

Process evaluation of a bio-behavioural HIV research combined with prevention among GBMSM in 13 European countries

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Comparative European data using Second Generation Surveillance System (SGSS) are scarce among gay, bisexual and other men who have sex with men. This study evaluated the implementation of Sialon II, a bio-behavioural HIV research combined with targeted HIV prevention in 13 European cities conducted in collaboration with community partners.

A mixed-methods process evaluation assessed the project's coverage, outputs, quality, challenges and opportunities for improvement. Data collected through structured questionnaire from 71 data collectors from community-based organisations and semi-structured interviews with 17 managers of participating gay venues were analysed.

Overall implementation was successful, achieving 4901 valid behavioural questionnaires and obtaining 4716 biological samples. Challenges in conducting bio-behavioural research in gay venues related to strict research protocols and unfavourable characteristics of venues. Formative research, collaboration with community gay venues, and offering HIV prevention emerged as facilitators. Community researchers' training was crucial for fidelity to research protocols, increased trust amongst communities and enabled data collectors to effectively address practical problems in the field.

Scientifically sound SGSS with community participation is feasible and allows for including "hard-to-reach" populations. Prevention benefits include awareness raising, capacity building and sexual health promotion in gay venues. The findings are beneficial for epidemiological research among other HIV key populations.

Keywords: HIV; evaluation; public health; second generation surveillance system; gay, bisexual and other men who have sex with men

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Introduction

Gay, bisexual and other men who have sex with men (GBMSM) are the most affected key population in concentrated HIV epidemics that characterise many low prevalence countries in Europe (UNAIDS, 2015; WHO, 2014). Recent estimates show that sex between men remains the predominant mode of HIV transmission, accounting for half of the new HIV diagnoses in 2018 with known route of transmission (ECDC/WHO Regional Office for Europe, 2019). To inform effective prevention, updated epidemiological evidence at local level beyond HIV routine monitoring data is needed, particularly amongst those deemed most at-risk and often 'hard to reach' for researchers.

UNAIDS and WHO recommend that monitoring and controlling the HIV epidemic requires a structured surveillance system, a common set of indicators (including behavioural risk) across countries, and specific prevention and HIV testing campaigns targeting key populations (Gios et al., 2016; Levi et al., 2016). The few European studies addressing all these approaches (Gios et al., 2016; Mirandola et al., 2009) highlight the need for large-scale reliable and comparable Second Generation Surveillance System (SGSS) data amongst GBMSM, paired with appropriate HIV/STI prevention, treatment and care (Gios et al., 2016). While several surveys targeting sexual risk behaviour amongst GBMSM have been implemented (Aghaizu et al., 2016; Kramer et al., 2016), collecting both biological and behavioural data has only been sporadically adopted (Dubois-Arber et al., 2010; Mirandola et al., 2009). The lack of comparable data across European countries thus represents a significant challenge in monitoring progress (Gall et al., 2017). Since GBMSM are often subjected to social stigma and marginalisation, engaging them in research to assess HIV serological status and risk behaviours can be difficult (Gama et al., 2017; Pachankis et al., 2015). The

challenge in reaching ‘hidden’ populations (Gama et al., 2017) has highlighted the need for alternative, but still rigorous research strategies. Venues where ‘hidden’ populations such as GBMSM gather (including commercial and non-commercial gay venues) have been shown to be key settings to successfully implement research along with health promotion and HIV prevention initiatives (Sherriff and Gugglberger, 2014; Sherriff et al., 2017). Participatory research was shown to be valuable to obtain relevant, valid, and useful information for understanding their health needs (Cargo and Mercer, 2008; Dias et al., 2018), but so far has been underused in epidemiological research.

The European Sialon II study aimed to build capacity among Non-Governmental Organisations (NGO), public bodies and academic partners in implementing bio-behavioural HIV research combined with targeted HIV prevention. A body of evidence demonstrates that bio-behavioural surveys are useful tools to assess HIV prevalence and its associated factors amongst key populations (Global HIV Strategic Information Working Group, 2017). However, documentation on how to effectively implement bio-behavioural surveillance in community-based settings is scarce.

This article aims to evaluate the implementation of the European Sialon II bio-behavioural surveillance study in community settings, and to describe the practical barriers to, and facilitating factors of its implementation. The lessons learnt may provide valuable information to develop effective and comparable HIV surveillance amongst GBMSM and other key populations in the future.

