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#### Aims

To discuss the need to develop ethical guidelines for researchers using sewage epidemiology to monitor drug use in the general population and specific precincts, including prisons, schools and workplaces.

#### Method

Describe current applications of sewage epidemiology, identify potential ethical risks associated with this science, and identify key means by which these risks may be mitigated through proportionate ethical guidance that allows this science to be fully developed.

#### Results

A rapidly advancing field of research is sewage epidemiology (SE) — the analysis of wastewater samples to monitor illicit drug use and other substances. Typically this research involves low ethical risks because individual participants cannot be identified and, consequently, review has been waived by human research ethics committees. In the absence of such oversight, ethical research guidelines are recommended for SE teams, peer reviewers and journal editors; guidelines will assist them to mitigate any risks in general population studies and studies of prisons, schools and workplaces. Potential harms include the stigmatisation of participants and, in the prison setting, austere policy responses to SE data that impact negatively upon inmate-participants. The risk of harm can be managed through research planning, awareness of the socio-political context in which results will be interpreted (or, in the case of media, sensationalised) and careful relations with industry partners. Ethical guidelines should be developed in consultation with SE scholars and be periodically amended. They should include publication processes that safeguard scientific rigour and be promulgated through existing research governance structures.

#### Conclusions

Guidelines will assist to promote an ethical research culture among SE teams and scholars involved in the publication process and this will work to protect the reputation of the field.

#### Keywords

Sewage epidemiology; Wastewater analysis; Ethics; Ethical

#### 1. Introduction

No specific ethical guidelines currently exist for researchers analysing wastewater to detect illicit drugs or indeed other drugs such as pharmaceuticals, alcohol or nicotine. This area of study, termed sewage epidemiology (SE), aims to estimate population rates of illicit and other drug use from quantitated excreted drug metabolites and residues found in wastewater using chromatography and mass spectrometry (Daughton, 2011, Daughton, 2001, Frost and Griffiths, 2008 and van Nuijs et al., 2011). Studies to date have been conducted on major illicit drug types, including cannabis, cocaine, heroin and other opioids, and amphetamine-type stimulants (Pal et al., 2013, Postigo et al., 2008, van Nuijs et al., 2011 and Vazques-Roig et al., 2013). While most studies have concentrated on mapping indicators of population drug consumption, several studies have applied SE in specific settings, such as prisons (Postigo et al., 2010), schools (Panawennage et al., 2011) and music festivals (Lai et al., 2013). This emerging field has attracted multiple research teams in Europe (e.g. Zuccato et al., 2005, Zuccato et al., 2009, Bijlsma et al., 2012, De Voogt et al., 2011, Thomas et al., 2012, Kasprzyk-

Hordern et al., 2009, Huerta-Fontela et al., 2008 and Postigo et al., 2010) as well as teams from North America (e.g. Metcalfe et al., 2010 and Banta-Green et al., 2009) and Australia (Irvine et al., 2011 and Lai et al., 2011). Disciplines contributing to this research include chemistry, biology, mathematics, engineering, epidemiology and criminology (Prichard et al., 2012). Objective indicators – such as the rate of academic publications, the level of research funding and conferences on SE and illicit drugs – suggest that this field will continue to grow strongly over the next decade. Fig. 1 presents the numbers of articles listed on PUBMED as published between 1995 and 2013 (up to 18 October) relating to sewage epidemiology and illicit drug use.1

# Fig. 1.

Articles by year relating to sewage epidemiology and illicit drugs.

The growth in publications, which does not account for books, book chapters or articles not listed on PUBMED, indicates a strong upward trend since 2005. Of the 135 articles identified on PUBMED, 122 were published between 2008 and 2013.

This field has developed because of worldwide interest in measuring the effectiveness of policies that seek to minimise drug related harm. Conventional survey approaches to monitoring drug consumption are limited by methodological problems and lack of timeliness (Prichard et al., 2012 and Hall et al., 2012). By comparison SE reduces reliance on individuals' self-reported drug use in surveys, which are comparatively expensive and time consuming and under-represent consumption. Secondary indicator data from police services, customs agencies and health care systems is influenced by the allocation of resources and is subject to various data management limitations.

