. (2006). Face-to-face interviewing in predonation screening: lack of effect on detected human immunodeficiency virus and hepatitis C virus infections. *Transfusion Medicine*, 46, 1380-1387.
- Openshaw, S. (1984). *The modifiable Areal Unit Problem*. Norwich: Geo Books.
- OPSI (office of Public Sector Information). (2007). Statutory Instruments 2007 No. 1263 -EQUALITY - The Equality Act (Sexual Orientation) Regulations 2007 - section 28 (3). Office of Public Sector Information website.
- Pathela, P., Braunstein, S., Schillinger, J., Shepard, C., Sweeney, M. and Blank, S. (2011) Men who have Sex with Men Have a 140-Fold Higher Risk for Newly Diagnosed HIV and Syphilis Compared with Heterosexual Men in New York City. Journal of AIDS, 58: 408-416.
- RCN (Royal College of Nursing). (2011). Conference 2011: Item 10: Blood donation: Motion to remove the exclusion on gay and bisexual men donating blood Royal College of Nursing Website.
- Robinson, W.S. (1950). Ecological correlations and the behavior of individuals *American Sociological Review* 15, 351-357.
- Rose, G. (2001). Sick individuals and sick populations. *Int J Epidemiol*, 30, 427-432; discussion 433-424.
- SaBTO (Advisory Committee on the Safety of Blood, Tissue and Organs) (2010). Home page. Department of Health website: Department of Health.
- SaBTO (Advisory Committee on the Safety of Blood, Tissue and Organs) (2011) Donor Selection Criteria Review. Department of Health website (accessed 28.01.13)
- Sanchez, A.M., Schreiber, G.B., & al., e. (2005). The impact of male-to-male sexual experience on risk profiles of blood donors. *Transfusion*, 45, 404-413.
- Simmonds, P., Kurtz, J., & Tedder, R. (2002). The UK blood transfusion service: over a (patent) barrel? *Lancet*, 359, 1713.
- Sojka, B., & Sojka, P. (2003). The blood-donation experience: perceived physical, psychological and social impact of blood donation on the donor. *Vox Sang*, 84, 120-128.
- Sothern, M. and Kesby, M. (2011). The blood service should ask donors about practice, not just partners. Journal British Medical Journal. 343:d5793
- Standerwick, K., Davies, C., Tucker, L., & Sheron, N. (2007). Binge Drinking, sexual behaviour and sexually transmitted infection in the UK. *International Journal of STD and AIDS.*, 18, 810-813.
- Stillwell, J., & Van Ham, M. (Eds.) (2010). *Ethnicity and Integration: Understanding Population Trends and Processes Vol. 3.* : Springer: Dordrecht.
- Tatchell, P. (2008). Bloody bigots. The Guardian.

- The Body. (2010). Health Department Highlights Health Risks of Unprotected Anal Sex Among Heterosexual Women in New York City: press release April 21 2010. . The body website.
- THT (Terrence Higgins Trust). (2010). Blood donations by people at higher risk of HIV our policy. THT Website.
- Titmuss, R.M. (1970). The gift relationship. London: Penguin.
- Treichler, P. (1999) How to have Theory in an Epidemic. Durham NC: Duke University Press.
- UKBTTTS. (2010). Guidelines for the Blood Transfusion Services in the UK: section 1.2. UK Blood Transfusion and Tissue Transplantation Services website.
- Vivancos, R., Abubakar, I., & Hunter, P. (2008). Sex, drugs and sexually transmitted infections in British university students. *International Joounal of STD/AIDS*, 19, 370-377.
- Weinberg, P.D., Hounshell, J., Sherman, L.A., Godwin, J., Ali, S., Tomori, C., et al. (2002). Legal, financial, and public health consequences of HIV contamination of blood and blood products in the 1980s and 1990s. *Annals of internal medicine*, 136, 312-319.
- Wainberg, M.A., Shuldiner, T., Dahl, K., & Gilmore, N. (2010). Reconsidering the lifetime deferral of blood donation by men who have sex with men. *Cmaj*, 182, 1321-1324.
- Watkins, N., Brailsford, S. and Kelly, D. SaBTO review of blood donor selection criteria related to sexual behaviour. *Transfusion Medicine*, 2011, 21, 363–364
- Welsh Blood Service. (2011). Am I eligible? Welsh Blood Service Website.
- Woolf, M. (2011). Gays win fight to donate blood. The Sunday Times London.
- Young, R., & Meyer, I. (2005). The Trouble With "MSM" and "WSW": Erasure of the Sexual-Minority Person in Public Health Discourse. *American Journal of Public Health*, 95 1144-1149.

