

Institution: University of Brighton		
Unit of Assessment: A3 Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: The 'One-Stop' care community model to achieve Hepatitis C elimination		
Period when the underpinning research was undertaken: 2011 – 2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (eg job title):	Period(s) employed by submitting HEI:
Sumita Verma	Professor and Honorary Consultant in Hepatology	2007 – to date
Ahmed Hashim	Clinical Research Fellow in Hepatology	2015 – 2018
Stephen Bremner	Professor of Medical Statistics	2015 – to date
Period when the claimed impact occurred: 2013 – 2020		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact Brighton and Sussex Medical School (BSMS) research led to the development of a simplified Hepatitis C Virus (HCV) care pathway for high-risk populations (drug users and homeless) and played a major role in achieving the national goal of eliminating HCV by 2025. As a result, the number of drug users and homeless individuals in Brighton and Hove receiving HCV treatment increased by > 100%, contributing to a 48% reduction in HCV-related liver disease mortality over the same period. Two of the largest national HCV centres (Operational Delivery Networks) adopted elements of this nationally commended good practice model to achieve NHS England (NHSE) HCV elimination targets. The research changed understanding of integrated HCV care pathways with drug services and has been adopted by a leading international pharmaceutical company. This led to their successful 2019 NHSE HCV elimination tender, securing the greatest share of patients treated with their drugs.</p>		
<p>2. Underpinning research In May 2016, the UK joined 193 other member states signing the 2016 WHO Global Sector Strategy with the aim to eliminate Hepatitis C Virus (HCV) by 2025, five years earlier than the WHO 2030 target. This goal seems achievable with the rollout in 2015 of new effective oral HCV treatments (direct-acting antivirals (DAAs)) by NHSE. Alongside the widespread introduction of DAAs, NHSE created that same year, 22 HCV Operational Delivery Networks (ODNs) to coordinate HCV care at a national level. Brighton and Sussex University NHS Hospital Trust is the hub of the Sussex ODN overseeing treatment in this area.</p> <p>There are currently estimated to be around 89,000 people living with HCV in England who need to be urgently identified and treated to achieve HCV elimination by 2025. In England, HCV prevalence is highest in under-served populations such as people who use drugs (PWUDs) and the homeless. In Brighton and Hove, between March 2016 – March 2017, Public Health England (PHE) identified 2,065 cocaine and opiates users (ie 1:300 of the local population); and in 2019 the homeless charity Shelter stated that 1:75 of the local population (n=3,804) were homeless. Due to their lifestyle choices, competing priorities and perceived stigma, this vulnerable population does not engage with secondary care HCV treatment services. With the availability of safer oral DAAs, a novel solution is to move HCV care from the traditional hospital to community-based sites such as addiction centres and homeless sites attended by this most at-risk population.</p> <p>On-going pioneering work by Professor Sumita Verma and colleagues has provided the research-based evidence for the successful delivery of such HCV care models in community settings within Brighton and Hove. Verma collaborated with addiction specialists, social workers, peer mentors, GPs, qualitative researchers, health economists, charities (HCV Trust and HCV Action) and local commissioners, and led the three studies described below that underpin the impact claims in Section 4.</p> <p>The aim of the first study, conducted by nurse Mucha Marufu, and supervised by Verma, was to assess the feasibility of undertaking blood borne virus (BBV) screening in PWUDs at the largest addiction centre in Brighton (Pavilions; approximately 1,900 registered clients), with subsequent referral to secondary care. During the 6-month study, <10% of newly diagnosed HCV patients</p>		

attended hospital appointments, with none being treated [references 3.1, 3.6]. This study highlighted the need for integrated HCV services within a community setting.

