Hepatitis C: Increasing Awareness and Improving Access to Testing for the South Asian Community in Bedford

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Opal Greyson-Mary Seacole Development Award
Executive Summary

Hepatitis C: Increasing awareness and improving access to testing for the South Asian Community in Bedford

Hepatitis C virus (HCV) is a blood borne virus that is recognised as a significant national and international health problem.\(^1\) People chronically infected with the HCV often have no symptoms and can remain unidentified until the onset of end stage liver disease. De Leuw et al have identify that end stage liver disease is often associated with poorer outcomes and increased morbidity and mortality.\(^2\) However, pegylated interferon and ribavirin medication have been shown to be effective in eradicating the virus; the National Institute for Health and Clinical Excellence (NICE) considers these therapies to be cost effective.\(^3\)

In the United Kingdom (UK), the majority of individuals infected with the virus are past or present injecting drug users.\(^4\) However, Uddin et al reported a higher than average HCV prevalence among the South Asian community compared with the general population in the UK.\(^5\) Uddin et al recognised that the Pakistan community had a greater than 2% prevalence of HCV, despite the majority of them never having injected drugs.\(^5\) Taylor believes this presents a serious public health challenge as ethnic minorities are known to access health services quite late in the course of their illness compared to the general population.\(^6\) Therefore, they are less likely to be diagnosed and treated for HCV before advanced liver disease or premature death occurs.\(^7\)

This is a concern for Bedford, as there are approximately 13,500 South Asians: 7,100 (Indian); 3,100(Pakistan); 1,900 (Bangladesh) and 1,400 from other Asian communities between the ages of 16-59 who might be at risk of the infection and unaware of their risk. This is out of a total population of 420,000.\(^8\) Therefore; there is an urgency to increase awareness about the disease, to identify those individuals that may be infected with HCV through health education, opportunistic case finding and voluntary testing after appropriate counselling in order to offer appropriate treatment.

**Aim:**
The aims of the project are three-fold and targeted at the South Asian Community in Bedford. They include:
1. Increasing awareness of HCV
2. Improving access to testing for HCV
3. Assessing the prevalence of HCV antibody by testing individuals to determine exposure to the virus

Methodology
Awareness raising ran over six month-period in clinical and non-clinical settings. Individuals were offered a HCV oral swab test. The viral hepatitis specialist nurse (specialist nurse) opted for using the OraQuick HCV Rapid Antibody Test (oral swab) as it is a flexible and simple device that provides rapid results within 20 minutes. However, as the device was new to the specialist nurse, all individuals who sought a HCV test were also sent to the local hospital to confirm the results with a venous blood sample test. A hepatitis B virus (HBV) test was also performed as HCV and HBV have similar risk factors. All individuals were given pre- and post-test counselling by the specialist nurse.

Results:
Seventy-four individuals: 17 (Indians), 4 (Bangladesh), 53 (Pakistan) had a hepatitis C test. Of the 74 individuals; 62 (84 %) also attended the hospital for viral hepatitis (HCV and HBV) blood testing. Three individuals tested HCV antibody positive on oral swab and were confirmed as HCV antibody and HCV RNA positive on venous sampling at the local laboratory. Seven percent of those tested from the Pakistani community were identified with viral hepatitis, (HCV RNA: 3 individuals and HBV: 1 individual). It is important to state all the individuals who tested positive for either virus had no symptoms.

Conclusion:
Awareness raising among health professionals and the South Asian community was the key to encouraging those at risk to come forward for a HCV test. However, having an accessible and approachable HCV testing service with dedicated general practitioners (GPs) working in collaboration with the specialist nurse and a hepatitis C health champion (an interpreter with knowledge of hepatitis C) were crucial in ensuring those at risk took up HCV testing.
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2.0 Introduction

The All Party Parliamentary Hepatology Group (APPHG) identified that, HCV is a blood borne virus that is preventable and curable. However, due to poor awareness and stigma the virus is now recognised as a significant national public health problem in the UK and worldwide. The World Health Organization estimates that approximately 170 million people worldwide are chronically infected with HCV and in the UK the HPA estimates that there are approximately 216,000 people chronically infected with the virus. However, HPA reported that only 70,000 individuals were identified with HCV in 2009. Therefore, the importance of identifying those infected with the virus cannot be underestimated before the burden of disease becomes overwhelming. The HPA considers that increasing awareness of HCV is key to reducing the number of undiagnosed infections.

In 2002, the Department of Health (DH) published guidelines suggesting how prevention, diagnosis and treatment could be improved to address the management of HCV. These guidelines were later followed by the Hepatitis C Action Plan in 2004 which specified that increasing awareness and promoting testing in a range of accessible clinical and community setting were important to increase diagnoses. However, Bedfordshire Primary Care Trust (PCT) had not been able to fully implement these guidelines locally, leaving a large number of undiagnosed HCV infections in the community.

