

Following Lives Undergoing Change (Flux) Study:

Profile of an Online Cohort of Drug Use among Gay and Bisexual Men in Australia

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Abstract

Background: The use of crystal methamphetamine, erectile dysfunction medication (EDM), and amyl nitrite have been associated with sexual risk behaviour and HIV infection among gay and bisexual men (GBM).

Objective: This paper describes an online prospective observational study of licit and illicit drug use among GBM and explores baseline prevalence of drug use in this sample. Capturing these data poses challenges as participants are required to disclose potentially illegal behaviours in a geographically dispersed country. To address this issue, an entirely online and study specific methodology was chosen.

Methods: Men living in Australia, aged 16.5 years of age or older, who identified as homosexual or bisexual or had sex with at least one man in the preceding 12 months were eligible to enrol.

Results: Between September 2014 and July 2015, a total of 2251 participants completed the baseline questionnaire, of whom, 1711 (76.0%) consented to six monthly follow-up. The majority (65.7%) were recruited through Facebook targeted advertising. At baseline, over half (50.5%) the men reported the use of any illicit drug in the previous six months, and 28.0% had used party drugs. In the six months prior to enrolment, one-third had used amyl nitrite (32.1%), 21.8% had used EDM, and 12.0% had used crystal methamphetamine. Among the 1711 men enrolled into the cohort, 790 men had used none of these drugs.

Conclusion: Ease of entry and minimal research burden on participants helped ensure successful recruitment into this online cohort study. Study outcomes will include the initiation and cessation of drug use, associated risk behaviors, and health consequences, over

time. Results will provide insights into the role of gay community networks in patterns of drug use among GBM.

Key Words: automated methodology, cohort, drug use, gay and bisexual men, online methodology, online surveys

Highlights

- Over half of GBM in this sample reported the use of any illicit drug in the previous six months
- Almost half indicating no use of crystal methamphetamine, amyl nitrite, and erectile dysfunction medication
- The majority of GBM were recruited through Facebook targeted advertising
- Online methodology facilitates confidential reporting of illicit behaviour
- Sophisticated automation process can reduce labour and other costs associated with data collection
- Automated digital recruitment and follow-up process allows participants to decide their own level of engagement and participation at each stage of the research

Background

The prevalence of licit and illicit drug use among gay and bisexual men (GBM) is higher than in other population groups (Bolding, Hart, Sherr, & Elford, 2006; Cochran, Ackerman, Mays, & Ross, 2004; Hickson, Bonell, Weatherburn, & Reid, 2010; Lea et al., 2013b; Newcomb, Ryan, Greene, Garofalo, & Mustanski, 2014; Roxburgh, Lea, De Wit, & Degenhardt, 2015). In Australia, more than half of GBM reported recent illicit drug use (Lea et al., 2013b). One in twenty (5.6%) reported recent injection drug use (Lea et al., 2013a). Few studies have reported on incidence, or risk factors for, initiation and cessation of, or changes in, drug use over time, or on the harmful outcomes of such use, among Australian GBM.

Associations between drug use and sexual risk behaviour among GBM

Condomless anal intercourse with casual male partners (CLAIC) is the primary risk factor for HIV infection among GBM (Elford, 2006; Jin et al., 2009; Zablotska, Prestage, Middleton, Wilson, & Grulich, 2010). Drug use, particularly when used to enhance sexual pleasures has been associated with CLAIC and with incident HIV infection among GBM (Bolding et al., 2006; Buchacz et al., 2005; DiFranceisco, Ostrow, & Chmiel, 1996; Koblin et al., 2003; McCabe, Hughes, Bostwick, West, & Boyd, 2009; Prestage, 2009; Prestage, Grierson, Bradley, Hurley, & Hudson, 2009a; Rusch, Lampinen, Schilder, & Hogg, 2004; Solomon, Kiang, Halkitis, Moeller, & Pappas, 2010). Specifically, crystal methamphetamine and erectile dysfunction medication (EDM), both used separately or in combination, have been most strongly implicated with sexual risk behaviours and HIV infection (Prestage, Jin, Kippaz, Zablotska, Imrine, & Grulich, 2009b; Fisher, Reynolds, & Napper, 2010).

Most studies to date have focused on drug use and HIV risk behaviours among GBM as a simple one-way association, often implying direct causality but lacking clear evidence. Far

less is known about the role of social, community, and interpersonal factors in predicting uptake, cessation, and harmful drug use.

Research into motivations for drug use among GBM has typically focused on individual psychological factors including the effects of homophobia, social isolation, and sexual abuse (Hatzenbuehler, 2009; Stall et al., 2001). Participation in gay community networks has been associated with increased levels of drug use (Lea, Reynolds, & De Wit, 2013c). Participation in networks of sexually adventurous GBM in the context of intensive sex partying is a key factor in sexual risk behaviour and HIV infection (Halkitis & Palamar, 2008; Halkitis, Palamar, & Mukherjee, 2007; Mansergh et al., 2001; Prestage, 2009; Prestage et al., 2009a; Prestage et al., 2009b; Semple, Zians, Strathdee, & Patterson, 2009; Solomon et al., 2010). This suggests that relationships between sexual risk behaviour, HIV acquisition, and drug use among GBM are mediated by social and community networks and subcultural affiliations.