Methods

Study context

Sialon II was a multi-centre bio-behavioural cross-sectional survey conducted in 13 European cities. Details of the study methods are described elsewhere (Gios et al.,

2016). The project adopted a participatory approach by involving members of local GBMSM communities in all aspects of the study, from its conception, development, implementation (including formative research, participant recruitment, data collection and prevention activities), evaluation, to the interpretation and dissemination of the findings along with other stakeholders (e.g. the WHO, European Centre for Disease Prevention and Control, and UNAIDS).

Two sampling methods designed to enrol hard-to-reach populations were adopted: (1) Time-Location Sampling (TLS) was used in gay venues in cities where formative research indicated viable numbers of venues and GBMSM (Dudareva-Vizule and Marcus, 2013; Mirandola et al., 2009): Brussels (BE), Sofia (BG), Hamburg (DE), Warsaw (PL), Lisbon (PT), Ljubljana (SI), Barcelona (ES), Stockholm (SE), and Brighton (UK); (2) Respondent-Driven Sampling (RDS) based on a peer-to-peer recruitment process (Heckathorn, 1997) was used in cities with few gay venues where GBMSM social network was considered as a viable medium to implement the survey: Verona (IT), Vilnius (LT), Bucharest (RO), and Bratislava (SK) (Mirandola et al, 2018).

Formative research informed the selection of data collection settings for TLS and RDS, the development of the sampling frames for TLS, and explored prevention needs (Dudareva-Vizule and Marcus, 2013). In the TLS arm, bio-behavioural data were collected in gay-friendly commercial venues (i.e. cafés, bars, discos, sex-clubs, saunas, porn-shops) and non-commercial sites (i.e. community centres, cruising areas). In the RDS arm, data were collected in general healthcare facilities selected through the formative research. Seeds were selected in collaboration with local gay organisations and were invited to recruit peers from their social network. Participants ('seeds') were provided with appropriate incentives and with three numbered coupons to recruit

eligible peers, who at their turn were requested to invite other peers using coupons. This process was repeated in waves producing chains of reference.

After obtaining informed consent, a self-administered anonymous pen-and-paper questionnaire was used to collect participants' socio-demographic and behavioural data including data to construct Global AIDS Monitoring (GAM) indicators for GBMSM (Mirandola et al., 2018; UNAIDS, 2017). The questionnaires included 36 and 45 questions for TLS and RDS study arms respectively. Biological samples (oral fluid in TLS cities and blood sample in RDS cities) were collected for HIV antibody testing after behavioural data collection. All respondents were entitled to collect their test result at a nominated centre indicated to the participant during study enrolment. In case of a positive result, a referral procedure was put in place in line with the local standard procedures to ensure linkage to care for further testing, counselling, clinical follow up and ARV treatment.

To ensure standardisation of procedures, data collectors received a two-days dedicated training on study's purpose and procedures, confidentiality issues, safety, ethical issues, and capacity building. Most data collectors were staff from local HIV and/or gay community-based organisations or individuals experienced in HIV prevention for GBMSM communities. Data collectors used standardised tools (i.e. questionnaire, prevention manual) translated into their local language. Data collectors also acted as prevention outreachers: they distributed a prevention "info-pack" containing condoms and lubricants and a leaflet with information on local HIV prevention and testing services. A "scratch-card" in quiz-format was used to engage the participants in communication on sexual health in a playful manner.

The SIALON II protocol was approved by the WHO Research Project Review Panel (RP2: A65- SIALON II), by the WHO Research Ethics Review Committee

(WHO-ERC: RPC557), and by the ethics committee in each participating country. The current evaluation study was approved by the Comitato Etico per la Sperimentazione Clinica delle Provincie di Verona e Rovigo (Italy) and by the Ethical Council of Instituto de Higiene e Medicina Tropical (Portugal) and Institutional Review Board of the Institute of Tropical Medicine (Belgium). Participation was voluntary, anonymous, confidential and informed consent was obtained from all participants.

Evaluation study

To assess the implementation process of the Sialon II project, a mixed-methods evaluation study was conducted between November 2013 - March 2014. It assessed the project's coverage, process, outputs and quality, as well as challenges experienced and opportunities for improvement. An evaluation framework defined the main implementation indicators, which were examined in the current study. A structured questionnaire was administered to 71 Sialon II data collectors and semi-structured interviews were conducted with 17 managers of participating gay venues.

