

Institution: Glasgow Caledonian University (GCU)		
Unit of Assessment: 3: Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: Reducing HIV infections in key vulnerable populations by informing Scottish, UK and wider European prevention policy and practice.		
Period when the underpinning research was undertaken: 2012-2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Claudia Estcourt	Professor of Sexual Health & HIV	2016 - present
Dr Jamie Frankis	Reader in Sexual Health Psychology	2000 - present
Professor Paul Flowers	Professor of Health Psychology	1999 - 2019
Professor Sharon Hutchinson	Professor of Epidemiology & Population Health	2013 - present
Professor David Goldberg	Professor of Public Health	2013 - present
Dr Alan Yeung	Research Fellow	2019 - present
Dr Andrew McAuley	Reader in Public Health	2014 - present
Period when the claimed impact occurred: 2016-2020		
Is this case study continued from a case study submitted in 2014? No		
1. Summary of the impact Research at GCU has been instrumental in reducing transmission of HIV by directly shaping policy in Scotland and the Republic of Ireland, and by changing models of care in Scotland, and by influencing European HIV Pre-exposure prophylaxis (PrEP) guidance. In Scotland, PrEP has reduced by two thirds the overall risk of acquiring HIV in men who have sex with men, and recently acquired infections have decreased by 40% since PrEP was introduced in 2017. People who inject drugs in western Scotland are among the first world-wide to benefit from a PrEP service to prevent HIV transmission.		
2. Underpinning research The interdisciplinary GCU HIV prevention group conducts programmatic, mixed methods research with diverse populations. Approaches and methods span basic social science to addressing wider issues of implementation and policy. The breadth of our research expertise, prominence of our senior researchers in national/international clinical and public health, and strong links to key community-based organisations have enabled very rapid translation of research findings into practice, often ahead of publication. PrEP is a new biomedical prevention tool in which people take anti-HIV drugs to prevent them acquiring HIV. PrEP had been demonstrated to be highly effective in men who have sex with men (MSM) in clinical trials but by 2015, PrEP had not been implemented at scale and its acceptability in the “real world” context was unknown. Our early Celtic nations survey research (2015/2016 [R1], funded by NHS Lanarkshire [G1], was the first study to accurately assess PrEP acceptability amongst high-risk MSM and showed that willingness to take PrEP rose as HIV risk behaviours increased. A subsequent mixed-methods study [R2], funded by NHS Lanarkshire [G1] and the UK Medical Research Council (MRC) [G2] provided additional granularity, showing that almost half of all MSM at high risk of sexually acquired HIV in Scotland, (those who would benefit most) would use PrEP when available. Bio-behavioural survey research led by GCU (Drs McAuley, Palmateer, Prof Hutchinson), published in Lancet HIV, 2017-18 showed that prevalence of HIV among people who inject drugs (PWID) in NHS Greater Glasgow & Clyde (NHS GGC) had increased ten-fold from 1% to 11% because of an outbreak [R3, G3]. The study also generated the first empirical evidence of		

the key individual and environmental factors associated with infection: homelessness, incarceration, and a major shift to injection of cocaine.

The survey findings [R3] led us to explore qualitatively, in one of the first studies worldwide, the acceptability of PrEP among people who inject drugs (PWID) in Glasgow at very high risk of HIV during the ongoing outbreak (2019-2020). We showed that many found PrEP acceptable and would take it if offered [R4, G4].

As other UK countries rolled out PrEP programmes (2017-2020), Prof Estcourt, led a Five Nations (UK & Republic of Ireland) initiative to develop an evidence-based dataset for regular reporting of PrEP clinical activity and outcomes, to develop a harmonised monitoring system for PrEP across five closely related nations, funded within [G3]. We used a modified Delphi Technique to develop and refine the data variables and demonstrated utility with Scottish national data. The dataset has informed the 2021 European (ECDC) guidance on PrEP monitoring, led by Prof Estcourt [G5].

Finally, in 2019-2020 we conducted complex epidemiological analyses of Scottish national datasets to provide the first “real-world” data on impact of PrEP at population level [R5, G3]. We used a retrospective cohort approach with readily available data from over 12,000 MSM, contributing over 20,000 person-years of follow-up. We showed that compared to the pre-PrEP period, risk of HIV in MSM in the PrEP period was reduced by 75% among those prescribed PrEP at least once.