Other drug-related harms and consequences

Although less often explored, the prevalence of drug-related harms such as dependence and overdose is high (Bolding et al., 2006; Prestage et al., 2009b; Semple et al., 2009; Stall et al., 2001; Zablotska et al., 2010). Social support provided by some gay community sexual networks can mediate individuals' drug use to prevent associated harms (Bauermeister, 2008). Further insights into specific behavioural practices and social networks may identify barriers to the adoption of harm reduction messages and inform better targeting of harm reduction programs within these networks.

Attitudes and beliefs about drug use in gay communities

Sexual practices among GBM are influenced by shared understandings of HIV risk and gay community norms, particularly those regarding 'safe sex' (Kippax, 1993). This may also be

true of drug-using behaviours and attitudes toward harm reduction. Further research is required about the role of specific gay community subcultures, and how engagement in particular sexual and social networks influences the initiation and cessation of drug use and changes in drug use over time.

The shared understandings of risk and pleasure in relation to drug use and sex among GBM are likely to be key factors in their drug using behaviour. Broad attitudes toward drug use among GBM have been explored elsewhere (Halkitis, Fischgrund, & Parsons, 2005; Jerome, Halkitis, & Siconolfi, 2009; Palamar & Halkitis, 2006) but normative beliefs about drug use within Australian gay community networks have not been previously investigated.

Study Aims

In this paper, we describe the methodology and report baseline prevalence of licit and illicit drug use among men enrolled in the Following Lives Undergoing Change (Flux) study.

Flux was established to:

1. Identify individual and contextual factors associated with initiation and cessation of drug use and changes over time in patterns of sexual and drug use behaviours among GBM men.
2. Describe the relationship between social and community norms and drug use behaviours and beliefs among GBM.
3. To describe the role of particular gay community subcultures, and sexual and social networks, in relation to attitudes and beliefs about drug use and drug-use behaviours.

We developed sophisticated and automated procedures specific to this study. This paper will demonstrate the novel application of this methodology to address the study aims; and provide details of the characteristics of the cohort and their drug user profile.

Methods

The Flux study is being conducted nationally using online survey techniques. We systematically enrol and follow-up individual GBM to collect information about drug use, risk behaviour and associated harms, and gay community engagement. We obtained additional optional consent at enrolment for linkage to hospitalisation datasets to identify drug-related presentations, and to the national HIV registry to confirm prevalent and incident HIV infections. The Flux protocol and all supporting documentation have been approved by Human Research Ethics Committee of the University of New South Wales.

Study design

We enrolled a broad sample of GBM including both current users and non-users of illicit drugs at baseline. The study will monitor changes in drug use and associated harms, beliefs and attitudes, and engagement with gay community networks over time through self-completion of online questionnaires at six monthly intervals.

A unique integrated system of digitally linking individually tailored questionnaires, study databases, and communications with participants, was developed for this study and was named the Flux Automatic Management eSystem (FAME). It was designed to be specific to this study but can be adapted to other research projects.

Power calculation and sample size

The event-driven approach was used for sample size calculations in order to compare the incidence of drug initiation between men who reported CLAIC in the last 6 months and those who did not. To enable a 80% statistical power to detect a two-fold increase in the incidence of drug initiation of amyl nitrite, erectile dysfunction medication or crystal methamphetamine, a minimum of 67 cases of initiation use of these drugs is required over a total of 540 person-years of follow-up. Based on our previous studies, we assumed an incidence of 10 per 100 person-years of initiation of these drugs (Prestage et al., 2009b) and a prevalence of 25% in men reporting CLAIC in the Gay Community Periodic Surveys (ongoing behavioural surveillance survey of GBM in Australia). Therefore, we proposed to recruit 360 men who did not have a history of using these drugs at baseline with an average follow-up of 1.5 years. From the Health in Men study, around 75% of men reported a history of using any of the three drugs (Prestage et al., 2009a), hence the total sample size of 1440 men.

Eligibility and participation

Eligibility criteria for the study were being male, currently living in Australia and aged 16.5 years or older, and identifying as a gay/homosexual or bisexual man or had sex with at least one man in the preceding twelve months.

No incentives were provided to promote enrolment. Recruitment into the Flux study was achieved entirely online. Advertising through a wide range of social media was used to reach a diverse sample of GBM across Australia, with varying degrees of gay community engagement. These included: Popular gay and bisexual 'dating' sites and apps; and Facebook. The study was also promoted through gay community events and organisations, with potential participants being provided a direct link to the study website. Advertising aimed to reach a broad sample of GBM [Appendix I] but some advertising was more targeted

to specifically attract drug use naïve (GBM who were not using drugs) participants [Appendix II].

Enrollment commenced in September 2014 and was completed in July 2015. Two-thirds (65.7%) were recruited through Facebook advertising, which obtained 286,346 views, with, on average, each person seeing the advertisement 2.74 times. There were 13,004 clicks on the advertised link that directed potential participants to the Flux study website.

In total, 21,014 clicks were received on the study's website and 6,810 clicked through to the consent form. Of these, 4,306 clicks were received past the first page of the consent form where they indicated their level of consent (six-monthly follow-up or baseline only). A total of 2943 people completed the consent form (six-monthly follow-up or baseline only) and 2705 men commenced survey responses, of whom 2251 (83.2%) provided sufficiently complete baseline data for tracking trends in drug use over time. Of the 2251 participants who completed the baseline questionnaire, 1711 (76.0%) gave consent to follow-up at six-monthly intervals. Of those who consented to follow-up, 1478 commenced the baseline questionnaire immediately, and 233 deferred their baseline entry and completed it at a later time. Of the 1711 participants who provided consent to follow-up, 1015 (59.3%) also provided any consent to data linkage.