Participants and procedures

Overall, 110 male data collectors were trained to implement Sialon II (TLS survey: n=92; RDS survey: n=18). Almost 65% (n=71) consented to participate in the evaluation study: 55 TLS data collectors (n=11 DE, n=9 PL, n=7 PT, n=7 SI, n=5 ES, n=5 SE, n=4 BE, n=4 BG, n=3 UK) and 16 RDS data collectors (n=8 SK, n=7 IT, n=1 LT). Those not participating stemmed from the following countries (n=12 BE, n=12 SE, n=6 DE, n=2 PL, n=2 PT, n=2 RO, n=2 UK, n=1 BG).

Data were collected using a self-administered questionnaire with closed-ended questions to assess the survey's preparation, implementation and GBMSM receptiveness, as well as open-ended questions to explore the challenges experienced in

data collection and solutions suggested. The semi-structured interviews were conducted with managers and owners of commercial gay venues in the cities participating in TLS arm (n=4 PL, n=2 BE, n=2 DE, n=2 ES, n=2 PT, n=2 UK, n=1 BG, n=1 SE, n=1 SI). Participants were selected purposively from those who accepted to collaborate with SIALON II and whose commercial venues represented the diversity of participating venues, i.e. bars, clubs, saunas, sex shops and sex venues. Interviews were conducted in local languages by members of the Sialon research team. The topic guide included questions on the experience of collaboration with Sialon II, implementation of the survey and suggestions to improve similar research initiatives. All interviews were audio-taped and transcribed in the national languages.

Data analysis

Quantitative data from the questionnaires were entered in an Excel database by each country partner. After merging the databases, descriptive analyses were performed by the Sialon II Evaluation team. Qualitative data was analysed using thematic analysis (Vaismoradi et al., 2013). In brief, each country partner identified categories in their qualitative data and translated them into English. All the categories provided by the partners were organised by the project Evaluation team and a final list of content categories was constructed. This list was then used to develop a codebook which was revised and finalised by all country partners. It consisted of codes and respective definitions. The codebook was used by each country partner to code their entire transcripts using line-by-line coding. Quotes that best illustrated each code were translated into English. The evaluation team checked the validity of the codes against transcribed data extracts. Discrepancies in coding were identified and clarified. The evaluation team also synthesized the results obtained from all country partners. Final

verification checks were made to ensure that the themes and categories consistently represented the data corpus across all countries.

Results

Project implementation indicators

Overall, 18 community-based organisations were involved in the project (Table 1). A total of 4,901 valid questionnaires were completed and 4,716 valid biological samples were obtained. Over 9,000 prevention info-packs were distributed during the survey.

[Table 1 near here]

Data collectors' perspectives

Over half of data collectors reported that the overall process of data collection had been easy (n=36; mostly from BG, ES, IT, LT, PL, PT, SE, UK) (Table 2), more frequently those in the TLS arm (n=29/55) than in the RDS arm (n=7/16) (data not shown in table). Over a quarter of data collectors expressed a neutral opinion (n=19; mostly DE). Data collectors who found the data collection process difficult (n=14; mostly SK and BE) were more frequently RDS (n=5/16) than TLS data collectors (n=9/55) (data not shown in table).

Most data collectors viewed the initial preparation of the survey as excellent/good, including the communication between the fieldwork coordinators (n=63) and the quality of training (n=60) (Table 2). A higher proportion of RDS data collectors assessed these components as fair compared to TLS data collectors. In the TLS arm, most data collectors (n=49) considered the relations with the venues' managers and staff as excellent/good.

Several data collectors expressed their positive experiences of the data collection stating that *“it was the first intervention in saunas and cruising areas, it was a great*

approach!” (PT). One data collector emphasised that *“the project was right at the edge of what MSM felt was acceptable for testing in a commercial venue”* (UK). A few data collectors did not experience any difficulty in implementing the survey: *“Overall, data collection went well, we were lucky to have very supportive venues and able to use our trusted and established reputation to recruit participants”* (UK).

Most data collectors reported that all components of the bio-behavioural survey were easy/very easy to implement, with the prevention activities considered as the easiest part (Table 2). The majority (n=50) reported that the info-packs were well received by GBMSM (data not shown in table). More than half of data collectors reported that the questionnaires and forms completion and the biological sample collection had been easy. The most difficult components for TLS data collectors were participant recruitment, while in the RDS arm it was asking participants to give coupons to peers and the questionnaire completion.

[Table 2 near here]

Challenges experienced during survey implementation and suggested solutions

In contrast to an overall positive experience, several data collectors reported specific challenges (Table 3).