The primary limitation of SE from a policy perspective is that it cannot produce data about individuals patterns of drug use — their routes of administration, the combination of drugs that they consume, their frequency of use, and the effects of drug use on health, and risk-taking behaviours. This limitation means that SE is generally advocated as a supplement rather than a replacement for conventional methods of monitoring illicit drug use.

## 2. The need for ethical guidelines in SE drug research

The governance of research ethics occurs through a variety of mechanisms in most countries, including through state legislation, professional self-regulation and professional codes of practice and guidelines. In Australia, for example, ethical research practices across all disciplines are largely governed by the Australian Code for the Responsible Conduct of Research (NHMRC, 2007b). Subsidiary documents specify ethical research practices for broad areas, such as research involving humans (NHMRC, 2007a) and animals (NHMRC, 2013). Such documents tend to be updated periodically and their content promulgated to universities and research funding bodies.

Understandably, some fields raise more complex ethical issues than others because of the nature of the topic investigated, the methods employed, or issues pertaining to the publication process. As ethical complexity increases, often so does the need for detail in ethical guidelines — especially where human research is concerned (e.g. WMA, 2009: 94). For instance, the UK's governance of scientific research relating to human tissue stored in biobanks includes detailed protocols and guidelines (UK Biobank, 2007). Of the multiple ethics codes and guidelines in existence, it appears that most have a national focus and are discipline-specific; less common are international and interdisciplinary instruments (CESSDA, 2012).

Most of these codes and guidelines do not obviously apply to the conduct of SE precisely because it does not involve collecting data on individuals. Relatively little attention has been paid to the ethics of SE research (for exceptions see Frost and Griffiths (2008) and Hall et al. (2012)) in part because of its novelty and in part because it is not readily amenable to traditional approaches to research ethics.

Related domains of human research ethics provide little guidance, namely, drug use epidemiology (e.g. Fry and Hall, 2004), public health surveillance (e.g. Lee, 2010 and Lee et al., 2011), environmental health research (Resnik, 2008), and epidemiology in general (e.g. Capron, 1991). Ethical issues most often arise in these domains when researchers collect data from individuals on their self-reported drug use, infectious disease serostatus, and biological samples. The ethical foci are understandably on ensuring: (a) participants provide informed consent (Fry and Hall, 2004), (b) protecting the confidentiality of sensitive information (Fry and Hall, 2004), and (c) specifying the circumstances in which de-identified data may be used without participants' consent (Lee, 2010).

These considerations do not resonate with SE drug research because the intermingled urine of many 1000s of people cannot be used to identify individual drug use (Prichard et al., 2012 and Griggs et al., 2013). As a consequence, to the authors' knowledge only one human research ethics committee has required review of a SE drug study and it approved the study as low-risk. Other human research ethics committees have declined to review SE studies on the grounds that they raise no ethical issues.

The conclusion of human research ethics committees that SE studies involve very low ethical risks is reassuring. But on the other hand, in the absence of oversight by ethics committees some level of caution is required. For reasons outlined in more detail elsewhere (Hall et al., 2012) we agree with the ethics committees that have concluded that the ethical risks of SE drug research involving large sewage catchment areas are low. Any such risks are minor and can be managed through relatively simple procedures in the research and publication process.

Nonetheless, the objective of this paper is to propose that SE researchers develop their own professional 'living' ethical guidelines to deal with ethical issues that may arise in research in settings on drug use in identifiable groups, such as disadvantaged communities, prisoners and school students. Ideally these guidelines should be interdisciplinary and international and reflect as much as possible the cross-jurisdictional characteristics of this area. These guidelines ought to be parsimonious. That is, they should aim to promote ethical research (including in publication processes) with minimal detail and restrictions. Rather than attempting to iterate the guidelines here, our view is that the guidelines should be developed with the input of key interdisciplinary SE researchers and journal editors. A suggested strategy for the promulgation of the guidelines will be needed that can be adapted to different countries. The reasons for these recommendations are set out below.

