Institution: University of Bath

Unit of Assessment: 3. Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Evidence-based safer injecting equipment for users of illicit drugs

1. Summary of the impact

The health of people who inject illicit drugs, the formulation of harm-reduction policies, and the work of associated businesses and social enterprises have all benefited from the University's laboratory and practice research into the safety and efficacy of materials and equipment used in needle-exchange programmes. The research has informed the development of safer acids for injection preparation, safer injecting paraphernalia (e.g., spoons and filters) and an information film which has been distributed from needle exchanges on DVD and viewed over 50,000 times online. The research has led to enhanced support and protection for injecting drug misusers, and to advances in harm reduction in the UK, France and Canada.

2. Underpinning research

The key contextual information is that, according to estimates, over 300,000 people in England are dependent on opiates and/or crack cocaine (*Hay, G., Gannon, M., Casey J., Millar, T., (2010) Estimates of the prevalence of Opiate Use and/or Crack Cocaine Use, 2009/10: Sweep 6 report.* *http://www.nta.nhs.uk/uploads/prevalencestats2009-10fullreport.pdf*). Many of them inject these drugs and this entails multiple risks. The road to abstinence can be long and often requires many attempts at sustaining a drug-free lifestyle. Harm reduction is an accepted approach that aims to cut the damage caused by illicit drug-taking. In 2003 and 2005, UK legislation was changed to permit the supply of injecting paraphernalia, including acids to facilitate solubility of drugs, preparation vessels (e.g., spoons) and filters to remove particles from injections. There is no requirement in law for this equipment to be tested for safety or effectiveness prior to marketing, but there are consumer protection and moral issues around the supply of untested equipment. These are drivers of the research at Bath.

The research underpinning the impacts described in Section 4 is a blend of practice research and laboratory-based pharmaceutical science investigations.

In 2002-03, Dr Jennifer Scott (Senior Lecturer in Pharmacy Practice and Medicines Use at Bath since 1999) and Rhys Ponton (Bath PhD student, 2002-06) interviewed and observed injecting drug users to establish a reproducible method of heroin injection preparation as a basis for scientific study. This method was built upon and expanded by Scott in 2003-04 through work undertaken in collaboration with researchers at the University of Paisley and funded by the Scottish Executive. The work also looked at the preparation of crack cocaine injections. The outcomes were reproducible, controllable preparation methods for a range of illicit drug injections, allowing detailed study in the laboratory of each aspect of the process.

Laboratory work in 2001-03 by Scott and in 2003-05 by Scott and Ponton using street heroin examined the use of various acids in the injection-preparation process. These investigations included a microbiological comparison of the use of household products with sterilised, pharmaceutical-grade citric acid [1]. The work also looked at resulting drug content in prepared injections, to establish user acceptability and aspects of injection stability. In addition, the researchers studied the performance of filters for use by injecting drug users (IDUs) and produced data on acceptable pore size and flow rate [2]. Laboratory work by Scott from 2005 to 2006, funded by the Scottish Executive, examined the safety and effectiveness of a wider range of filters in more detail, as well as the leakage of aluminium from preparation vessels. The results of this work led to the development of the aluminium-free Spoon® by Frontier Medical and modification to the Stericup® by Association Apothicom.

Work by Scott during this time, conducted in collaboration with Bristol Drugs Project, also focused on the microbiology of the hands of injecting drug misusers. It compared the performance of two methods of hand cleansing. [3]

3. References to the research

1. Ponton, R. & Scott, J. 'Injection preparation processes used by heroin and crack cocaine injectors', *Journal of Substance Use*, 9(1): 7-19, 2004. DOI: 10.1080/14659890410001665041
2. Scott, J. 'Laboratory Study of the Effectiveness of Filters used by Heroin Injectors', *Journal of Substance Use,* 10:5, 2005. DOI: 10.1080/14659890412331319425
3. Scott, J. 'Study of the Safety, Risks and Outcomes from the Use of Injecting Paraphernalia', [report] Edinburgh: Scottish Executive, March 2008. Available online: http://www.scotland.gov.uk/Resource/Doc/127313/0057758.pdf

4. Details of the impact

Research at Bath has had an impact on:

1. Practitioners and services, evidenced by the supply of improved and new products, literature and web information by Exchange Supplies, Association Apothicom and Frontier Medical.
2. Public policy, evidenced by the influence on the Advisory Council on the Misuse of Drugs and subsequent health policy.
3. And, through these, on the health and welfare of drug misusers.