Recruitment of participants

About one in five data collectors found it challenging to deal with participants' different reactions to the survey: *“There was a broad variety of participants. Some were very receptive, some not at all”* (DE). Challenges included participants being afraid of or reluctant to participate: *“...some MSM weren't interested in participating because they already knew their HIV status (negative or positive)”* (PT). Such reactions required being able to explain the study rationale well. The informed consent procedures were

perceived as too long and challenging: “...it is difficult to explain to participants why they have to sign informed consent even though the project is anonymous” (SK), in particular when there was no trust from the participants and they “didn’t believe it was anonymous” (SI).

Most common suggestions to improve participation in similar studies were adopting additional strategies to approach participants, such as providing incentives (e.g. sweets, a welcome drink, gadgets, lottery with different prizes or a coupon for free internet), but also explaining the research benefits: “give respondents more reasons to participate in the study” (SE) and “emphasise individual and community benefits of study participation” (DE). Improved communication strategies to promote the study before the data collection, for instance through “public announcement in the gay community” (DE) were also suggested. For two data collectors, activities of sexual health promotion, e.g. “to speak about STIs” (SK) could contribute to improve GBMSM’s acceptance of similar surveys. One data collector highlighted the importance of “the strong involvement of the gay community since the start of the study” (IT). Other suggested approaches related to the data collectors’ characteristics to ensure they are “friendly, inspire trust and are good communicators” (ES), and “blend into the environment (...)” (SE).

Some TLS data collectors perceived the context of the venue itself as a barrier to recruitment, as “many [GBMSM] were out to have fun and didn’t want to talk about serious issues like HIV” (SE); this applied mainly to cruising venues or places where “people coming there [a fetish/sex shop] did not really want to be disturbed” (BE). Data collectors also reported that non-overtly gay venues made it difficult to identify eligible participants. In addition, venue characteristics such as lack of a private space were found to be challenging for participant recruitment.

For some TLS data collectors, having to comply with strict sampling frames (i.e. fixed recruitment schedules and limited number of recruitment sites), as well as the period of data collection (e.g. summer months when people may travel) were further barriers to recruitment.

RDS data collectors perceived the incentive system as the greatest challenge to guarantee the continuity of the chains as “*participants had to be very motivated to allow an impact in recruitment*” (IT). Some RDS data collectors doubted the effectiveness of the sampling strategy; in their words “*[the] coupon method does not guarantee deep infiltration to MSM society and restricts the access only to people who would be interested*” (SK).

Questionnaire administration

For some data collectors, administering the behavioural questionnaire was challenging because of its length in venue contexts where “*people wanted to get back to their friends or party*” (SE). This resulted in difficulties with keeping participants motivated and avoiding withdrawal. According to data collectors, the use of an electronic questionnaire could make its completion less time consuming. They recommended to use a language more adapted to the GBMSM’ discourses, i.e. use exact terminology to distinguish between gay and homosexual, and include some personal questions “*as for example ‘How difficult is it for you to be gay in your life?’*” (SK). Other critical aspects mentioned were that “*participants felt unpleasant about some questions in questionnaire*” (SK) and “*participants often asked ‘What do you mean by...?’*” (SK). Questions perceived as particularly difficult and repetitive were those referring to different recall periods (12 months, 6 months).

Contingent on local venue characteristics, confidentiality and privacy in the social venues was difficult to ensure (e.g. when participants showed the questionnaire to

their friends/partners) according to some TLS data collectors. Unfavourable venue characteristics included loud music, no place to stand or write, and poor lighting for completing the paperwork (consent, questionnaires, etc.).

Biological sample collection

Biological sample collection posed particular challenges. Some TLS data collectors reported that “*participants could be easily approached, however, as soon as oral fluid sampling for testing was mentioned, many became reluctant*” (DE), leading to exclusion from the final sample. In some cases, GBMSM who were HIV-positive refused to provide oral fluid because they felt “*it was unnecessary to prove it with a test*” (SE). Venue characteristics were sometimes perceived as a barrier to oral fluid sample collection, because some GBMSM were reluctant to take an oral swab in a bar or disco, and even more at cruising venues. For a TLS data collector, collecting biological samples before behavioural data could contribute to more participation and less dropouts. Another TLS data collector suggested to “*provide secluded areas for oral fluid sampling*” (DE). On the other hand, a RDS data collector pointed out that in sample collection in experienced workplaces for HIV/AIDS prevention it is better to maintain the “*standard routine procedures and methods for collecting and labelling samples with test results and participants*” as they are already settled, than “*introducing schemes and methods from the project*” that can be unnecessary and interfere with the original standard system (SK).