Measures

Questionnaire items include: Demographic characteristics; social and community engagement with gay men; HIV and viral hepatitis status; licit and illicit drug use during lifetime and in the previous six months; drug use pleasures and harms; sexual behaviours; stigma and mental health; attitudes to gay community and drug use; and access to harm reduction resources and treatment services.

Previously used measures of drug use (Degenhardt, Day, Gilmour, & Hall, 2005), as well as additional items devised specifically for GBM are used, as well as our previously validated measures of sexual risk behaviour and engagement in gay community networks and subcultures (Jin et al., 2009; Zablotska, Kippax, Grulich, Holt, & Prestage, 2011). Measures of gay community engagement include two different kinds of measures: Scales measuring the extent of community engagement, and indicator variables for types of engagement (Kippax et al., 1998). The generalised anxiety disorder assessment (GAD7; Spitzer, Kroenke, Williams, & Löwe, 2006), the sexual sensation sensation-seeking (Kalichman, Heckman, & Kelly, 1996), and the patient health questionnaire (PHQ9; Kroenke, Spitzer, & Williams, 2001) were also included.

FIGURE 1

Procedures for streamlined digital processing and data protection - FAME

The FAME process was designed to enable maximum digital management of the study and to ensure a simple, smooth experience for participants. Each participant was digitally assigned a unique study identifier (USID) through the survey platform upon entry to the consent form. The USID is used to link to their unique records on all study data sources. The USID will remain the participants' unique identifier throughout the study and is central to the implementation of FAME. All communications with participants are automatically generated using their USID to automatically link to their own records. Individual participants' records from the consent form, baseline questionnaire, and all follow-up rounds will be matched through the USID. Access to any data or identifying information is protected by secure barriers at each level of access (see Figure 2).

FIGURE 2

The Flux Webpage

All recruitment advertisements and recruitment email invites were directed to the Flux web page (<http://www.flux.org.au>), which provided a detailed description of the study aims, requirements for participation, the time required for survey completion, information about ethical approval, and study contact information. Once the participant clicked on the “Enrol Now” button on the Flux website, they were redirected to the online consent form.

Online platform

All study forms are hosted by Survey Gizmo™, an online survey creator with many features that permitted us to design customised questionnaires tailored and automated to the specific needs of the project. Specifically, this allowed us to confidentially link data using the FAME process between study websites, external databases, and study questionnaires. Linking data in this way allowed us to maintain separation between information provided on the study consent forms and participants’ survey responses.

Online Consent Form

Participant confidentiality is strictly maintained at all times. For added protection, the consent form and subsequent survey forms were designed as separate online self-complete forms.

They needed to be digitally linked automatically to minimise processing of individual forms and potential errors. The consent and survey forms were created separately, and then digitally linked via the FAME process using the digitally generated USID.

The consent form described the study and explained study requirements and a link back to the Flux website if participants wanted more detail. At this point, participants could decide whether to join the Flux cohort and agree to six-monthly follow-up surveys, or simply complete the baseline survey anonymously.

Those participants who chose to complete the baseline questionnaire anonymously were re-directed into the baseline survey form (by-passing the cohort-specific consent requirements). Their USID and consent type were the only items automatically inserted into the baseline survey form. Upon completion of the baseline survey form, these non-cohort participants were again offered the option to join the Flux cohort with follow-up questionnaires. Those indicating an interest in full enrolment were re-directed back into the consent form with their USID copied back to the new consent form. A total of 108 participants (20.0%) who initially chose to anonymously complete the baseline questionnaire changed their mind at the end of the baseline entry to subsequently join the Flux cohort.

Participants who chose to join the cohort study moved on to the next page of the consent form, which listed additional, optional consents for data linkage. Participants were required to create a Flux user account to enable ongoing contact with them during the life of the study. They were asked to enter their full name, email address, and phone numbers, and their preferred method of contact. To further protect the participants' identity, they were also required to create a Flux profile name. The Flux profile name is comprised of the name of participants' first pet and the name of the first street on which they lived. This name was used in all communications with the participants.

Baseline assessment

Once their Flux account was created, participants could either commence the baseline questionnaire immediately or defer until a later time. Participants who deferred their entry were automatically emailed a PDF copy of their consent form via the FAME process which was addressed to their Flux profile name, and a unique link to their baseline survey form [Appendix III]. The link contained the USID which would be pushed into the baseline survey form when the link was triggered. These deferring participants were sent an email reminder

to complete their questionnaire the following week, also containing their USID and unique link to the survey form. This process was automatically executed by the FAME process.

Participants who chose to immediately proceed to the questionnaire were automatically moved to the baseline survey form and FAME would automatically send an email to the participant with their consent form and their unique link back into the survey form. By clicking this link, participants would automatically return to the point where they left off should they close their session, either intentionally or unintentionally. Providing each participant with their own unique link prevents duplicated and lost entries.

Upon entry into the baseline survey form, the participants' USID and Flux profile name were automatically inserted from the consent form into the baseline survey form. No identifying details were included in survey forms.

