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Pharmaceutical HIV prevention technologies in the UK: six domains for social science research

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The development of pharmaceutical HIV prevention technologies (PPTs) over the last five years has generated intense interest from a range of stakeholders. There are concerns that these clinical and pharmaceutical interventions are proceeding with insufficient input of the social sciences. Hence key questions around implementation and evaluation remain unexplored whilst biomedical HIV prevention remains insufficiently critiqued or theorised from sociological as well as other social science perspectives. This paper presents the results of an expert symposium held in the UK to explore and build consensus on the role of the social sciences in researching and evaluating PPTs in this context. The symposium brought together UK social scientists from a variety of backgrounds. A position paper was produced and distributed in advance of the symposium and revised in the light of this consultation phase. These exchanges and the emerging structure of this paper formed the basis for symposium panel presentations and break-out sessions. Recordings of all sessions were used to further refine the document which was also redrafted in light of ongoing comments from symposium participants. Six domains of enquiry for the social sciences were identified and discussed: self, identity and personal narrative; intimacy, risk and sex; communities, resistance and activism; systems, structures and institutions; economic considerations and analyses; and evaluation and outcomes. These are discussed in depth alongside overarching consensus points for social science research in this area as it moves forward.

Keywords: HIV prevention; pharmaceutical prevention technologies; social sciences; research and evaluation; symposium

Background

Pharmaceutical HIV prevention involves the use of antiretroviral (ARV) drugs by HIV-negative and HIV-positive individuals to reduce HIV acquisition and transmission, respectively. Current pharmaceutical HIV prevention technologies (PPTs) include pre-exposure prophylaxes (PrEP) – administered either orally or topically, post-exposure prophylaxes (PEP) and treatment as prevention (TasP). Clinical science has delivered a consistently high effect size for TasP and a range from 0% to 73% reduction in incidence across placebo-controlled PrEP trials (Mayer, 2014; McCormack, Gafos, Desai, & Cohen, 2014). Although trial evidence for PEP is less robust, it has been widely used as a PPT for some time now (McCormack et al., 2014).

Whilst some have hailed PPTs as having the potential to end the AIDS pandemic (Havlir & Beyrer, 2012), others are circumspect (Miller, Powers, Smith, & Cohen, 2013; Wilson, 2012). Reservations sometimes focus on epidemiological factors, with the point being made that many new instances of exposure and transmission emanate from those most recently infected who have not yet had the opportunity to test for HIV (Cohen, Dye, Fraser, Miller, & Powers, 2012; Delpech, 2012). Others focus on implementation and acceptability, citing

psychosocial and interpersonal factors mediating individuals' interactions with HIV treatments and their capacity to use PPTs (Adam, Maticka-Tyndale, & Cohen, 2003; Keogh, 2013; Persson, 2012; Rosengarten, Imrie, Flowers, Davis, & Hart, 2004). There are concerns that PPTs are being considered solely as a clinical intervention devoid of social context, where both effectiveness and the passive compliance of the target population are assumed (Adam, 2011; Davis & Squire, 2010; Kippax & Stephenson, 2012; Nguyen, Bajos, Dubois-Arberd, O'Malleye, & Pirklef, 2011; Seeley et al., 2012; Squire, 2012). With only a few examples of research and commentary on the topic (Bourne, Dodds, Weatherburn, & Keogh, 2011; Davis & Squire, 2010; Imrie, Elford, Kippax, & Hart, 2007; Mykhalovskiy & Rosengarten, 2009; Patton, 2011; Rosengarten, 2009), social sciences in the developed Global North have not kept in step with clinical and epidemiological developments with key questions around implementation remaining unexamined (Kippax & Stephenson, 2012; Young & McDaid, 2014).

These concerns are of relevance in the UK context, a high-income country with a concentrated HIV epidemic. An estimated 98,400 people are living with HIV in the UK (Aghaizu, Brown, Nardone, Gill, & Delpech, 2013). Men who have sex with men (MSM) and Black African

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men and women are the two groups most affected by HIV making up approximately 42% and 32% of the overall UK population of people with HIV (PWHIV), respectively. Free, accessible HIV treatment and care has resulted in high treatment coverage in the UK with an estimate of 85% of the diagnosed population in care. Approximately 48% of the entire HIV population had an undetectable viral load in 2011 (Aghaizu et al., 2013). Clinical guidelines in the UK have been updated to take account of the efficacy of TasP with the expectation that all those accessing clinical services are to be fully informed about the prevention benefits of treatment (Williams, 2014). Moreover, there is also an implementation study of PrEP among MSM being undertaken in the UK by the Medical Research Council (see <http://www.proud.mrc.ac.uk/>).