Prevention activities

Data collectors reported that the prevention activities were generally well accepted by the participants: “*most of participants took part only just to receive prevention pack*” (BG). Some suggestions to achieve a wider testing coverage were made, such as test

more people, expand the scope of the test and include also testing for other STIs. It was also suggested that the study could distribute the tests and materials “*without a survey*” (SE).

Notwithstanding, a few data collectors found it difficult to retain participants for prevention activities due to the time needed for data collection. Therefore, the scratch-cards were not always used. The characteristics of the venues also hindered interaction: “*Talking about prevention issues was difficult in a discotheque setting*” (DE).

Data collectors proposed to improve the implementation of prevention activities by strengthening the collaboration with community’ representatives and NGOs, “*using ‘key associates’ from different sub-groups*” (BG) and “*include more NGOs in the project*” (SK). An RDS data collector also pointed to the need of “*igniting conversation on a personal level*” and therefore “*employing somebody with a spiritual and/or psychological background to support them [participants] in opening up to confront the real issue*” (SI).

Other suggestions to improve the prevention component included offering condoms for oral sex, giving out more detailed leaflets “*to inform people about diseases, symptoms, etc.*” (SI) and offering a reward, “*maybe scratchable lottery [cards], movie tickets*” (SE).

[Table 3 near here]

Venues managers’ perspectives (TLS only)

The interviews with the managers of commercial gay venues focused on their perspectives on collaboration with Sialon II, including the implementation of the TLS survey, and suggestions for similar initiatives.

Collaboration with Sialon II

About half of the managers perceived all aspects of project collaboration as positive. Two managers specifically mentioned the relationship and collaboration with community partners (e.g. NGOs) as positive aspects, expressed by clear rules and responsibilities defined for both parties. Established relationships with community partners and participation in previous studies were mentioned as enabling collaboration. Two managers perceived the opportunity to implement “*something different*” in the venue (ES) as good. Showing customers that they “*cared about other things than earning money*” (SE) would potentially increase the popularity of the venue, while being beneficial for the community. According to four managers, customers’ feedback about the Sialon II project had generally been good. They described customers as receptive and as appreciating the opportunity to try the oral fluid sampling, although some customers reacted with distrust and lack of interest.

Implementation of the survey

Several positive aspects of the data collection were highlighted by most venue managers. Generally, data collection was perceived as adequate, smooth and professional, and good collaboration with data collectors and easy communication with the project leaders were highlighted. Data collectors’ discretion, non-intrusiveness and blending in the venue (i.e. respect for the dress code) were pointed out as relevant. Managers also pointed out that data collection procedures were implemented in appropriate periods and respecting confidentiality. Offering the possibility to receive the test result after ten days was also appreciated. However, three managers’ feedback was negative, mentioning that data collection was at times disturbing (BG, SE, SI).

Suggestions for improvement

Overall, managers were in favour of their stronger involvement as research partners in similar initiatives. Collaboration in similar projects was seen as potentially beneficial for good reputation of venues in gay communities. Subsequently, raising other venues managers' awareness of research benefits was proposed. Several other suggestions that managers believed could potentially improve participation in studies emerged from the data: feeding back study results to both managers and to participants, incentives (for instance, free condoms), additional prevention activities, to provide a designated room for data collection to increase privacy as well as free HIV testing in sex venues (BE, SI, UK), and implementing activities at night or "*do it more often on the weekends*" (PT). It was also recommended to engage other types of venues "*to attract different types of MSM as married gay men will not go [...] some venues for fear of being recognised*" (UK). In addition, a reduction of days for data collection, and a better adjustment of data collection schedules to the working hours of the venues were proposed.

Discussion

With implementation in 13 European cities, Sialon II was one of the largest bio-behavioural surveys ever conducted to assess HIV prevalence and behavioural risk factors among "hard-to-reach" and most-at-risk subgroups of GBMSM.

This evaluation study shows that although being a challenging undertaking, the implementation of this bio-behavioural survey including prevention activities was largely successful and accomplished the envisaged project objectives. Our findings show that methodologically sound epidemiological results can be achieved with community participation, potentially increasing the quality of the data collected. The qualitative evidence confirms benefits in terms of awareness raising, capacity building and sexual health promotion. As multi-centric bio-behavioural surveillance studies are

scarce in Europe, comparable relevant data between countries is almost non-existing. This creates considerable difficulties for the development of responsive transnational policies and strategies at Member State and EU levels. The use of common standardised indicators for HIV/STIs conferred a high degree of comparability of data on HIV prevalence and related risk behaviours among GBMSM across the 13 participating European countries.