## 2.1. Ethical framework

The approach we have previously adopted to analyse the ethics of SE drug research draws on influential ethical principles in biomedical and epidemiological research ethics (Hall et al., 2012) and social science research (NHMRC, 2007a). The three principles that are most pertinent to this discussion are the principles of respect for participants' autonomy, non-maleficence and beneficence (Table 1).

Table 1. Principles of ethical research.

Respect for participants' personal autonomy must provide fully informed consent before they can participate in research; and that participants' confidentiality and privacy is maintained (2004) Beauchamp and Childress (2001); Fry and Hall

Non-maleficence Requires researchers to avoid placing participants at the risk of harm or to Brody (1998)

Beneficence Requires that research has a reasonable prospect of producing benefits to the participants, or at least to society in general Beauchamp and Childress (2001)

Ethical assessments of research projects necessitate, among other things, weighing these principles. To what extent is the autonomy of the participants respected and to what extent can harm be mitigated? Are minor breaches of respect and non-maleficence justifiable on the grounds that the research benefits the participants or society?

With regards to non-maleficence, it is important to note that 'harm' in ethics has a much lower threshold than typically found in civil or criminal law — encompassing emotional responses such as 'distress', 'anger', 'embarrassment' or 'social stigmatisation' (e.g. NHMRC, 2007a: 16). Human research ethics committees also conceptualise 'harm' as arising from situations where research (in part, or as a whole) is brought into disrepute (NHMRC, 2007a).

2.2. General population SE studies: media, stigma, policing and potential harm It has been argued that the use of SE to measure population drug consumption will typically involve very few ethical complexities (Hall et al., 2012). Consent is not secured from the population who contribute to the catchment studied. However, the autonomy of the participants is respected by virtue of the fact that general population studies involve sampling at sewage treatment plants and, consequently, participants' contributions to sewage water are intermingled and non-identifiable. The risk of harm is accordingly low. Further, such studies satisfy the principle of beneficence in that the results of the research may serve the public good even if those who contribute to wastewater are unlikely to personally benefit from the research.

The media have demonstrated a strong interest in reporting SE studies, as indicated in the worldwide coverage of the first published study in Milan (Povoledo, 2005) and media-funded tests in Thames (Orr and Goswami, 2005). In Europe, media coverage of SE studies has attracted national television coverage (National Geographic, 2013) as well as multiple reports in the print media — sometimes with sensationalised overtones (see for example Viellaris, 2013).

The media play an important role in civic society, which is one reason why freedom of the press is safeguarded to an extent in democratic societies. Where scientific developments are concerned, the media are a conduit between research and the general public, who, in the main, do not read academic papers. Consequently, how the media communicate research to the public can become cardinal. Accurate communication by the media about SE can highlight the potential health benefits of the research for the community. Conversely, erroneous media communication may result in sensationalism and stigmatisation of vulnerable groups, discussed further below. In this context, our view is that SE scholars bear an important responsibility to minimise the potential for erroneous media communication. One objective of SE guidelines would be to assist SE scholars to observe this responsibility in their academic publications and interaction with media outlets.

Predicting the outcomes of media coverage can be difficult, especially on a potentially emotive topic like substance use. For instance, in the Netherlands in 2012 (Spits newspaper, 2012) a television presenter's parents' home was vandalised after the presenter reported SE data obtained from the KWR Watercycle Research Institute. The vandalism appeared to be an act of retribution because the presenter had used the SE data to claim that the town in which her parents lived had very high rates of use of cocaine and MDMA (Causanilles et al., 2013).