This paper represents the culmination of a process that focused around an expert symposium of HIV social scientists held in London in December 2012. It was motivated by a desire to ensure that HIV prevention in the UK would not emerge from this “biomedical moment” with insufficient support critique and theorisation from the social sciences. The process involved nearly 40 social scientists specialising in HIV from a range of backgrounds: cultural sociologists, health service researchers, psychologists, economic sociologists, demographers, mathematical modellers, policy analysts, social epidemiologists and those with expertise in complex evaluations. Its purpose was to explore and build consensus on the role of the social sciences in researching and evaluating new and emerging HIV prevention technologies in the UK and to produce a discussion document to inform future work.

Rather than using established consensus-building approaches such as Delphi or nominal group techniques (Van Teijlingen, Pitchforth, Bishop, & Russell, 2006), the process was less formal, though still systematic. A draft discussion document was prepared by the authors in advance of the symposium and distributed to all participants prior to the symposium and comments invited. These comments were integrated into a final pre-symposium draft. The symposium consisted of a panel of presenters who were invited to give a background to each thematic area followed by break-out workshops where subgroups engaged in facilitated discussion around each theme. These groups then fed back to the main symposium. The panel presentations and group feedback were recorded audio-visually and are available online (see <http://vimeo.com/61718033>). The subgroup discussions were audio-recorded. These recordings were used to amend the discussion document further with subsequent drafts redistributed to workshop participants for further comments. Here we present the final discussion document emerging from this extensive consultative process. It is important to state the

limitations of this process. Attendees were selected for their expertise and experience in this area. Although the conclusions and consensus points presented in this paper are those of an expert group and are evidence-based, they are also still opinion and as such, are open to challenge.

Domain 1: self, identity and personal narrative

Sociologists have worked to describe the ways in which individuals engage in “identity work” to forge identities and responses to the epidemic which reinforce or undermine overarching social and cultural norms (Baumgartner, 2007; Flowers et al., 2006; Green & Sobo, 2000; Halkitis et al., 2005). Thus, we articulate the lived experience of ‘being’ HIV-positive or HIV-negative and describe selves who are sick/healthy, responsible/irresponsible, moral/immoral, etc. (Adam, 2005; Davis & Flowers, 2011; Doyal, 2013; Flowers, 2010; Flowers, Duncan, & Frankis, 2000; Keogh, 2008a, 2008b; Kinsman, 1996). We can also identify relevant events or narratives in people’s biographical construction, for example, testing for HIV, HIV diagnosis, illnesses, changes in clinical markers (viral load or CD4 count) and starting treatments which each hold considerable significance for that individual.

PPTs have the potential to disrupt such identities and narratives. For example, by requiring those with a negative diagnosis to take treatments, PrEP has the potential to disrupt established distinctions between sick and healthy or HIV-positive and HIV-negative. Moreover, the status of key events in personal narratives (such as an HIV test or commencing treatment) changes as individuals test for different reasons and take various actions depending on the result. Finally, the question of locating the moral or responsible self becomes more complex as PrEP and TasP are targeted to those at greater risk through their sexual behaviours (Centers for Disease Control and Prevention, 2013). For example, delaying treatment initiation or sub-optimal adherence may take on a moral dimension as viral suppression is linked with potential for HIV transmission. Will those not adhering be judged differently if they are seen to increase the risk of infection to sexual partners?

To make better sense of people’s changing sense of self, symposium participants proposed the deployment of concepts such as *therapeutic citizenship* (Nguyen, Yapo Ako, & Niamba, 2007) as a means of describing how PWHIV negotiate the conflicting moral economies of PPT implementation. Likewise, it was suggested that the concept of *biomedicalisation* (Clarke, Mamo, Fosket, Fishman, & Shim, 2010; Williams, Gabe, & Davis, 2009) may support theorisation of how identities are shaped through embracing or resisting clinical technologies. Moreover, it was stressed that we require continuity with past research focusing on rights, responsibilities and

morality as individuals engage with HIV technologies (Green & Sobo, 2000; Lupton, McCarthy, & Chapman, 1995a, 1995b).