The baseline questionnaire included 199 questions. All items, where applicable, had non-response options (i.e., not applicable, none of the above, etc.). Approximately 30% of items were deemed key to measuring drug use behaviour over time and were therefore made mandatory. At any point, participants have the ability to return to a previous page and change their responses.

Due to the detailed and lengthy nature of the questionnaire, extensive survey logic (adaptive questioning) and custom scripts were written so that the baseline survey form was executed in a personalised and logical manner. That is, each participant completing the baseline survey form experienced a unique pattern based on their previous responses. Irrelevant questions were not displayed. For example, if someone had indicated they had never used drugs, all other questions about drug use behaviours were skipped. This reduced the number of questions displayed to the participant, and the time required for survey completion. This also meant that the more experience a participant had with drugs, the longer the questionnaire they

experienced. To make this more manageable, the baseline survey form was split into two parts: Part A asked about the participants demographics, drug use, and sexual behaviours, and part B measured participants' attitudes. Participants also had the option to save their responses to part A and return to part B at a later time. Participants who chose to defer part B, automatically received an email via the FAME process, with their unique link which would return them to their last point of entry. This feature also prevents duplicated entries. A total of 51 participants (2.3%) chose to defer entry into part B, of which 36 participants returned to complete their entry.

Upon submitting their final responses, participants received an automatically generated email via FAME confirming their completion of the baseline questionnaire.

Follow-up questionnaires

Six months after completing the baseline questionnaire, participants were invited to complete their first follow-up questionnaire. Invitations were sent by email and an accompanying SMS addressed to their Flux profile name. Every participant received an email containing a unique link to their personally tailored survey form. Clicking this link redirected them to a welcome page. Here, they verify that their USID was correct. Once confirmed, key responses from their baseline questionnaire were automatically loaded into the follow-up survey form. Using their baseline responses, the follow-up survey form was executed in a unique pattern, skipping redundant questions to ensure they were only asked relevant questions. For example, if a participant was not using drugs at baseline and reported using drugs at follow-up, specific questions about those changes in drug using behaviours were displayed. So, relevant questions were only asked of those who meet the specific criteria. The follow-up questionnaire included 187 questions.

Study database

A separate encrypted and protected study tracking database was specifically designed to track participants' progression throughout the study and store the Flux mailing list. Other than participants' own chosen email addresses, no identifying information was included in the tracking database and the USID was used to link with participants' own records.

An export of only the USID, Flux profile name, email address, mobile number and completion status, was captured from the consent form and survey forms and downloaded into the survey study database. Upon conversion to the study database file, it was stored in a protected, designated folder. Whenever the study database was launched, it automatically updated the enrollment and completion status for each participant. Complete datasets for each of the consent and survey forms are maintained in separate, protected databases.

To identify which participants were due to be invited or reminded, and on what dates, a query was created within the study database, automatically generating a list of only those being invited into the next round, or those being reminded about survey completion. Upon generation, these lists were uploaded into Survey Gizmo, from where each participant received an email uniquely addressed to their Flux profile name, with the link to their survey form containing their USID. Upon clicking this link, they were returned to their current position in the questionnaire.

Cohort maintenance

To maintain a large volunteer online cohort, it is essential to closely monitor participation to ensure the accuracy of participants' contact information, and completion of data. The emails sent to participants upon enrollment also provided an opportunity to determine if they had provided valid email addresses. Initially, some participants entered incorrect email addresses, posing a problem for ongoing participation. A customised email verification was embedded into the consent form requiring participants to enter their email address twice. A custom

script ensured that participants were unable to proceed unless the two email addresses matched. Only two emails bounced during the subsequent seven months of recruitment.

To prevent duplicate entries, the USID was appended to the end of each survey link, disabling that number from being re-used as an entry (regardless of the location or IP address). If the link was previously activated, the participant would be sent to the last page they had completed. This also provided a user-friendly way for participants to save and continue their participation.

The automated weekly query within the study database identified participants who had not completed their responses to each survey round. This process was repeated for ten weeks or until each individual participant completed his questionnaire. From the useable responses, 1576 (92.1%) completed the baseline questionnaire without needing an email or SMS reminder. Sixty-three participants completed their response after the first reminder, and 54 completed after the second reminder; only 18 required subsequent reminders.

A key aspect of cohort maintenance is to ensure ongoing engagement with, and feedback to, study participants. A Flux Facebook page (www.facebook.com/fluxstudy) maintained an online public presence for participants. This page posts current events of relevance to the Flux study and the latest information about the study. In addition, a quarterly eNewsletter is sent to the participants with study developments and findings, milestones, and events.

Data linkage

The optional consents were to link participants' responses with external databases.

Identification and verification of self-reported baseline and incident HIV infections within the cohort will be achieved by linkage to the HIV registry. Linkage with hospital separations

will identify drug-related incidents within the cohort. Data linkages will be completed at the end of the study period.

Results

A total of 2251 participants completed the baseline questionnaire, of whom, 1711 enrolled in the prospective observational study with six-monthly follow-up; 540 completed the same survey anonymously and declined to participate in the cohort.

The majority of participants (both enrolled or anonymous) were recruited through Facebook targeted advertising (Table 1). About one in six were recruited through popular gay dating sites and one in twenty through smartphone dating apps. Small proportions were recruited through participants' own personal networks and gay community organisations or events.