While this sort of violent reaction to SE media coverage may be unpredictable or rare, other potential harms are easier to foresee. Our view is that SE researchers should be especially sensitive to reporting drug consumption in a suburb or district with high levels of social disadvantage. If SE researchers publicly identify such a district, there is a risk that the media might misrepresent or sensationalise the findings. Negative media coverage could entail a number of harms to residents of the area. The simplest is that the residents would experience the sorts of emotional harms referred to above, such as 'shame' or 'embarrassment'.

A greater concern is that the coverage could amplify social stigmatisation and labelling. Stigmatisation and labelling have been widely studied in many settings, including health (Harris,

2011), substance use (Room, 2005), race (Howarth, 2006), mental health (Perlin, 2000), poverty (Reutter et al., 2009) and criminal justice (Braithwaite, 1989 and Garland, 1996). The research indicates that labelling groups can influence how they are treated by society and the state (e.g. Stuber and Schlesinger, 2006 and Garland, 1996). It is worth noting that some local governments in the USA have reportedly declined to participate in SE studies because of the fear that the results could tarnish the reputation of their cities (Bohannon, 2007 and Hagerman, 2008). Arguably, this suggests that media reports of SE studies could feasibly stigmatise already marginalised suburbs or districts.

A more immediate effect of negative media coverage of SE findings is that they could generate an intense political need to be seen to respond to actual or perceived social problems. Where drug consumption is concerned this might involve a politically popular high profile increase in police street patrols to 'get tough' on drug use and crime (see Walker, 2011 and White and Perrone, 2010). This type of policing can displace more effective strategies (Walker, 2011), such as evidence-led (Ratcliffe, 2004) or problem-oriented (Weisburd et al., 2010) policing. It may also bring more drug users into the criminal justice system (e.g. for drug possession) through a phenomenon known as 'net-widening' (see generally Austin and Krisberg, 1981 and Roberts and Indermaur, 2006). Finally, an intensification of police resources in a marginalised area may result in increased arrests and related crime data (Willis et al., 2011), acting as a self-fulfilling prophecy. It is feasible that increased crime statistics may be seen to verify media claims — whereas the data may actually be the result of the media coverage.

#### 2.3. Site-specific SE studies: risks in prisons

Site-specific SE research, such as that in prisons (Postigo et al., 2011), involves greater ethical complexities because these studies have greater prospects of both benefitting and possibly harming participants. Arguably, there is no greater domain of civic society where SE can be of assistance because drug use in prisons is notoriously difficult to measure (Carpentier et al., 2012). By providing more objective data on drug use, SE could enable prison authorities to measure the effectiveness of anti-drug strategies (Prichard et al., 2010) thereby potentially reducing drug-related harms such as: health and safety risks (Chandler et al., 2009 and Jurgens et al., 2009); violence and fatal overdoses and BBV infections in prisoners (Jurgens et al., 2009). SE studies in prisons consequently rank highly in terms of beneficence — potential benefit to participants and the community.

The chances of SE data being used to identify individuals in a prison (e.g. inmates, prison staff or visitors) appear remote but there are other ethical risks. Hall et al. (2012) highlighted the need for researchers to understand the policies that prison authorities may apply in response to SE findings in order to reduce drug demand and supply. Prison authorities could, for example, react to evidence of drug consumption by inmates with austere measures, such as eliminating contact visits for inmates' families. It is true that this sort of reaction might also occur as a result of prison authorities' intelligence, drug seizures, overdose deaths or urinalyses of individual prisoners. However, an outcome that may be justified as prison policy can be more ethically problematic in research. This is because in such a scenario a SE study could be the cause of harm (e.g. emotional distress) to participants who did not provide consent to be included in the research. Careful discussion of potential prison policy responses would be wise in this field. This point is particularly pertinent if SE research teams are invited to do research in countries with poor respect for human rights in correctional settings. Some researchers may conclude that seeking formal approval from human research ethics committees within their universities is an effective way to plan prison research projects and develop procedures tailored to specific contexts. Stigmatisation is very relevant in the prison setting. Mismanagement of SE research findings may precede media reports on prison drug consumption that embarrass inmates or contribute to negative community sentiments about the rehabilitation and reintegration of ex-prisoners back into society.