Focusing on 'one-stop' care models, Verma and her team conducted the ITTREAT study investigating the feasibility of an integrated HCV service for PWUDs at Pavilions. From 2013 – 2020, a community nurse (Margaret O' Sullivan, Verma as supervisor) offered community-based HCV screening/treatment and non-invasive assessment of liver scarring, working alongside addiction teams, peer mentors and social workers, delivering a non-judgemental, personalised and holistic service [3.2,3.3,3.4,3.7]. ITTREAT was delivered in collaboration with Professor Heather Gage (University of Surrey) who led on the health economics, Dr Chrissie Jones and Professor Helen Smith (University of Brighton) who led on the qualitative analysis and Anna-Marie Jones (Sussex Partnership Foundation Trust) who led on the statistical analysis. The primary outcome of ITTREAT was improved HCV cure rates, and secondary outcomes included service uptake/compliance, changes in Health-Related Quality of Life (HRQoL), and cost per HCV case detected and cured. ITTREAT results showed that the integrated HCV care model designed and assessed by Verma and colleagues was feasible with high cure rates (90%) and high engagement/compliance (> 95%) [3.3]. Significant improvements in generic and liver specific HRQoL after HCV cure were observed and achieved at modest costs (approximately GBP880 per HCV case detected and treated) [3.3]. As this cohort do not attend hospital, a cost comparison was not feasible. Qualitative data indicated that the integrated and holistic nature of the HCV service improved patient engagement [3.4].

The third study, VALID (2015 – 2018), evaluated a similar model of care at homeless hostels in Brighton [3.5]. The project was led by Sussex Research Fellow Hashim and Verma, in collaboration with Professor Guru Aithal (University of Nottingham), Professor Stephen Bremner (University of Sussex) and Arch Healthcare, the only homeless primary care practice in Brighton. Its primary outcome was the prevalence of clinically significant chronic liver disease (CSCLD) amongst the homeless. Its secondary outcomes included service uptake/compliance and HCV cure rates. About 1:4 patients had CSCLD, with again high compliance (>95%) and HCV cure rates (82%) [3.5, 3.8].

Verma has secured a 42-month research grant (2019 – 2023; GBP269,000) from Gilead Sciences to develop similar care models in East and West Sussex.

3. References to the research

- [3.1] Marufu, M., Williams, H., Hill, S. L., Tibble, J., & Verma, S. (2012). Gender differences in hepatitis C seroprevalence and suboptimal vaccination and hepatology services uptake amongst substance misusers. *Journal of Medical Virology*, 84(11), 1737–1743. <https://doi.org/10.1002/jmv.23389> [Quality validation: leading peer-reviewed journal].
- [3.2] Hashim, A., O'Sullivan, M., Williams, H., & Verma, S. (2018). Developing a community HCV service: Project ITTREAT (integrated community-based test – stage – TREAT) service for people who inject drugs. *Primary Health Care Research & Development*, 19(2), 110–120. <https://doi.org/10.1017/S1463423617000731> [Quality validation: leading peer-reviewed journal].
- [3.3] O'Sullivan, M., Jones, A.-M., Gage, H., Jordan, J., MacPepple, E., Williams, H., & Verma, S. (2020). ITTREAT (Integrated Community Test - Stage - TREAT) Hepatitis C service for people who use drugs: Real-world outcomes. *Liver International*, 40(5), 1021–1031. <https://doi.org/10.1111/liv.14403> [Quality validation: leading peer-reviewed journal].
- [3.4] Phillips, C., Schulkind, J., O'Sullivan, M., Edelman, N., Smith, H. E., Verma, S., & Jones, C. J. (2020). Improving access to care for people who inject drugs: Qualitative evaluation of project ITTREAT—An integrated community hepatitis C service. *Journal of Viral Hepatitis*, 27(2), 176–187. <https://doi.org/10.1111/jvh.13214> [Quality validation: leading peer-reviewed journal].
- [3.5] Hashim, A., Bremner, S., Macken, L., Worthley, T., Aithal, G., & Verma, S. (2019). FRI-231-Hostel-based models can improve the engagement of homeless individuals with liver services: VALID (vulnerable adults liver disease) study. *Journal of Hepatology*, 70(1, Supplement), e496–e497. [https://doi.org/10.1016/S0618-8278\(19\)30976-4](https://doi.org/10.1016/S0618-8278(19)30976-4) [Quality validation: nominated for the Royal College of Physicians Excellence in Patient Care Awards 2017].