Most participants identified as cisgender men (99.2%) and there were 17 transgender or intersex men (0.8%). The mean age of the sample was 33.0 years (SD 12.6; range 16.6 to 81.0) however 35.9% were aged less than 25. Most identified as gay or homosexual, but about one in twelve identified as bisexual. Only seven identified as heterosexual and a small proportion reported other identities such as: Uncategorised, queer, pansexual, bi-curious, asexual, and fluid. Men who did not consent to follow-up, and were not enrolled in the cohort were younger ($p=0.001$), and significantly less likely to identify as gay ($p<0.001$) compared to men who consented to follow-up (Table 1).

TABLE 1

Over half (50.5%) the men reported that they had used any illicit drug in the previous six months. Over a quarter (28.0%) had used party drugs (ecstasy, speed, cocaine, crystal methamphetamine, gamma hydroxybutyrate [GHB], ketamine, lysergic acid diethylamide [LSD]) in the previous six months. The most common drugs used were marijuana, amyl

nitrite, and ecstasy (Table 2). About one in eight men (12.0%) had used crystal methamphetamine in the previous six months. Men who did not enroll in the cohort were less likely than men who did to have used any of the illicit drugs listed in the previous six months ($p=0.019$).

TABLE 2

Among the 1711 men enrolled into the cohort, 1487 (86.9%) had not used crystal methamphetamine in the six months prior to enrolment, 1133 (66.2%) had not used amyl nitrite, and 1315 (76.9%) had not used erectile dysfunction medication. In total, 790 men (46.2%) had used none of these drugs (Table 3). Among the 540 men who participated anonymously, 495 (91.7%) had not used crystal methamphetamine in the six month prior to completing the baseline questionnaire, 395 (73.1%) had not used amyl nitrite, and 445 (82.4%) had not used erectile dysfunction medication. In total, 316 men (58.5%) who participated anonymously had used none of these drugs (Table 3).

TABLE 3

Discussion

We have established an entirely online cohort study of incidence and risk factors for initiation, cessation, and changes in drug use over time among Australian GBM. The characteristics of both the enrolled and the anonymous participants in the Flux sample, while somewhat younger, are otherwise comparable to those of other samples of Australian GBM (Lea et al., 2013b; Prestage et al., 2009a; Zablotska, Holt, & Prestage, 2012). We have demonstrated the ability to collect sensitive information while protecting participants' confidentiality and that participants will provide valid personal contact details to enable successful follow-up. Flux has further demonstrated that it is possible to achieve these

outcomes with minimal direct labour costs, by developing the FAME system to digitally link study databases, online data collection tools, and communications with study participants. Investing in this technical infrastructure facilitates flexible and individually tailored study participation. The greater efficiency, ease of participation, and protection of data integrity against human error is an advantage compared to non-online cohorts. It also allows participants to decide their level of engagement, participation, and flexibility.

The initial recruitment target, which was based on our sample size calculations, was surpassed. This was achieved due to large enrolments obtained through targeted advertising, particularly of younger men.

As has been found in other samples of GBM (Roxburgh et al., 2015; Zablotska et al., 2012), men in this study reported rates of substance use that were substantially higher than in the adult male population as a whole. Whereas general population studies have found that about one in six (17.3%) adult men report recently using any illicit drug use, with 2.5% using recently using crystal methamphetamine (Roxburgh et al., 2015), half (50.5%) of men in the Flux study were found to recently use illicit drugs with 12.0% recently using crystal methamphetamine. However, in comparison to other convenience samples of Australian GBM (Lea et al., 2013b; Prestage et al., 2009a), participants in the Flux study were no more likely to report the use of drugs, and in some cases could be described as being somewhat less likely.

The processes and tools developed to administer this entirely online cohort study have substantially reduced the workload and resources required for a study of this type. This process also provides further protection of confidentiality by minimising the need for direct involvement by study staff with individual participants or their data. Participants are able to progress through the survey forms, at their own pace and in a setting of their choosing, and

there is a smooth transition and carriage of data across survey rounds. Whether the cohort includes few or many participants or is a national or international study, the cost and time management essentially remains the same when using the FAME system. This has contributed to a high completion rate once survey responses were commenced.

In addition to its high efficiency and minimal staff requirements, the design and execution of an online methodology provided many advantages. We were able to conduct a large national study in a geographically dispersed country and to attract both men that are engaged and not engaged with gay community life (Table 2). Online self-completion protects participant confidentiality by minimising direct involvement with study staff. Similar to Audio Computer-Assisted Self-Interview Software (ACASI), the online methodology potentially reduces social desirability bias in reporting illegal or stigmatised behaviours (Davis, Couper, Janz, Caldwell, & Resnicow, 2010; De Vaus, 2013; Engel & Schutt, 2016). The online methodology also provides a streamlined experience for the participants. Questions and sections of each survey were tailored to match participants' previous responses; not just within the current round, but also from previous rounds.

Nonetheless, an entirely online cohort removes direct human interaction with participants. The absence of an interviewer also removes the ability for interviewers to clarify and probe participant responses (Davis et al., 2010; De Vaus, 2013; Engel & Schutt, 2016). However, as this study sought detailed information about sensitive and potentially illegal behaviours, self-completion in the privacy of their own homes, at their own time and pace, may reduce social desirability bias (White, Day, & Maher, 2007).