Generic exclusion criteria			
•	Age <17 or > 66 (if new donor - existing donors can donate up-to 70)		
•	Previous donation within 12 weeks (men) or 16 weeks (women)		
•	Weight under 50kg		
•	Active cough, sore throat, or cold sore		
•	Pregnant or woman with baby less than 6 months old		
•	Taking prescribed medication (except HRT, the pill or other birth control)		
Indefinite Deferral			
•	Woman who received a donated egg or embryo since 1980 or treated with		
	gonadotrophin of pituitary origin or Metrodin HP		
•	Blood transfusion since 1980		
•	Family history of CJD		
•	Tested positive for HIV or Hepatitis C or think you may be infected with either		
•	Been given money or drugs for sex		
•	Injected illegal or non-prescribed drugs		
Twelve month deferral			
•	Visited Malarious area		
•	Sex with someone who may have had sex in parts of the world where HIV is		
	common (including most of Africa)		
•	Sex with someone who has received money or drugs for sex or has injected drugs		
•	Man who has had oral or anal sex with another man, whether or not a		
	condom was used.		
•	Women who have had sex with a man who has had sex with another man		
•	Sex with someone HIV positive or who has Hepatitis B or C		
Four r	month deferral		
•	Acupuncture, tattoo, piercing, or other cosmetic treatment puncturing the skin		
	(unless performed by healthcare professional in which case seek advice)		
Seek a	advice		
•	Seen doctor/dentist/healthcare professional < 7 days (other than routine		
	screening)		
•	Serious illness, seen doctor about your heart, or taken medication in past 7 days		
•	Contact with infectious disease or had immunizations in past 8 weeks		
•	Ever had hospital investigations, tests, or operations		
•	Been outside the UK in past 12 months		
•	Malaria or unexplained fever associated with travel		
•	Had Jaundice or Hepatitis B		
•	Born or lived outside the UK for 6 months or more		

• Ever visited Central or South America for a period of four weeks of more.

**Table 1:** Summary of deferment questions used in the UK Donor Health CheckQuestionnaire www.blood.co.uk/can-i-give-blood/donor-health-check/

# **Opening statement:**

While all donated blood is screened there is always the possibility that mistakes are made and contaminated blood enters the blood supply. The first step in reducing these risks is to trust all donors to reflect on, and to truthfully report, issues that might mean donated blood presents a risk to recipients. You generously give blood because you know the lives it can save – including your own or that of your loved ones – you should therefore feel reassured that all donors are asked to answer these same questions in order to ensure the continued safety of the blood supply.

Question	Deferral
Have you already taken and considered the online pre- donation questionnaire	Please defer until you have reviewed this document.
[ question related to generic exclusion and indefinite deferral (see table 1) <mark>]</mark> • Do you • Have you Etc	Sorry but you may not give blood

The best science suggests that we can remove some of the risk of collecting infected blood if we ask people about both their partner group and about their actual practices. First, please identify yourself with one of the following groups.

- Man who only has sex with women (MSW)
- Woman who only has sex with men (WSM)
- Man who has sex with other Men (MSM) (but may also have sex with women)
- Women who only has sex with women (WSW) (if you also have sex with men tick WSM)
- Not sexually active (no sex in the last 12 months regardless of usual partner type)

Sexual practice is varied and complex – so we focus below on a few practices that carry a higher chance of exposure to a sexually transmitted infection

Have you had unprotected sex with someone in – or from - a region of High HIV prevalence in the last 12 months	If yes: • All – defer (12 months)
Have you had unprotected anal sex – with a new partner in the last 12 months	If yes: <sup>9</sup> • MSM – defer (12 months) • If partner (or their partner) was black African – defer (12 months) • All women – defer (12 months) • MSW – defer (4 months)
If you have had only one partner in the last 12 months - and if you have engaged in unprotected sex – is there a possibility your partner had another partner in the in the same period.	If yes: • MSM – defer (12 months) • If partner (or their partner) was black African – defer (12 months) • All women – defer (12 months) • MSW – defer (4 months)

<sup>&</sup>lt;sup>9</sup> Exact length or deferral periods for different categories of donor could be adjusted regularly in light of bio-medical data and evolving epidemiological data.

**Table 2:** Some example questions for a new hybrid risk-group/practice-based DHC

Question	Deferral
<ul> <li>Do any other the following apply to you:</li> <li>Tattoo in last 12 months</li> <li>Unprotected anal sex with a new partner in the past 12 months</li> <li>Multiple partners (some without the use of a condom) in the past 4 months</li> <li>Had unprotected sex in the last 4 months with a partner who may have had another partner</li> <li>Had sex with someone who may have been in parts of the world where HIV is common</li> <li>Had sex whilst under the influence of drugs or alcohol – and unable to recall if condoms were used.</li> <li>Visited a Malarious Area in the past 12 months</li> </ul>	Then you should defer for 12 months

**Table 3:** Example of a broad question format designed avoid embarrassment and to stimulate deferral but not generate good data useful to further epidemiological analysis