Key research grants

- [3.6] Sumita Verma [PI], Gilead Sciences, 2011, 'Hepatitis C virus seroprevalence and engagement with Hepatology services amongst substance misusers', GBP22,000.

[3.7] Sumita Verma [PI], Gilead Sciences) and Brighton and Hove Commissioners, 2013 – 2021, 'Project ITTREAT – Integrated Community Based Test-Stage-Treat HCV Service for PWID'. Total funding GBP175,071.

[3.8] Sumita Verma [PI], Dunhill Medical Trust, Kent Surrey and Sussex Deanery and Gilead Sciences, 2015 – 2018, 'Non-invasive detection, stratification and treatment of chronic liver disease in vulnerable elderly adults in the community-VALID Study'. Total funding GBP205,821.

4. Details of the impact

Verma and team, via the ITTREAT and VALID projects, provided the research-based evidence essential to the development and implementation of an innovative community-based HCV model of care for high-risk populations. This led to a substantial increase in access to and treatment of HCV in the Brighton and Hove area, improving the care experience for vulnerable members of the community. It also provided a robust good practice care model that is now leading the way for further replication of improved care services in England.

4.1 Increased access to and treatment for HCV

As of June 2018, ITTREAT and VALID studies have linked 700 homeless individuals and PWUD to care services in Brighton and Hove. The number of PWUDs and homeless individuals referred from the community to receive treatment increased from 0 in 2011 to 153 between 2014 – 2018 [3.3, 3.5]. The then local lead commissioner (Alcohol and Substance Misuse), Ms Kathy Caley, linked the increased number of individuals accessing HCV treatment services to the successful delivery of the BSMS innovative model: *'The intensive support provided by the [ITTREAT] HCV nurse means that service users are more open to being tested, and are more informed about treatment options. The integrated nature of the HCV nurse with substance misuse treatment services has been very important in driving forward the success of this project [ITTREAT]. The outcomes of the service have been very positive with a significant increase in the number of individuals that are now accessing HCV treatment services (October 2015)'* [5.1]. This view is seconded by Dr Tim Worthley, GP at the only homeless surgery in Brighton (Arch Healthcare), one of the VALID study sites, who notes: *'The significant impact that BSMS VALID study had is that it immediately removed all major blocks for our patients to access HCV care: patients did not need to go to hospital to receive treatment, they did not have to stop using drugs or alcohol, and the treatment was not based on interferons thus rendering the treatment protocol more acceptable for adherence. In a short space of time, our GP surgery went from 5% to approximately a third of our patients [total registered patients 1400] accessing treatment for HCV* [5.2].

In Brighton and Hove, the percentage of PWUDs tested for HCV has increased from 87.6% in 2012 – 2013 (prior to ITTREAT project) to 96.4% in 2017/18 (5 years into the ITTREAT project). This represents the highest rate in South East England [5.3a]. Mortality from advanced HCV-related liver disease/ liver cancer, has reduced by 48% from 2012 – 2014 to 2016 – 2018, compared to a 9% reduction in mortality nationally over the same period [5.3b]. ITTREAT and VALID studies were the only clinical research conducted in the area during this period, specifically targeted at improving HCV testing and treatment of these high-risk populations. Dr Worthley acknowledged the impact of BSMS research on their approach to provide HCV care, noting that *'[they] were able to emphasise with other healthcare services the importance of getting this population tested for HCV because for the first time there was the possibility of treatment'* [5.2]. The BSMS HCV care model has since been adapted to other services in the area, and in the last 5 years Dr Worthley has run specialist community clinics in diabetes and respiratory diseases.