This study design meant that there was no opportunity for clinical data collection to verify self-reported medical conditions. We will, however, collect information such as drug-related hospital admissions, HIV status, and deaths for those who gave consent to data linkage. As

with most social and behavioural populations engaged in illicit or stigmatized behaviours, whether online or face-to-face, we could not guarantee individuals' identity. Nonetheless, for those consenting to follow-up, we were able to verify a valid email address.

Conclusions

Having successfully implemented the FAME system to establish the first entirely online cohort study of drug use among Australian GBM, the Flux study will be able to provide data on incidence and factors associated with, initiation and cessation, and changes in patterns of drug use and related harms over time, among GBM. We will achieve these outcomes at a significantly reduced cost compared to traditional cohort studies while maintaining high levels of participant engagement and confidentiality at all stages. The high rates of illicit drug use in this sample indicate the need for longitudinal enquiry and follow up to assess continuing and changing patterns of drug use over time within this population.

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Author Agreement/Declaration

All authors certify that they have seen and approved the final version of the manuscript being submitted. All authors warrant that the article is the authors' original work, hasn't received prior publication and isn't under consideration for publication elsewhere.

Table 1: Characteristics of the sample

	Enrolled full cohort participants n=1711 (76.0) n (%)	Anonymous baseline only participants n=540 (24.0) n (%)	Total N=2251 N (%)
Mean age in years (SD) **	33.7 (12.5)	30.9 (12.6)	33.0 (12.6)
Sexual orientation ***			
Gay	1544 (90.2)	446 (82.6)	1990 (88.4)
Bisexual	122 (7.1)	77 (14.3)	199 (8.8)
Heterosexual	2 (0.1)	5 (0.9)	7 (0.3)
Other	43 (2.5)	12 (2.2)	55 (2.4)
Recruitment Source **			
Social media (Facebook)	1137 (66.5)	341 (63.1)	1478 (65.7)
Dating site (Manhunt/Squirt)	293 (17.1)	100 (18.5)	393 (17.5)
Phone apps (Grindr/Jack'd)	69 (4.0)	43 (8.0)	112 (5.0)
Personal networks	81 (4.7)	24 (4.4)	105 (4.6)
Gay community organisations	43 (2.5)	6 (1.1)	49 (2.2)
Community events (Fair day)	20 (1.2)	7 (1.3)	27 (1.2)
Other	68 (4.1)	19 (3.6)	87 (3.9)
Geographical location *			
New South Wales	697 (40.7)	198 (36.7)	985 (39.8)
Victoria	428 (25.0)	135 (25.0)	563 (25.0)
Queensland	265 (15.5)	91 (16.9)	356 (15.8)
Northern Territory	12 (0.7)	5 (0.9)	17 (0.8)
Western Australia	118 (3.9)	34 (6.3)	152 (6.8)
South Australia	99 (5.8)	42 (7.8)	141 (6.3)
Australian Capital Territory	67 (3.9)	12 (2.2)	79 (3.5)
Tasmania	18 (1.1)	15 (2.8)	33 (1.5)

Overseas	5 (0.3)	4 (0.7)	9 (0.4)
Did not answer	2 (0.1)	4 (0.7)	6 (0.3)

*p<.05

**p<.01

***p<.001

Table 2: Use of illicit drugs in previous six months

	Enrolled full cohort participants n=1711 (76.0) n (%)	Anonymous baseline only participants n=540 (24.0) n (%)	Total N=2251 N (%)
Cannabis	522 (30.5)	140 (25.9)	662 (29.4)
Amyl nitrite	578 (33.8)	145 (26.9)	723 (32.1)
Ecstasy	329 (19.2)	69 (12.8)	398 (17.7)
Meth/amphetamine (speed)	109 (6.4)	26 (4.8)	135 (6.0)
Cocaine	229 (13.4)	52 (9.6)	281 (12.5)
Lysergic acid diethylamide (LSD)	72 (4.2)	9 (1.7)	81 (3.6)
Crystal methamphetamine	224 (13.1)	45 (8.3)	269 (12.0)
Ketamine	74 (4.3)	11 (2.0)	85 (3.8)
Gamma hydroxybutyrate (GHB)	132 (7.7)	24 (4.4)	156 (6.9)
Heroin	3 (0.2)	0 (0.0)	3 (0.1)

Table 3: Combined use of crystal methamphetamine, EDM, and amyl nitrite

	Enrolled full cohort participants n=1711 (76.0) n (%)	Anonymous baseline only participants n=540 (24.0) n (%)	Total N=2251 N (%)
Used crystal methamphetamine only	26 (1.5)	4 (0.7)	30 (1.3)
Used erectile dysfunction medication only	289 (16.9)	65 (12.0)	354 (15.7)

Used amyl nitrite only	252 (14.7)	75 (13.9)	327 (14.5)
Used crystal methamphetamine + erectile dysfunction medication	28 (1.6)	10 (1.9)	38 (1.7)
Used crystal methamphetamine + amyl nitrite	30 (1.8)	9 (1.7)	39 (1.7)
Used erectile dysfunction medication + amyl nitrite	156 (9.1)	39 (7.2)	195 (8.7)
Used all three	140 (8.2)	22 (4.1)	162 (7.2)
Used none	790 (46.2)	316 (58.5)	1106 (49.1)

