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# Sewage epidemiology and illicit drug research: The development of ethical research guidelines

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## HIGHLIGHTS

- We examine ethical issues re drug use and sewage epidemiology.
- We discuss potential harms for marginalised social groups.
- We note the lack of oversight by research ethics committees in this field.
- We call for ethical research guidelines in this field.
- We explain how the guidelines should be developed.

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## ABSTRACT

*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.


## 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, 2001, 2011; Frost and Griffiths, 2008; 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; 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

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festivals (Lai et al., 2013). This emerging field has attracted multiple research teams in Europe (e.g. Zuccato et al., 2005, 2011; van Nuijs et al., 2009; Terzic et al., 2010; Karolak et al., 2010; Harman et al., 2011; Boleda 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; Postigo et al., 2010) as well as teams from North America (e.g. Metcalfe et al., 2010; Banta-Green et al., 2009) and Australia (Irvine et al., 2011; 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]

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; 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).

[1] The search string used was ("substance abuse detection" or "illicit drugs" or "street drugs" or "cocaine" or "heroin" or "cannabis" or "methamphetamine" or "mdma") and ("waste water"[Mesh] or "sewage"[mesh] or "waste water"[nm] or "wastewater" or "sewage epidemiology").

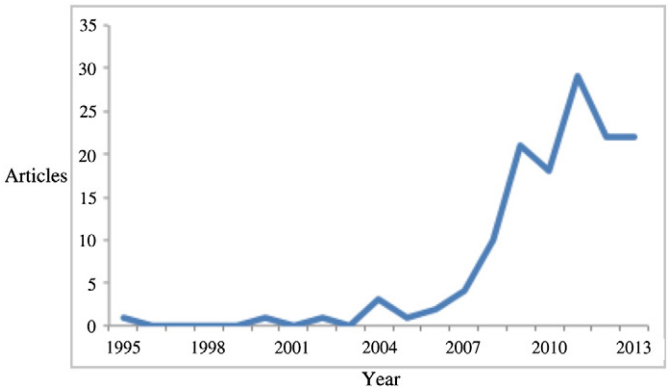


**Fig. 1.** Articles by year relating to sewage epidemiology and illicit drugs.

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; 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; 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.