Impact on practitioners and services

Exchange Supplies is a social enterprise, formed in 2001, which provides products, information and services that reduce the harms of illicit drug use. Dr. Scott has been collaborating with Exchange to examine the use of various acids in the injection-preparation process and the resulting drug content in prepared injections. An important impact of this research was its crucial influence on the development by Exchange Supplies of Citric and VitC acidifier sachets, which are much safer than alternatives, such as lemon juice, often used by injecting drug users. The Managing Director of Exchange Supplies has remarked [1], *"We have had a long association with Dr Jenny Scott at the University of Bath, whose understanding of the chemistry of illicit drug injection process is second to none. When we were first establishing the business, and developing our first product (a single use sachet of citric acid to be added to heroin or crack cocaine as a safer alternative to vinegar or lemon juice) the advice we received from Dr Scott was invaluable. Her research provided a scientific rationale for the amount, and type, of acid we should supply in the sachet. The positive impact of launching the product on the basis of a solid scientific foundation in its subsequent success cannot be underestimated"*.

The move to evidence-based provision of the products manufactured by Exchange Supplies by most NHS services in the UK has been the foundation upon which the company has been built and transformed into a thriving social enterprise, turning over almost £3 million per year, and employing 15 people. The Exchange team includes current and former drug users for whom paid, flexible and supportive employment, and additional training opportunities, are provided [1].

The Managing Director further notes that [1], *"Dr Scott's expert evidence to the Advisory Council on the Misuse of Drugs was a significant causal factor in them recommending amendments to the Misuse of Drugs Act so that acids, spoons, filters and foil could be legally provided. This combination of impact on injecting drug users technique, drug worker practice, and UK public policy have combined to achieve significant impact on the health and welfare of injecting drug users both in the UK and worldwide"*.

Correct use of the Citric product was encouraged via the production of a collaborative film by Dr Scott and Exchange Supplies in 2006 [2]. This demonstrated in the laboratory the correct use of Citric with street heroin, and addressed concerns that injectors had been using the whole sachet rather than the correct amount, an error which could (and did) result in vein damage. The DVD was distributed to needle exchanges, it was shown in waiting rooms, and handed out free to IDUs. In 2008, a drug user activist posted the film on YouTube, prompting Exchange Supplies to launch a YouTube channel and publish the film in HD format. Total YouTube views for both versions of the film currently stand at over 50,000.

Association Apothicom (France), a not-for-profit association created in 1992 for information and prevention, conducts public health research programmes and develops tools for drug use-related harm reduction. **Apothicom** created and developed a unique prevention kit, Steribox™, and invested considerable effort to make it available to illicit drug users. Subsequently, Stericup® and Sterifilt®, single-use cup and filter, respectively, completed the kit. Today, Steribox2™, which contains these prevention tools, is supplied by pharmacies, syringe exchange programmes and automatic vending and dispensing machines. The founder of Apothicom, has stated [3], *"Dr Scott's efforts were pivotal in the early 2000s in convincing the U.K. Home Office to change its position on harm reduction tools for illicit drug users (specifically, the supply of acidifying agents and the provision of sterile filters). Evidence presented by Dr Scott to the U.K. Advisory Council on the Misuse of Drugs (ACMD) informed subsequent legislation changes on paraphernalia supply. In turn, this convinced the French authorities that the supply of harm reduction tools for drug users was warranted. Further, Dr Scott alerted Apothicom in 2008 of a possible risk associated with the metal composition of our Stericup®, a problem which has now been resolved such that 50,000 drug users are now using this tool every day"*.

As further examples of the reach of Dr Scott's research and its impact in the REF period, in 2009, Apothicom and the Centre de Biologie Médicale Spécialisée de l'Institute Pasteur, Paris, sought permission from the Scottish Executive to translate the 'Study of Safety, Risks and Outcomes from the Use of Injecting Paraphernalia' [4] into French, to inform French policy on needle exchange equipment supply. Apothicom's founder also notes that, *"Jenny Scott's report, 'Study of the Safety, Risks and Outcomes from the Use of Injecting Paraphernalia' (Edinburgh: Scottish Executive, March 2008) is a reference work for French decision makers, and greatly influenced our document, "Référentiel de Réduction des Risques". Her work has contributed to best practice recommendations and to ensure that harm reduction supplies are available to public health services in many countries. For example, her studies are often cited when a choice between acidifiers or other materials is to be made; as an illustration, see Best Practice Recommendations for Canadian Harm Reduction Programs That Provide Service to People Who Use Drugs and Are AT Risk For HIV, HCV, and Other Harms (2013)"*. [5]

Frontier Medical Group (Wales) provides a range of safe and appropriate products (usually distributed through pharmacies) for the prevention of harm in intravenous drug users. One of Frontier's products was an aluminium cup in which IV drug users dissolved heroin in water, typically adding an acidifier and applying heat. Scott undertook research to address a concern that there was a risk that aluminium from the cup might contaminate the "hit" and cause harm to the user. Although this work revealed that the cups were in fact quite safe, and that the release of aluminium was unlikely to pose a health risk, Frontier decided, on the basis of Scott's results, to develop its own brand stainless steel spoon that is now a highly successful product, millions of which have been sold throughout the world [6].