Figure 1: Flux study pathway

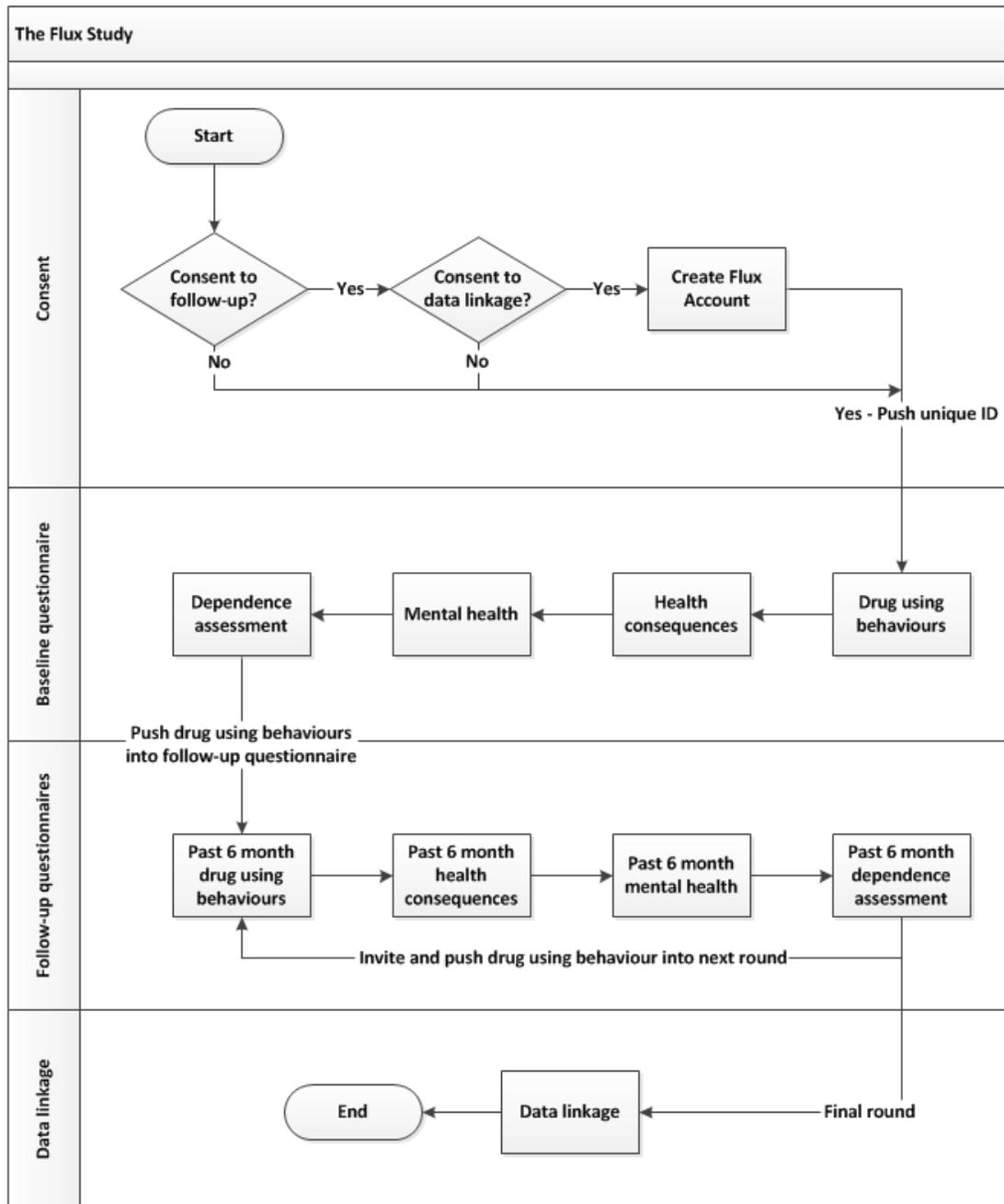
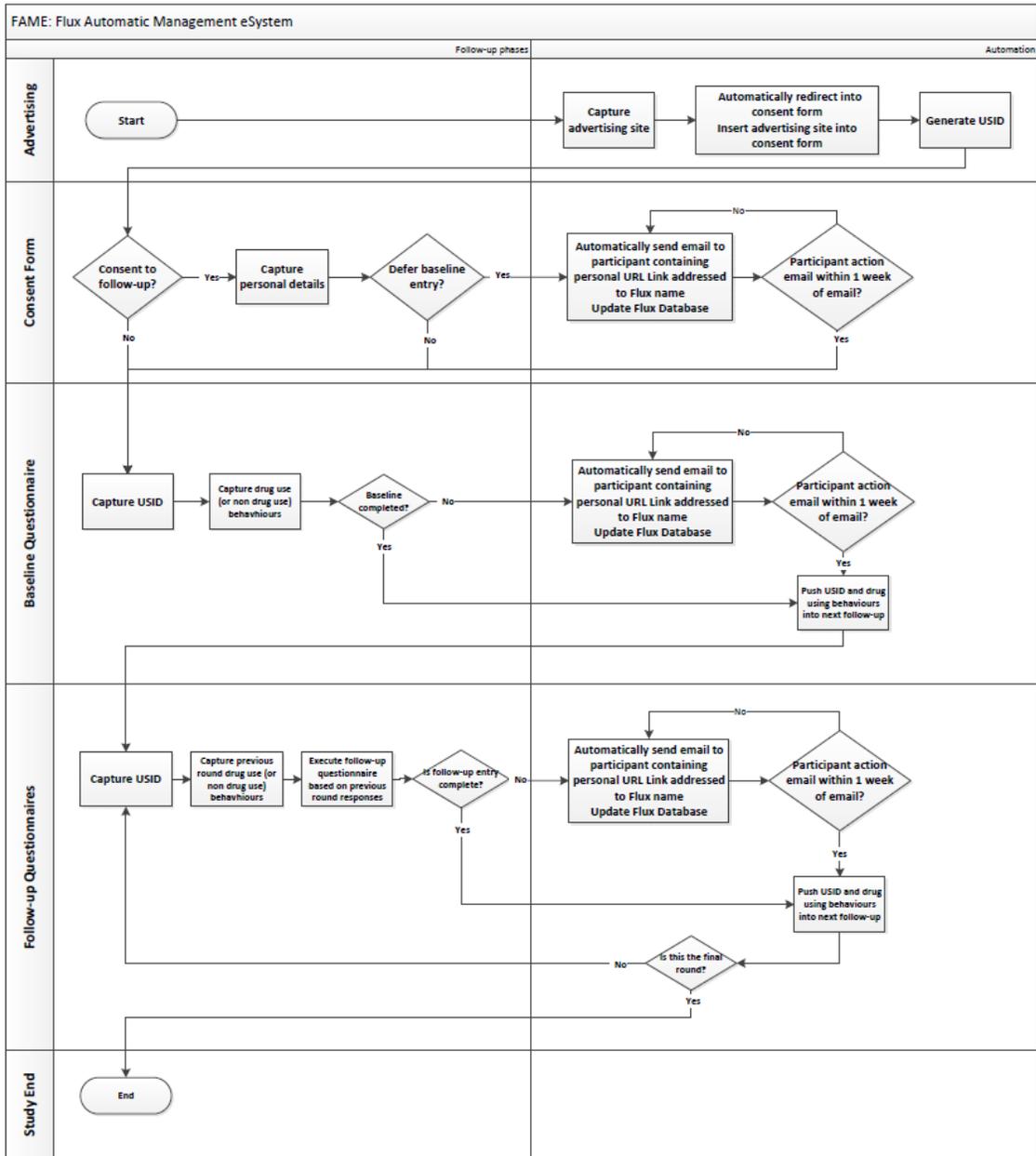
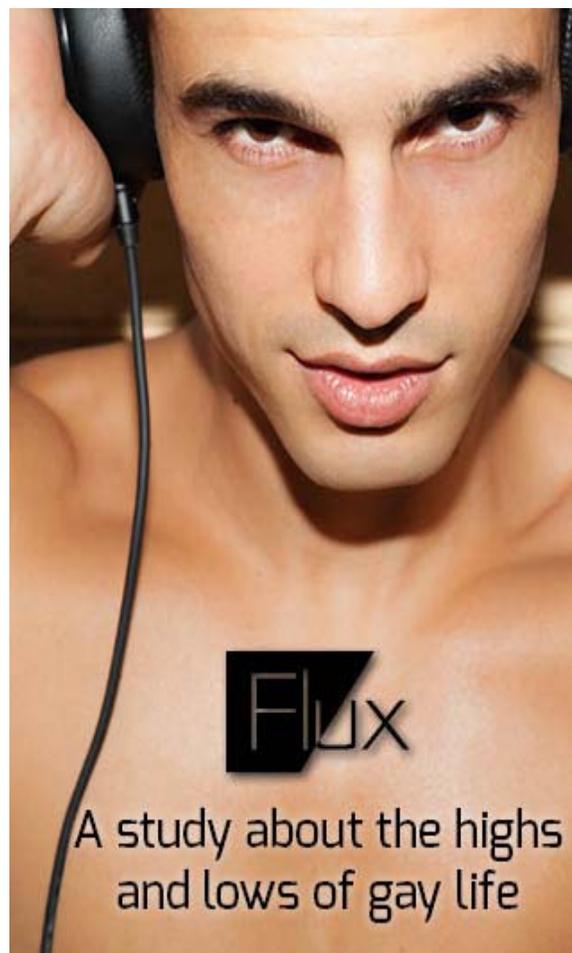


Figure 2: The FAME Process



Appendices

Appendix I



Appendix II



Appendix III

From: MED Kirby Flux
To:
Cc:
Subject: FLUX: Consent Form

Message: FLUX+-+Following+Lives+Undergoing+Change.pdf (353 KB)



Hi Teddy Bear,

Thanks for enrolling in the FLUX study. Attached, you will find a copy of your consent form.

You have agreed to complete a follow-up FLUX questionnaire in six months. That's great! This will help make the study much more successful. When the time comes, we will send you an email with the link and you can complete the questionnaire at your leisure. Don't forget your FLUX name **Teddy Bear**. You will need this to sign in (we'll remind you just in case).

If you cannot finish your entry all at once, simply [CLICK HERE](#) and we'll take you right back to where you left off.

If you have any questions or comments, feel free to reply to this email or call us on 02 9385 0700 and we'll get right back to you.

Also, don't forget to like us on [Facebook](#). It will help us stay in touch and you can get the latest news on the study.

Thanks again for being part of FLUX, and helping our community respond to issues that affect us all.

Have a great day!
The FLUX team.

Note: This is your personal link. Do not share this email because it provides you with access to your own questionnaire.



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