3. References to the research

Our underpinning papers include key new knowledge from a large online survey involving complex statistical analyses [R1], mixed methods studies with integration of several datasets [R2], a large cross-sectional analysis of four cross-sectional, anonymous, bio-behavioural surveys of almost 4000 PWID [R3], one of the first studies to explore acceptability of PrEP use in PWID [R4] and complex epidemiological analysis of large national data sets which reported population impact of routinely implemented PrEP for the first time [R5].

- [R1] Frankis J, Young I, Lorimer K, Davis M, and Flowers P. Towards preparedness for PrEP: PrEP awareness and acceptability among MSM at high risk of HIV transmission who use sociosexual media in four Celtic nations: Scotland, Wales, Northern Ireland and The Republic of Ireland: an online survey. *Sexually Transmitted Infections*. 2016 Jun 1;92(4):279-85. <https://dx.doi.org/10.1136/sextrans-2015-052101>
- [R2] Frankis J, Young I, Flowers P, McDaid, L. (2016). Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?: Understanding PrEP Awareness and Acceptability amongst Men Who Have Sex with Men in the UK-A Mixed Methods Study. *PloS one*, 11(4), e0151385 <https://doi.org/10.1371/journal.pone.0151385>
- [R3] McAuley A, Palmateer NE, Goldberg DJ, Trayner KMA, Shepherd SJ, Gunson RN, Metcalfe R, Milosevic C, Taylor A, Munro A, Hutchinson S. Re-emergence of HIV related to injecting drug use despite a comprehensive harm reduction environment: a cross-sectional analysis. *Lancet HIV*. 2019 May;6(5):e315-e324. [https://doi.org/10.1016/S2352-3018\(19\)30036-0](https://doi.org/10.1016/S2352-3018(19)30036-0)
- [R4] Smith M, Elliott L, Hutchinson SJ, Metcalfe R, Flowers P, McAuley A. Perspectives on Pre-exposure Prophylaxis for People Who Inject Drugs in the context of an HIV outbreak: a qualitative study. *International Journal of Drug Policy*: Volume 88, February 2021, published online 26.11.20. <https://doi.org/10.1016/j.drugpo.2020.103033>
- [R5] Estcourt C, Yeung A, Nandwani R, Cullen B, Goldberg D, Wallace L, Steedman N, Hutchinson S (last author). Population-level effectiveness of a national HIV pre-exposure prophylaxis programme in men who have sex with men: a retrospective cohort study within real world implementation in Scotland. (*AIDS*: accepted 30.11.20, published online ahead of print 7.12.20. <https://doi.org/10.1097/QAD.0000000000002790>

Research Grants

- [G1] Dr Frankis' & Prof Flowers' work was funded as part of NHS Lanarkshire and GCU partnership funding for Blood Borne Viruses research [1.10.12 – 31.5.14] (£20,000 plus 20% salary costs; Title: Social Media, Men who have sex with men and Sexual Health Study).
- [G2] HIV & the Biomedical- Investigating the Acceptability of Biomedical Interventions for HIV Prevention in Scotland, the qualitative research component, was awarded to Dr Ingrid Young and Prof McDaid, funded by the UK Medical Research Council (MRC) (MC_U130031238/MC_UU_12017/2), as part of core-funding for the Sexual Health Programme (now the Social Relationships and Health Improvement programme) at the MRC/CSO Social and Public Health Sciences Unit, University of Glasgow. Sponsor: GCU and University of Glasgow.
- [G3] Part of Dr McAuley's work and Prof Estcourt's leadership of the national evaluation of PrEP and related work (P5, P6) were both funded as part of Hutchinson SJ (PI), Goldberg DJ. Analytical research to inform on the effectiveness of services to prevent, diagnose and treat blood borne viruses in Scotland using data collected as part of the Scottish Government's Sexual Health & BBV Framework (2015-2020). (Funded by Health Protection Scotland, 2015-2020, £1,805,110). Sponsor: Health Protection Scotland.
- [G4] Dr McAuley's work was also funded by the Needle Exchange Surveillance Initiative (NESI). The initiative was initially funded by the Scottish Government as part of the Hepatitis C Action Plan. More recently the initiative has been funded under the auspices of the Scottish Government's Sexual Health and Blood Borne Virus Framework. NESI provides information to evaluate and better target interventions aimed at reducing the spread of infection amongst PWID. The GCU team took over the delivery of the NESI study in 2017 as part of a seven-year collaboration and research agreement with Public Health Scotland (then Health Protection Scotland), value £600,000 January 2017 to March 2024. Sponsor: Health Protection Scotland.
- [G5] Professor Estcourt was invited to present the Five Nations minimum dataset for PrEP monitoring at an HIV prevention workshop at The European Centres for Disease Prevention and Control (ECDC) in November 2018. Following this, she was invited to apply for (and was awarded) the contract from ECDC, Office of Chief Scientist Service, Contract ECD 9879, Support to European Member States on implementation and monitoring of pre-exposure prophylaxis for HIV, NP/2019/OCS/10701, 2020, €49,922, Sponsor: GCU.