Finally, participants discussed the potential for PPTs to interact with the self as inscribed within overarching social structures. HIV epidemiology is stratified by gender, ethnicity, social class and sexual identity. This is due in part to factors associated with the biology of HIV transmission but is also reflective of social/power inequities. PPTs offer the potential for individuals, especially women, to take greater control of their own transmission risk. Thus, we should explore how PPT implementation might be mediated by structural difference and how PPTs might re-balance structural asymmetries through shifting the control of sexual risk.

Domain 2: intimacy, risk and sex

The imperative to engage with sexual HIV risk defines the parameters of intimate relationships and constrains sexual and reproductive decision-making for PWHIV (Anderson & Weatherburn, 2004; Bourne, Dodds, Keogh, Weatherburn, & Hammond, 2009; Bourne, Dodds, Weatherburn, & Keogh, 2011; Bourne, Hickson, Keogh, Reid, & Weatherburn, 2012; Davis et al., 2002; Green & Sobo, 2000; Keogh, Weatherburn, & Stephens, 1999; Klitzman & Bayer, 2003; Marks & Crepaz, 2001; Persson, 2008; Van de Ven, Kippax, Knox, Prestage, & Crawford, 1999). Landscapes of risk may be redrawn by PPTs with individuals having additional factors to weigh up in calibrating their sexual risk practices. Moreover, potential for new relationships may develop. For example, sero-different relationships may be more feasible if responsibility for avoiding infection is increasingly shared (that is, where both partners are taking ARVs and engaging with the clinic together, and using clinical markers to negotiate risk).

Conceptualisations of individual risk propensities have shifted towards a conception that sexual HIV risk involves individuals negotiating protean “landscapes of risk” (Green & Sobo, 2000; Lupton, 1999). Thus reductive or deficit models of risk have been supplanted by an approach that characterises risk as productive in terms of the self and the possibilities afforded by intimate relationships. Technologies that increase complexity around risk, and promote the agency of those living with that risk, have the potential to shift us further from past deficit models. Conversely, however, as they also herald greater involvement of the clinical sciences in measuring the impact of PPTs on risk behaviour, we may also see a resurgence of research utilising positivist models of risk.

Domain 3: communities, resistance and activism

PPTs imply that people’s experience of and relationship with the virus and the clinic will change. Many people who have received a negative HIV diagnosis will be the subjects of medical interventions akin to those who have been diagnosed positive. As the identities/self-concept of “HIV-positive” and “HIV-negative” lose definitional power so too will they alter in terms of their collective, political and cultural meanings. Such meanings have been instrumental in defining interest groups united by common experiences (for example, PWHIV, gay men/MSM and African communities) and determining how groups have organised themselves to attain political ends (Altman, 1994; Berridge, 1996; Epstein, 1998; Heywood, 2009; James, 2011). Although community formations will retain social and political currency, relationships within and between them are likely to change as are the aims and methods of AIDS activism.

PPTs appear to be already having an impact on such relationships with the interests of AIDS activists, treatment advocates, communities, drugs companies, clinical providers and governments increasingly difficult to unpick. Moreover, enthusiasm for PPTs is unlikely to be shared equally in all quarters. For example, human rights concerns are emerging regarding compulsion to comply with treatments (European AIDS Treatment Group, 2014; GNP+, 2012; International AIDS Alliance, 2012). Reassurance is needed that clinical and treatment decisions will be guided by clinical need rather than cost.

At the symposium, attention focused on the extent to which social scientists should engage in activist and/or communitarian agendas around PPTs. It was argued that the limited notions of “patient and public involvement” relied upon by UK research councils should be challenged by social researchers. Of considerable concern is the way in which social research on PPTs is predominantly conceived within clinical research models which tend to utilise positivist approaches. The social sciences can offer more meaningful participatory research models while being mindful of the ways in which knowledge production can generate or consolidate power asymmetries. Finally, social sciences emphasise exploratory and speculative approaches alongside positivistic or experimental approaches. Such approaches were seen as essential to ensure that research in this area is produced with, by and for PWHIV.