4.2 Improved patients' HCV care experience, understanding of HCV, and other health-related outcomes

The community-based HCV cure was associated with significant improvements in HRQoL, including improved mental and physical health, decreased distress and, most importantly, a reduction in the stigma associated with HCV [3.3]. This innovative model of care also contributed to an improved treatment experience in this group with the trusting client-provider relationship being instrumental in the individual's recovery pathway and their own health awareness [3.4]. This is illustrated by patient testimonials: *'I thought it was a little less, err, impersonal. You just feel like you're a cow being forced through, like a sheep dip kind of system in hospitals. But here you know they know your name and they're a little bit more personal with you. I think a little bit*

more caring cos they have a little bit more time' [3.4]. By providing a simplified HCV care pathway, patients experienced benefits over and above that related to the liver. According to Dr Worthley: *'patients [...] immediately became more engaged with their healthcare, knowing they no longer had to face the numerous hurdles for them to access care. It thus provided them with the opportunity to regain control of their health. It also had a significant impact on their understanding of the disease and their ability to access treatment. As a result, once treated for HCV, they were able to address other issues in their lives such as their drug or alcohol use'* [5.2].

4.3 Developed a good practice care model for replication by HCV healthcare professionals

The BSMS holistic model of care for HCV has been commended by NHSE following its review of the Sussex ODN in 2018: *'the 'one-stop shop' model of community service provision provided easy access for clients and provided a great model to replicate around the country'* [5.4]. This view was seconded by Professor Graham Foster (ODNs National Clinical Lead) and Peter Huskinson (NHSE Commercial Director of Specialised Commissioning) who stated that *'Brighton's initiative to treat people who are homeless [...] indicate the ingenuity and determination of colleagues who are pushing the boundaries of treatment access'* [5.5]. Consequently, Sussex ODN treats the highest number of people with HCV in addiction centres nationally, representing >20% of all its total treatments [5.6]. Public Health England's HCV in England 2020 Report states: *'The majority of patients (78.5%) were treated in secondary care, with the remainder receiving treatment in either drug services, prisons or elsewhere [...] with Nottingham and Sussex, [each] treating around a fifth of [their] patients in drug services'* [5.6]. The research by Verma and colleagues has been credited by the Sussex ODN manager as being key to the Brighton and Sussex University Hospital Trust *'achieving the NHS targets because it allowed the Trust to address the long patients' waiting list'* [5.7]. It provided the evidence-base to convince Trust executives across the 3 Trusts in the Sussex ODN to support business cases for 3 community nurses, thereby ensuring roll out of the HCV care model across East and West Sussex. In 2016 – 2017, 11% of the Sussex ODN patients were treated in the community, with the majority of them in Brighton, but as of 2019 – 2020, approximately half of the ODN patients are treated via the community-based HCV services. This has become the principal HCV service delivery within the Sussex ODN.

The BSMS HCV care model has been endorsed as a good practice model by the British Viral Hepatitis Group and the largest national charity (HCV Trust/HCV Action) as evidenced by the HCV Action website hosting the ITTREAT case study and related business case template for other ODNs to consult. Since April 2018, the case study has had 585 views and the template 748 [5.8]. Birmingham ODN and Nottingham ODN – two of the largest ODNs in England – credited BSMS work as *'leading the way of HCV care in the community'* [5.9a] and providing *'an innovative set of solutions to a very difficult clinical problem'* [5.9b] to find, test and treat high-risk groups with HCV. Professor Stephen Ryder, Clinical Lead at the Nottingham ODN added that *'Verma's HCV care model was innovative [...] it triggered a complete overhaul of the way we provide HCV care to this high-risk population (ie homeless and PWUDs)'* [5.9b]. Both ODNs adopted elements of the BSMS HCV care model, adapting to their patients' needs and local settings. This resulted in the Birmingham ODN being able to cure >200 patients whom they would have struggled to reach before [5.9a]. Similarly, Nottingham ODN used the BSMS model to expand their services and in particular their HCV care delivery to the homeless [5.9a]. As Chair of the HCV Coalition (a group of stakeholders working together to influence HCV policy and ensuring that HCV elimination target in England is met), Ryder and colleagues have used BSMS research data to advocate for HCV treatment for hard-to-reach groups, specifically the homeless. They used the BSMS model as an effective and successful clinical intervention for HCV care targeting this high-risk group [5.9b]. Both ODNs agreed that the work conducted by Verma and colleagues was one of the significant drivers for England to reach the target set to eliminate HCV by 2025, and that without this research-based evidence it will be difficult if not impossible to achieve it [5.9a, 5.9b]. [text removed for publication] [5.10].