This evaluation study was set up to gain insights into the factors that may lead to a successful implementation of bio-behavioural surveys in “hard-to-reach” populations. Adopting a community-based participatory research approach (Dias et al., 2018; Nöstlinger and Loos, 2016) is likely to be one such key factor by providing opportunities for community partners to meaningfully participate in the full research cycle, to share their expertise, knowledge, and concerns. An approach encouraging open dialogue, critical review and group problem-solving potentially strengthens research procedures (e.g. recruitment strategies, instrument development and validation), and contributes to validate the findings (Simpson et al., 2013). In Sialon II, the participatory approach helped to build trust with the study population, venue managers, collaborating HIV/LGBT NGOs, and the research team. Similarly important, this approach ensured the study’s acceptability and feasibility in a variety of different contexts.

Within its participatory nature, a key focus of Sialon II was to build the capacity of academic and community partners, as well as community-based data collectors to implement the study in local community settings. Our findings suggest that involving the community partners already at the stage of formative research, i.e. in the elaboration of the research protocol, in training as data collectors, and in the development and delivery of prevention activities, contributed importantly to the successful implementation of the main study.

Prevention activities were an integral part of the project's design alongside data collection. Although prevention effects were not directly measurable, the qualitative findings suggest that these activities were highly acceptable to GBMSM at the venues. The prevention component emerged as the most appealing element of the project, as evidenced by the data collectors' enthusiasm towards these activities. Prevention activities were perceived as directly benefitting the participants, being in line with other studies on the added value of community involvement in HIV prevention (Zhang et al., 2017). On the research level, GBMSM communities seem increasingly aware of and receptive to this kind of studies. Our findings support the need to integrate prevention and research, especially in sexual high-risk contexts.

In line with other research (Gama et al., 2017; Sherriff et al., 2011, 2014) our data show that commercial and community gay venues can be valuable settings for HIV surveillance and prevention. Indeed, recruiting in venues where GBMSM gather to socialise or find sexual partners enabled the enrolment of different groups of GBMSM with diverse HIV behavioural risk profiles (Marcus et al., 2018; Mirandola et al., 2017; Rosińska et al., 2018). In societal contexts where GBMSM may be difficult to be reached by mainstream public health approaches due to social stigma and discrimination (Nöstlinger et al., 2014), 'gay' businesses can be key sites to deliver research and health promotion interventions for 'hidden' and marginalised groups (Sherriff and Guggleberget, 2014). In this respect, it is a promising finding that the majority of venue managers appreciated collaboration, which suggests that prevention activities could be expanded to other type of venues. Clearly, venue managers can have a role in raising communities' awareness of the research, disseminating findings and assisting in HIV prevention planning. Building innovative alliances for co-production of knowledge are essential features of public health and should continue to be supported involving

commercial venues (Sherriff et al., 2011; Rovniak et al., 2010). However, our data also show that involving community partners and gay venues meaningfully in research is demanding and requires careful planning. The collaboratively developed formative research was necessary to enable the study teams to obtain accurate information on the venues' affluence, receptiveness, characteristics and potential drawbacks to plan and conduct the fieldwork. In the current times of COVID-19, we cannot underestimate its impacts on commercial venues as many faced severe restrictions of activities based on new regulations for public health protection or complete closure due to induced lockdowns. As a result, many of commercial gay venues may not survive the pandemic. In the future, these venues can be less representative for research in gay communities as they were before COVID-19, so alternatives to venues as settings for second generation biobehavioural research may be needed.

Lessons learnt

We draw several lessons pertaining to the observed implementation challenges.

Selection of data collectors

Data collectors and venue managers emphasised the importance of data collectors' personal characteristics such as, for example, discretion, non-intrusiveness, good communication, as important for a successful implementation. These quality criteria are, however, subject to training and capacity building, including ethics and skills building in the training to raise data collectors' awareness on these topics.