4. Details of the impact

Prof Estcourt's team's research has impacted on HIV prevention policy and practice in some of the most vulnerable and marginalised groups in Scotland, the UK and the Republic of Ireland. It has also influenced pan-European prevention guidance. In Scotland, this has contributed to a 40% reduction in new diagnoses of HIV in MSM in the last two years (a cost saving of £320,000 per transmission) and provided PrEP for PWID in the context of an uncontrolled outbreak, in the first example of this worldwide.

The Deputy Chief Medical Officer for Scotland is "indebted to Professor Estcourt and the team for their contribution to the national HIV prevention agenda. They are highly regarded in Scottish Government in terms of the quality and importance of their work in the SH and BBV fields" (S1).

Impact on Scottish HIV Prevention Policy:

The Scottish Medicines Committee approved PrEP for people at highest risk of HIV in April 2017 based on the recommendations from Scottish Health Protection Network Working Group [S2]. The Group used data from GCU research [R1, R2] to:

1) provide its estimate of PrEP uptake in MSM at high risk of HIV (58.5%) (R1, S2/page 4/para3), leading to the Group's recommendation for approval of PrEP and subsequently the estimate on which planning of national clinical PrEP services was based. Subsequently 1855 MSM were protected from acquiring HIV in the first year of roll out.(S3/page17/para3).

2) to determine risk-based eligibility criteria for PrEP. Evidence from [R2] suggesting that condomless anal intercourse with two or more previous partners in the last 12 months was a marker of HIV transmission risk, led to the Working Group recommending that this should be (S2/page4/para3) (and subsequently became, S3/page16/Fig 4.1) one of the eligibility criteria for PrEP. This enabled an additional 2776 MSM, a group at highest risk of HIV and poor sexual health, to be protected from acquiring HIV in the first two years of the PrEP programme (S4/page9/last para).

We improved understanding of HIV transmission in PWID which led to an expansion of targeted HIV testing and PrEP provision during an ongoing HIV outbreak.

Findings from our bio-behavioural and qualitative research [R3, R4] directly informed the public health response to the outbreak:

3) Enhanced testing initiatives were introduced in the “hotspot areas” identified in the research ahead of publication [R3] [S5,S6,S7]. which contributed to 112 PWID being diagnosed with HIV (2016-2019) and linked into effective HIV care. Dr McAuley provided evidence at Scottish Affairs Committee (2016-2019) inquiry on problematic drug use on 7 May 2019 [S5], which was referenced by the Scottish Government when endorsing plans for Scotland’s first safer drug consumption facility [S6]. Ahead of publication, the research also informed the business case for Scotland’s first Heroin Assisted Treatment (HAT) service which opened in November 2019 To date, 10 PWID have been successfully managed on HAT.

4) NHS Greater Glasgow & Clyde established a highly innovative PrEP service for PWID at high risk of HIV through sexual transmission, in identified “hotspot” areas [R3], [S7] Dr Smith’s qualitative study showed PWID would find PrEP acceptable if more widely offered [R4]. To date 37 PWID with concurrent sexual risk (largest cohort in Europe) have been protected from HIV by taking PrEP.

“... the research has undoubtedly had an impact on reducing the potential for onward transmission of the virus thus benefitting the health outcomes of the population most at risk (PWID). In addition, it is likely to have contributed to a major cost saving to the health board...” (S7, Chair of NHS Greater Glasgow & Clyde Outbreak Incident Management Team).

5) The minimum dataset for national reporting of Human Immunodeficiency Virus PrEP-related data has been incorporated into Public Health Scotland’s National Statistics reporting cycle (S8/page3/para1) [G3] helping policy and health planners to drive sustainable PrEP provision for the population.

6) Our national level epidemiological analysis [R6] has underpinned the decision to continue a Scottish national PrEP programme to reduce HIV transmission, widening PrEP eligibility criteria to include the two groups of MSM at very high risk of HIV [R6, S1]. As a result, an additional 1500 MSM are being offered protection from acquiring HIV per year.

“Our close links and joint working across research studies, policy and national strategies creates a unique partnership in which the views and needs of beneficiaries are central to the work from the very start” (S9, CEO HIV Scotland).