The risks of stigmatisation and labelling are also essential considerations in undertaking SE studies in other settings such as high schools and workplaces. Public dissemination of findings from specific schools could greatly distress children, parents and teachers (Roche et al., 2009) and feasibly

adversely affect the school's reputation. Likewise, the reputation of workplaces could be damaged and, in some circumstances, could result in economic harm. Beneficence needs to be closely assessed by researchers contemplating SE studies in schools or workplaces in order to decide whether the possible benefits of the study outweigh the potential risks of harm to (non-consenting) participants (Hall et al., 2012). In these cases, data need to be handled preserving the anonymity of the site and results reported in ways to minimise potential risks.

### 3. Process for SE guidelines development

Our view is that formalised governance of SE ethics is not required and that any ethical risks can be effectively managed by developing a living guidelines document. These guidelines should be developed with input from a relatively small pool of key SE researchers and journal editors. Their contributions would be drawn on to draft the guidelines and they would be given opportunity to comment on this draft. Unanimous agreement may not be possible on all aspects of the guidelines. However, it will be best to arrive at a consensus on most issues. We suggest this process for two reasons. First, it would assay the experience of key SE scholars to date — who may identify ethical issues beyond those discussed in this article and explain procedures that researchers have already used to manage ethical risks. Second, engaging with SE scholars in the development of the guidelines, we suggest, will help to promote acceptance of the document as a useful and pragmatic resource. SE scholars are also likely to be encouraged by the fact that, as a living document, the guidelines could keep apace with future developments in the SE field. Thought will need to be given on how to promulgate the guidelines so that current and future SE researchers know of their existence. The guidelines could outline strategies for promulgating the document through existing ethics governance systems in different countries.

Guidelines for the SE publication process should aim to develop a system that retains scientific rigour while protecting the anonymity of disadvantaged suburbs, prisons, schools and so forth. For example, in SE publications it is typical to report the estimated population size of the catchment studied. Yet, in some circumstances such information could be used to identify a vulnerable region or group which the researchers would prefer remained unidentified. We suggest that in these scenarios all data be scrutinised through the peer review process. However, in the resulting publication the risk of identifying the site could be minimised by only reporting population rates (e.g. per 100,000 people). After reading the publication, SE scholars who wished to see the complete population estimates could contact the authors. If SE scholars have an input in designing such a process, the guidelines are likely to provide a practical solution that is acceptable to the field.

## 4. Conclusions

SE research is likely to steadily grow and promises to provide a valuable new tool in studying illicit drug use and drug-related harms. It is important that this new tool is used responsibly to avoid causing unintentional harm to participants and bringing the method into disrepute. This responsibility lies mainly upon researchers, given that human research ethics committees have typically not required ethical review of SE studies. The strength of SE lies in the fact that it is so methodologically divergent from conventional approaches to studying illicit drug consumption. Yet, because it is novel, we need to consider novel ethical considerations that it may raise. In the main, ethical assessments of SE studies in large catchment areas will not be complex because individuals cannot be identified, the risk of harm is low and they possess clear potential to benefit society (if not the participants who are not affected or inconvenienced in any way by SE studies).

However, we recommend that living ethical guidelines should be produced to assist SE investigators to mitigate potential risks in studying smaller populations especially in specific study settings. The aim of the guidelines would be to promote an ethical culture among SE scholars that informs both research and publication processes (assisting peer reviewers and journal editors). A key focus of the guidelines would be to ensure the anonymity of regions where special sensitivities may apply, including marginalised residential districts, prisons, schools and workplaces. This would entail some consideration of how findings might be interpreted within the socio-political context of the research,

how media outlets might misrepresent findings and how policy makers may respond. The guidelines would invite SE teams to consider how they design their research, and how they manage relationships with research partners, such as prison and forensic authorities. Special care is required in dealing with media outlets. Study plans and results need to be always presented accurately and in a scientific manner, to ensure correct communication to the public and to avoid sensational media commentary.

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