Bristol Drugs Project (BDP). Scott's work [7] with BDP included a focus on the microbiology of the hands of injecting drug misusers. A comparison of the performance of two methods of hand cleansing resulted in the crafting and distribution of an advice pamphlet for intravenous drug users. Subsequently, in collaboration with Scott, BDP introduced Safer Injecting Workshops with four main foci: (a) use of a clean needle for each injection, (b) rotatable sites, (c) good technique for preparation and injecting, and (d) hygiene (including hand washing). As BDP's former Harm Reduction Team Leader notes [7]: *"… as a result of [Scott's] initial research, all washing facilities were revamped and hand-washing Gel dispensers were liberally installed around [BDP's] buildings and mobile units for clients to use".*

Impact on policy

Professor David Nutt, past chair of Advisory Council on the Misuse of Drugs (ACMD), invited Dr Scott to give evidence to this group on three occasions. The first two presentations informed the 2003 and 2005 changes in legislation on paraphernalia supply. The third gave an overview of research conducted for the Scottish Executive, which is cited in a 2009 ACMD report [8] which informs current policy on hepatitis C prevention.

Funding from the Scottish Executive and the publication on the Internet in 2008 of the report called 'Study of the Safety, Risks and Outcomes from the Use of Injecting Paraphernalia' [5] led to a

change in policy, not only in the UK but also in France and Canada during the REF period [4].

The 2011 Harm Reduction Training Manual published by the British Columbia Harm Reduction Strategies and Services department, part of the British Columbia Harm Reduction Program, used Scott's research findings to evidence their advice on paraphernalia use [6].

Health and welfare of drug users

The Managing Director of Exchange Supplies affirms that Scott's research, expert advice and advocacy: *"on injecting drug users' technique, drug worker practice, and UK public policy have combined to achieve significant impact on the health and welfare of injecting drug users in the UK and worldwide"* [1]. This view is fully endorsed by the Programmes Coordinator of the International Network of People who Use Drugs (INPUD, a global network that seeks to represent current and former drug users in international agencies, e.g., the UN, and those undertaking international development work), who states [9], *"[Scott] has been active in training practitioners working with drug treatment organisations… [her] involvement has reduced significant harm to many of the drug using communities".*

Thus, in summary, the main beneficiaries of this research are:

- Injecting drug users, who now have access to a range of sterile, fit-for-purpose equipment that has been tested for theoretical safety despite no legal requirement to do so. This has benefited their individual health. The supply of equipment has attracted IDUs into needle exchange services, which by proxy is thought to have contributed to the control of blood-borne viruses such as HIV and hepatitis C.
- Policymakers and harm-reduction agencies in a number of countries have been able to develop their thinking and their practical approaches in the light of scientific evidence from Bath.
- Companies that manufacture and distribute injecting paraphernalia, including Exchange Supplies and Association Apothicom have benefited from the provision of scientific data that has guided product development, contributing to the uptake of new products by health professionals and injecting drug users.

5. Sources to corroborate the impact

1. Letter from the Managing Director of Exchange Supplies (UK).
2. http://www.youtube.com/watch?v=e_hlxbW1v20&feature=c4-overview-vl&list=PL40D8E249F1025C7E
3. Letter from the Secrétaire General, Association Apothicom (France).
4. J. Scott, "Safety, Risks and Outcomes from the Use of Injecting Paraphernalia", (final report of the findings of a study into the impact of providing paraphernalia to injecting drug users), Scottish Government Social Research, 2008, http://www.scotland.gov.uk/Resource/Doc/127313/0057758.pdf.
5. 'Harm Reduction Training Manual' (for frontline staff involved in harm-reduction strategies and services). Vancouver: British Columbia Harm Reduction Strategies and Services. January 2011. Available online: http://www.bccdc.ca/NR/rdonlyres/C8829750-9DEC-4AE9-8D00-84DCD0DF0716/0/CompleteHRTRAININGMANUALJanuary282011.pdf
6. Letter from the Group Managing Director, Frontier Medical Group (Wales).
7. Email from the former (now retired) Harm Reduction Leader (until 2013), Bristol Drugs Project.
8. 'The Primary Prevention of Hepatitis C Among Injecting Drug Users'. Advisory Council on the Misuse of Drugs, London: Home Office, February 2009. (research referenced on pages 22 and 35). Available online: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/119144/acmdhepcreport2.pdf
9. Letter from the Programmes Coordinator of INPUD.