Impact on Republic of Ireland PrEP policy:

7) Estimates of PrEP uptake [R1], were used in the Republic of Ireland’s Health Protection Surveillance Report, on which the Irish National programme was based (S10/page7/3.4.3, page12/4.6, page14/5). 2289 people at high risk of HIV have benefitted from the Irish PrEP programme to November 2020.

Impact on Wider European PrEP guidance:

8) Prof Estcourt presented an early version of the minimum dataset at European Centres for Disease Control “PrEP in Europe”, workshops (2018 & 2020). It was so well received that it has been included in new European CDC PrEP Operational Guidance, (led by Prof Estcourt) as an

example of a robust monitoring tool for country-level data reporting and European-harmonised reporting to monitor progress against HIV prevention goals [S11, Annex 3] [G5].

5. Sources to corroborate the impact

- [S1] Testimony from Deputy Chief Medical Officer of Scotland.
- [S2] Nandwani R and Valiotis G, on behalf of the Scottish HIV Pre-Exposure Prophylaxis Short Life Working Group. PrEP in Scotland. Scottish Health Protection Network (SHPN) October 2016 <https://www.hiv.scot/Handlers/Download.ashx?IDMF=3552380c-0e28-472e-be2e-49eccc40d6ed> Scottish Medicines Committee short life working group submission paper on which decision to approve PrEP in Scotland was made and eligibility criteria informed by our work are evidenced. (our papers provide estimates for uptake and acceptability & are referenced).
- [S3] Implementation of HIV PrEP in Scotland: First Year Report (published online 26 February 2019) <https://www.hps.scot.nhs.uk/publications/hps-weekly-report/volume-53/issue-8/hps-release-hiv-prep-implementation-report/> Nicky Coia, Claudia Estcourt, David Goldberg (Chair), Pauline McGough, Rak Nandwani, Nicola Steedman, Ruth Robertson, and Lesley Wallace on behalf of the National Coordination Group and its subgroups (cites our papers on estimates of uptake & evidences impact of PrEP, actual uptake and success of the national programme).
- [S4] Implementation of HIV PrEP in Scotland: Second Year Report, Publication Date: 17 December 2019 <https://www.hps.scot.nhs.uk/web-resources-container/implementation-of-hiv-prep-in-scotland-second-year-report/>
- [S5] The Lancet HIV research was also discussed by Dr Andrew McAuley in his oral evidence to the Scottish Affairs Committee inquiry on problematic drug use on 7 May 2019 (<https://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/scottish-affairs-committee/problem-drug-use-in-scotland/oral/101819.pdf>) and the subject of a parliamentary question on HIV infection rates in the Scottish Parliament on 1 May 2019. (<https://www.theyworkforyou.com/sp/?id=2019-05-01.16.0>).
- [S6] Dr McAuley was directly quoted by the First Minister during First Minister questions in the Scottish Parliament, in response to a Parliamentary question on drug policy on 9 May 2019 (<https://www.theyworkforyou.com/sp/?id=2019-05-09.21.0>).
- [S7] Testimony Chair of NHS Greater Glasgow & Clyde Outbreak Incident Management Team. NESI research data on HIV among PWID was fed in prospectively to the NHS GGC HIV PWID Outbreak Incident Management Team.
- [S8] Implementation of HIV Pre Exposure Prophylaxis (PrEP) in Scotland: Minimum Dataset Reporting, 1 July 2017 to 31 December 2019, Publication Date: 23 June 2020. (<https://www.hps.scot.nhs.uk/web-resources-container/implementation-of-hiv-preexposure-prophylaxis-prep-in-scotland-minimum-dataset-reporting-1-july-2017-to-31-december-2019/>).
- [S9] Testimony, Chief Executive, HIV Scotland charity.
- [S10] Testimony, Lead Republic of Ireland National PrEP programme, HIV Pre-Exposure Prophylaxis (PrEP) in Ireland PrEP estimates for populations at risk of sexual acquisition of HIV in Ireland. <https://www.hpsc.ie/a-z/hivandaids/hivtreatmentandprep/Ireland%20PrEP%20report%20v1.0%202017.pdf>
- [S11] ECDC 2021 PrEP Principles of care and Evaluation. Estcourt lead author. 2019-2020 European CDC Support to European Member States on implementation and monitoring of pre-exposure prophylaxis for HIV. NP/2019/OCS/10701. Principal Investigator, 2019-2020. <https://www.ecdc.europa.eu/en/publications-data/HIV-PrEP-eueea-and-uk-implementation-standards-monitoring-guidance>