Domain 4: systems, structures and institutions

In the history of PPT development, key moments function as drivers. The Swiss Statement (Vernazza, 2008), the publication of HTPN 052 data (Cohen, Chen, McCauley, Gamble, & Bollinger, 2011), the iPrEx study results (Grant et al., 2010), the licensing of

Truvada as PrEP in the USA (US Food and Drug Administration, 2012) and discussions of a “functional cure” in 2013 (Persaud, 2013; Pollack & McNeil, 2013) are all examples of key moments which make PPT implementation appear increasingly inevitable. Less well known are scientific results that fail to support this momentum, where evidence of efficacy is equivocal, or models of roll-out suggest a lack-lustre epidemiological impact. Those working in science and technology studies are best placed to examine the ways in which systems, structures and institutions work to exploit or ignore such findings.

Moreover, as new prevention options emerge, the meanings and associations traditionally ascribed to HIV may be further re-framed. There is a potential, for instance, to reconsider the collective protections that widespread treatment access can afford entire populations (not just those who are already infected). This framing would contrast strongly with the individualised and stigmatised perceptions of the pre-ARV epidemic. The ways in which systems, institutions and structures utilise such a re-framing will be a key area of study (continuing work examining systemic responses in light of the introduction of ARVs post-1996; Moatti, Marlink, Luchini, & Kazatchkine, 2008; Nixon, Hanass-Hancock, Whiteside, & Barnett, 2011; Piot & Coll Seck, 2001; Yeatman & Dowsett, 2009). For example, arguments about the public health benefits of TasP have convinced the UK Government to remove charges for HIV treatment for those without recourse to public funds (Department of Health, 2012). Health policy analysts may seek to examine the way in which public health arguments shifted a policy that has proven immune to human rights advocacy campaigns.

Institutions such as clinics and voluntary agencies are already collaborating on the systemic delivery of PPTs. However these same institutions – for cultural, disciplinary, pragmatic, resourcing and territorial reasons – will also conflict, obfuscate or delay the progress of the PPT agenda. For example, evidence demonstrates resistance or ambivalence towards early initiation of ARV treatment among those who expected to prescribe it (Persson, 2013; Vernooji, 2013). Those studying health systems delivery, organisational sociology and policy analysis will find opportunities to explore the shifts, tensions and breakthroughs that impact how PPTs are conceptualised, managed and delivered at a systems level. With regard to implementation analysis, work is needed to understand the knowledge, attitude and skill capacities for those providing interventions around PPT uptake. Furthermore, in high-income countries with concentrated epidemics, initial PPT policy and clinical guidance appears to encourage targeting of patient groups most likely to benefit and sustain adherence. Adequate understanding of the dynamics of implementation of such guidance will

require, for example, analyses of consultant and patient interactions that incorporate theoretical understandings of power relations via social stratification and stigmatising processes.

Domain 5: economic considerations and analyses

In the UK (particularly England), severe public sector funding cuts have accompanied an overhaul of England’s National Health Service (NHS) which shifts responsibility for the delivery and oversight of public health. The infrastructure and pharmaceutical costs required to implement PPT policies are pressing concerns for those tasked with clinical delivery within this already highly pressurised context. Moreover, there are resourcing implications beyond the provision of the pharmaceuticals themselves. For example, TasP implementation requires frequent clinical contact and regular monitoring of patients’ CD4 counts and viral loads. This is at odds with arms-length models for clinical management of stable patient being developed to ease the burden on clinical resources (Adams, Ogden, Erlich, & Hay, 2013; Asboe et al., 2012). Moreover, there are questions about the abilities of the NHS to meet treatment budgets in the longer term. For example, London health care commissioners have already explored the feasibility of asking patients to switch to a less expensive treatment regime due to local fiscal pressures (National AIDS Trust, 2012). Finally, there are potential sectoral difficulties. For example, it is difficult to know how the Commissioning Board of the NHS in England (which commissions HIV care and treatment) will respond to calls for resourcing for preventive outcomes (which are now the responsibility of local government and which they may well consider beyond their remit). Feasibility studies of required frequency of HIV clinic visits, transferring of routine HIV care to primary care, and the potential for self-administered CD4 and viral load tests will assist our understanding of the economic implications of routinised self-care on PPT implementation. Moreover, there are ethical questions to be asked about the potential impacts of treatment plans that lack financial sustainability.

PPT clinical guideline development will inevitably necessitate the generation of cost effectiveness evidence within the NHS context. It is prescient for social scientists to start framing the types of questions that such evaluations should seek to answer. An array of services will compose PPT delivery including HIV testing, diagnostics, clinical and community services. Evaluations should consider the systemic costs and benefits, rather than simply considering treatment costs in isolation. Such economic evaluations are already under way in low and medium resource settings (Peter Vickerman and colleagues, personal communication, June 10, 2013) and should also be put into effect in

high-income countries with concentrated epidemics. In addition, such evaluations will need to take into account the various investments that are required at each stage along the patient trajectory given the considerable dropout rates that are known to occur at each stage (increasingly referred to as the “Treatment Cascade”; Gardner, McLees, Steiner, del Rio, & Burman, 2011).