Internationally, data from the ITTREAT study are contributing to the 2021 revised guidelines on *Recommendations for the management of hepatitis C virus infection among people who inject drugs* published by the International Network for Hepatitis in Substance Users [5.11].

4.4 Contributed to Gilead Sciences new patient access to care pathway initiatives leading to their successful NHSE tender in 2019

Gilead Sciences, an international pharmaceutical company (total revenue of USD22,400,000,000, 2019), has pioneered DAA development. Dr Murad Ruf, Director of Public Health Strategy and Implementation Science for Gilead Sciences, acknowledged the key role BSMS research played in their company's understanding of HCV care in England [5.12a]: *'Professor Verma and her team were key in Gilead's successful care implementation initiatives around HCV as they not only provided the research-based evidence that inform the new model of care, they also actively contributed to Gilead's understanding of the integrated care pathway and the importance of the patient centric approach.'* This understanding in turn informed Gilead's own patients' access to care initiatives that were a key element of the company's successful bid in response to the 2019 NHSE tender. Peter Smethurst, Director of the Patient Access to Care, Gilead Sciences, explained [5.12b]: *'BSMS ITTREAT study provided robust scientific evidence that co-location of care was a more effective way to deliver HCV care to this population, providing a measurable impact. The supporting principles of ITTREAT (co-location and patient-centric provision of care) have informed Gilead's strategy for this patient group to be more effectively diagnosed and treated in addiction settings.'* In partnership with Change Grow Live (CGL) – the largest provider of drug treatment services in England – the company demonstrated that this model of care could be successfully scaled up to more than 50 different drug services in England. This evidence formed part of Gilead Sciences elimination initiatives submitted in response to the NHSE tender, and for which the company was awarded Gold status (ie winning the greatest share of patients treated with the company's drugs). Gilead Sciences have since expanded the partnership with CGL to 4 other providers, thus covering most of the third sector and NHSE Addictions Providers. Approximately 90% of the clients in drug treatment services are being cared for by one of Gilead Sciences elimination partners who are moving towards greater co-location and integration of care, as per the ITTREAT work [5.12b].

5. Sources to corroborate the impact

- [5.1] Testimonial from the former B&H Lead Commissioner for Drug Misuse, Ms Caley, confirming the uptake of the BSMS HCV care model by service users.
- [5.2] Testimonial from Dr Worthley, Specialist GP at Arch Healthcare, explaining the significance of BSMS HCV care model for his surgery and patients.
- [5.3a] PHE Liver disease profiles "Persons in drug misuse treatment who inject drugs - Percentage of eligible persons who have received a HCV test" B&H vs England, [5.3b] and PHE Liver disease profiles 'Under 75 mortality rate from HCV related end-stage liver disease/hepatocellular carcinoma' B&H vs England [PDF available].
- [5.4] NHSE Sussex ODN Review Report 2018 [PDF available].
- [5.5] Professor Foster and Mr Huskinson, 05 January 2018, '[25,000 Hepatitis C patients receive new treatments](#)'. [PDF available; Accessed 09 February 2020]
- [5.6] Hepatitis C in England, 2020 report. PHE, London. [PDF available].
- [5.7] Testimonial from Mr Crofton-Biwer, former Sussex ODN Manager at BSUHT confirming the adoption of BSMS HCV care model by the Trust.
- [5.8] Email correspondence between HCV Action and Professor Verma reporting the site visits figures for the ITTREAT case study and business case template [PDF available]
- [5.9a] Testimonial from Professor Elsharkawy, and [5.9b] Professor Ryder, on the adoption of the BSMS HCV care model by Birmingham and Nottingham Hepatology ODNs.
- [5.10] [text removed for publication].
- [5.11] Testimonial from Professor Grebely, President of the International Network for Hepatitis in Substance Users, confirming BSMS HCV care model's contribution to the 2021 guidelines.
- [5.12a] Testimonial from Dr Ruf, and [5.12b] Mr Smethurst, Gilead Sciences, Director Public Health Strategy and Implementation and Director Patient Access to Care, confirming the impact of Verma's work on Gilead's understanding of the HCV care pathway.