Training

Adequate training of peer data collectors is important for smooth project implementation, ensuring that they acquire a common understanding of the research protocol. This requires resources (e.g. time, training skills). Viewing the project through

a prevention rather than a research-focused lens, calls for rigorous training on fidelity to standardised research procedures (see also below). Items to be included in training relate to the purpose and limits of research versus prevention activities, the study's methodological requirements and the importance of safeguarding scientific rigour. In addition, skills training to improve interactive communication, empathic questioning and active listening skills can enhance the quality of the data collection. Fieldwork support through continuous supervision and monitoring is also key to enable data collectors to address issues arising during the fieldwork, that influence study enrolment and adherence (Nöstlinger and Loos, 2016). As evidenced by other research, training community researchers to build research capacity will increase trust and reduce research fatigue among communities (Minkler, 2004).

Ethical challenges

The great emphasis put on ethics and confidentiality by both data collectors and venue managers reflects the high sensitivity of the research topic, linked to intersecting forms of stigma and discrimination that GBMSM often face (Pachankis et al., 2015). This may be particularly relevant in some central and eastern European settings (Takács et al., 2013). Training of data collectors should focus on ethical issues balancing participants' rights with study requirements, and emerging practical difficulties during data collection. By doing this, it is important to recognise the heterogeneous, highly contextualised sexual health needs of GBMSM across Europe (Platt et al., 2015).

Managing fidelity to the study protocol

Managing potential tensions between fidelity to the study protocol and data collection feasibility in practice contributes to successful implementation. Recruitment methods may have practical constraints to be considered to ensure a balance between scientific

rigor and practicalities (Dias et al., 2018; Simpson et al, 2013). As described, venue features such as loud music or insufficient light may reduce fidelity to complex study protocols (e.g. multiple data collection forms, questionnaire format and length), potentially influencing data quality. Some adaptation to the context may be needed, particularly in environments that are not conducive to data collection (e.g. cruising venues) but allow for direct access to groups at higher risk of HIV/STI acquisition. Questionnaire format (electronic, paper-pencil) and content should balance researchers' priorities (to collect as much meaningful information as needed from "hard-to-reach" populations) and context constraints (to collect the possible information). There is no one-size-fits all solution to this challenge. Scrutinising questionnaires for minimum length and consulting with communities beforehand should enable the collection of essential data without jeopardising participants' motivation and avoid consequent fatigue and drop-out. The systematic recording of all problems that arise during data collection will help to timely identify and overcome difficulties, as well as develop solutions adapted to the local context and needs in collaboration with communities.

Considering study context

In multi-centric studies like Sialon II, conducted in countries with different societal acceptance of sexual minorities, it is important to address contextual features. There is a great diversity among European countries in terms of gay sub-cultures' health seeking behaviour (Yousaf et al., 2015), HIV testing behaviour (ECDC, 2016), and acceptance of community-based HIV testing. This heterogeneity results in potential limitations when applying standardised research and prevention tools at the local level. However, as evidenced by our data, a common and harmonised approach is feasible and acceptable. Comparable findings across countries and cities clearly increase epidemiological relevance (Leung et al., 2004).

Study limitations

We adopted triangulation of different quantitative and qualitative data sources to increase the validity of the findings. However, limitations must be acknowledged. Our analysis was not able to systematically differentiate between the specificities of the two sampling methods and the country-level associated factors. Due to the time span between the Sialon II survey and the evaluation, participants may have not been able to recall all the significant experiences. Results must be interpreted with caution considering the low number of respondents for some topics, particularly of RDS data collectors. Since not all data collectors and venue managers participated in the evaluation study, a self-selection bias may apply. However, there were large similarities between data collectors' and venue managers' perceptions, which strengthens the results' trustworthiness.

Conclusions

This evaluation study showed that SGSS with active community involvement is feasible in atypical settings for bio-behavioural research, even in contexts where sexual activities are facilitated. Indeed, including such settings was critical to reach important subgroups of GBMSM who usually are "harder-to-reach" for epidemiological and prevention research.

While standardised research protocols safeguard scientific rigour, their contextualisation to different research settings using formative and participatory research approaches is key for successful bio-behavioural surveillance.

The integrated evaluation approach applied in Sialon II provides a thorough assessment of the encountered implementation challenges. The lessons learnt comprise crucial information to improve similar future initiatives for capacity building and feasible SGSS among GBMSM, and extend – through their emphasis on participatory

approaches and contextualization – to other key populations at increased risk for HIV/STI acquisition.

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Declaration of interest

The authors declare that they have no competing interests.

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Table 1. Indicators of Sialon II achievements.