Domain 6: evaluation and outcomes

Symposium participants stressed lack of consensus regarding complex evaluation approaches as an inhibitor to evaluation of behavioural HIV prevention programmes in the UK. For example, biomedical and social science disciplines differ on outcome indicators, the former favouring clinical or epidemiological markers and the latter interim measures such as changes in knowledge, attitudes and behaviour. Consensus about appropriate indicators is essential, and promising approaches that may help us achieve a better collective understanding of PPTs efficacy, effectiveness, impact and delivery were cited. At this stage in the potential implementation of PPTs, the role of mathematical modellers is likely to be important in policy development and planning, given their capacity to test a range of hypotheses and implementation variables. With improved collaboration between social scientists, clinicians and modellers, increasingly reliable variables can be selected for use. The work of the HIV Modelling Consortium considers the starting points for understanding and interpreting the complex relationships between PPTs, HIV prevention behavioural interventions and behavioural change (The HIV Modelling Consortium Treatment as Prevention Editorial Writing Group, 2012).

In the longer term, given the research funding environment in the UK, the symposium also noted that we are likely to be reliant upon naturalistic experimental approaches when designing complex evaluations of PPTs. It remains unclear how such approaches will be balanced with the imperative to carry out experimental implementation trials considering the ethical, resource and methodological challenges they entail.

Finally, as alluded to in prior sections, a policy analysis approach that incorporates the methods used by those in science and technology studies and the sociology of knowledge will also be essential to understand how and why particular research findings are widely known and counted as “evidence” of effectiveness, while others are not.

Discussion: overarching consensus points

The wide-ranging discussion prompted through this consultative process indicates substantial interest in PPTs from social scientists in the UK and a desire for a

robust social scientific response to the challenges and opportunities presented. The complexity of these challenges was recognised in the main symposium consensus point: that social scientific research in this area should be interdisciplinary, should employ a range of methodological and theoretical approaches and should be inclusive and multi-perspectival. These principles were seen as having the greatest capacity to generate useful, strategic and ethically robust research.

Participants distinguished between research that facilitates and evaluates PPT implementation and research that problematises this implementation. The former will need to engage meaningfully with clinical and implementation studies whilst the latter should critique knowledge production around PPTs and the way that they are being codified in clinical and public health discourses. Though these approaches should not be seen as oppositional or antagonistic, the relationship between them will always be troubled. Implementation and evaluative work should incorporate and respond to its own critiques and engage with research that theorises or problematises PPTs.

As PPTs touch on intimate, social and structural contexts, symposium participants called for inclusive research collaborations. Implementation and evaluation research necessitates joint-working between clinicians and social scientists from diverse backgrounds including epidemiologists, demographers, modellers, statisticians, economists, health service researchers, medical and cultural sociologists and community-based researchers. Moreover, research should be methodologically diverse, including experimental designs, natural experiments, surveys, qualitative and participatory/community approaches. The skills of modellers in the design of evaluations will be essential. Limited resources will necessitate creative evaluative methodologies, the coordination of contributions from a range of backgrounds and the employment of strategic planning devices such as gap analyses and logic models.

Given that PPTs are an evolution rather than a revolution, continuity with past HIV research is essential. Participants stressed the need to revisit sociological concepts such as stigma and sick role in the light of PPTs and to consider similar innovations (such as the oral contraceptive pill) and other disease areas (such as breast and lung cancer and epilepsy) that have been the subject of sociological scrutiny.

Participants agreed that research funders should seek to procure research that meaningfully includes PWHIV as co-creators of knowledge. Such involvement implies that future research should also seek to investigate strengths as well as deficits in PPT implementation, especially with regard to investigating the impact of PPTs on sexual and emotional intimacy or pleasure.

Finally, research commissioning needs to coordinate the disparate activities that contribute to the evaluation and the critique of PPT implementation. Such coordination should recognise that research is often conducted within a power-imbued system of funding that exacerbates disparities between those with and without funding to undertake specified research. Planning needs to account for and overcome these differences.

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