	Total	TLS survey		RDS survey	
	n	n	%	n	%
Number of community-based organisations involved (n)	18	12	66.7	6	33.3
Number of venues where data collection and prevention activities took place (n)	108	108	-	-	-
Number of valid completed questionnaires out of 4966 collected (n)	4901	3596	73.4	1305	26.6
Number of valid biological samples (n)	4716	3411	72.3	1305	27.7
Number of info-packs distributed (n)	9040	7560	83.6	1480	16.4
Number of scratch-cards distributed (n)	2010	2010	-	-	-

Table 2. Assessment of the data collection preparation and implementation, by data collectors.

	Total n (%)	TLS survey n (%)	RDS survey n (%)
Survey preparation			
Communication with the fieldwork coordinators (TLS/RDS data collectors, n=69)			
Excellent/Good	63 (91.3)	50 (92.6)	13 (86.7)
Fair	6 (8.7)	4 (7.4)	2 (13.3)
Bad/Very bad	0 (0.0)	0 (0.0)	0 (0.0)
Quality of training (TLS/RDS data collectors, n=71)			
Excellent/Good	60 (84.5)	49 (89.1)	11 (68.7)
Fair	11 (15.5)	6 (10.9)	5 (31.3)
Bad/Very bad	0 (0.0)	0 (0.0)	0 (0.0)
Relations with the venues' managers and staff (TLS data collectors, n=55)			
Excellent/Good	49 (89.1)	49 (89.1)	n/a
Fair	5 (9.1)	5 (9.1)	n/a
Bad/Very bad	1 (1.8)	1 (1.8)	n/a
Schedules for participants' recruitment (TLS data collectors, n=44)			
Excellent/Good	32 (72.7)	32 (72.7)	n/a
Fair	9 (20.5)	9 (20.5)	n/a
Bad/Very bad	3 (6.8)	3 (6.8)	n/a
Survey implementation			
Recruitment of participants (TLS data collectors, n=55)			
Very easy/Easy	25 (45.5)	25 (45.5)	n/a
Neutral	17 (30.9)	17 (30.9)	n/a
Difficult/Very difficult	13 (23.6)	13 (23.6)	n/a
Completion of questionnaires and data collection forms (TLS/RDS data collectors, n=62)			
Very easy/Easy	36 (58.1)	34 (61.8)	2 (28.6)
Neutral	17 (27.4)	15 (27.3)	2 (28.6)
Difficult/Very difficult	9 (14.5)	6 (10.9)	3 (42.8)
Biological sample collection (TLS/RDS data collectors, n=60)			
Very easy/Easy	34 (56.7)	30 (54.6)	4 (80.0)
Neutral	14 (23.3)	13 (23.6)	1 (20.0)
Difficult/Very difficult	12 (20.0)	12 (21.8)	0 (0.0)
Implementation of prevention activities (TLS/RDS data collectors, n=62)			
Very easy/Easy	46 (74.2)	39 (70.9)	7 (100)
Neutral	13 (21.0)	13 (23.6)	0 (0.0)
Difficult/Very difficult	3 (4.8)	3 (5.5)	0 (0.0)
Ask participants to give coupons to other GBMSM (RDS data collectors, n=7)			
Very easy/Easy	3 (42.9)	n/a	3 (42.9)
Neutral	1 (14.2)	n/a	1 (14.2)
Difficult/Very difficult	3 (42.9)	n/a	3 (42.9)

n/a: not applicable

Table 3. Main challenges experienced in each component of data collection, according to data collectors.

Recruitment of participants
Lack of receptiveness
Unfavourable characteristics of the venues
Inadequate recruitment schedules and periods
Difficulties in presenting the study and obtaining the informed consent
Questionnaire administration
Unfavourable questionnaire layout and unclear questions
Participants' withdrawal before questionnaire completion
Lack of compliance with confidentiality and self-completion procedures
Unfavourable characteristics of the venues
Biological sample collection
Apprehensive reaction from the participants
Refusal to provide an oral fluid sample
Unfavourable characteristics of the venues
Prevention activities implementation
Length of data collection process
Unfavourable characteristics of the venues
Suggestions for improvement
Recruitment of participants: provision of incentives, explanation of the research benefits, communication strategies to promote the study
Questionnaire administration: electronic questionnaire; language more targeted
Biological sample collection: sample collection before behavioural data collection; secluded areas for oral fluid sampling
Prevention activities implementation: wider testing coverage, distribution of condoms for oral sex and rewards, strengthening the collaboration with community representatives and NGOs using 'key associates' from different sub-groups