Awareness campaigns have been launched across the UK and have been partially successful. These campaigns mainly focused on injecting drug users. In the last two years Uddin et al identified that prevalence of HCV in South Asians, particularly in the Pakistani community was significantly higher than the rest of the UK population. With this information, the DH dedicated on-line resources to target the South Asian community to increase their awareness of HCV and encourage them to seek testing. The on-line resources also provided information for primary care services to highlight the impact of the virus on individuals. However, in spite of the national awareness campaigns, the specialist nurse observed a poor awareness and understanding of HCV among the primary healthcare professionals and the South
Asian community in Bedford, resulting in a lack of understanding as to who is at risk, low referral rates and diagnoses.

Data collated by Wonford in 2010 shows that there are approximately 13,500 South Asians living in Bedford (Table1) who may be at risk of HCV and are unaware of their risk. If Uddin’s prevalence rate is applied, there are approximately 114-135 individuals possibly infected with the virus but only four individuals were identified and referred to the Hepatology service for treatment between 2007 and 2010. Thus, reducing the number of undiagnosed HCV infections in the South Asian community presents an important public health challenge for Bedfordshire PCT. This project planned to tackle this by aiding the strategic direction of viral hepatitis services. This was achieved by going out into the community and increasing awareness of HCV among the South Asian community and by improving access to HCV testing.

| Table 1: Working age population, 16-64/59 years, Bedford |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Working age population, 16-64/59 years, Bedford |
| Asian or Asian British: Indian | Asian or Asian British: Pakistani | Asian or Asian British: Bangladeshi | Asian or Asian British: Other |
| 4600 | 2000 | 1400 | 700 |
| Total | 8700 |
| Working age population, 16-64/59 years, Central Bedfordshire |
| Asian or Asian British: Indian | Asian or Asian British: Pakistani | Asian or Asian British: Bangladeshi | Asian or Asian British: Other |
| 2500 | 1100 | 500 | 700 |
| Total | 4800 |
| Total working age South Asian population, Bedfordshire |
| 13,500 |

Source: ONS. Population estimates by ethnic group - mid 2007

2.0 Background

2.1 Those at Risk

According to the HPA, 92.5% of individuals infected with HCV are injecting drug users who contracted their virus as a result of sharing injecting paraphernalia
(spoons, filters, water and needles). Other risk factors that contribute to the overall burden of the disease include; individuals who received blood or blood products before 1991 in the UK (2.8%), sexual contact (1.4%), renal failure (0.7%) and transmission from mother to baby (0.5%). Although sexual transmission of HCV is low, between January 2008 and May 2009 a total of 105 newly acquired HCV cases were reported among men who have sex with men.

In the UK, the prevalence of HCV among ethnic minorities is unknown. However, the Uddin study highlighted that the prevalence of HCV in the Indian and Bangladeshi population were 0.5% which was similar to the general population, but the prevalence of HCV in the Pakistani population exceeded 2%. It transpired that the infection usually occurred while on visits to Pakistan and those born in Pakistan were usually infected through poor healthcare practices such as re-using needles by doctors administering injections, vaccinations and blood transfusions.

The prevalence of HCV among the South Asian community is a serious public health challenge. The Department of Health’s Advisory Group report that the morbidity and mortality due to chronic HBV and HCV, cirrhosis and hepatocellular carcinoma (HCC) are more common among ethnic minorities than the general UK population. Mann et al observed that ethnic minorities had 7-10 times more events of hepatitis C-related end stage liver disease and 16-35 times more events of HCC than expected. This suggests that ethnic minority populations in England are more likely than the general population to experience an admission for, or to die from, severe liver disease and are less likely to be diagnosed and treated for HCV before progression to advanced liver disease. If individuals from ethnic minorities remain undiagnosed, the NHS will be seriously impacted from complications of end stage liver disease (ESLD).

2.2 Complications of hepatitis C-related liver disease

Often people chronically infected with the virus are asymptomatic. Therefore, many individuals remain unidentified until the onset of ESLD. If the virus is left undiagnosed and untreated it can lead to liver cirrhosis, ESLD or HCC, requiring
complex and costly interventions such as a liver transplantation.\textsuperscript{2,16} The APPHG reported that deaths from liver disease is the fifth biggest killer in the UK and is continuing to increase year-on-year (Figure 1),\textsuperscript{9} unlike other major causes of death such as cancer, heart disease and stroke which are declining contributing to a potential national health crisis.\textsuperscript{8}

In 2011, the HPA reported that the number of deaths from ESLD or HCC in those with HCV mentioned on their death certificate increased from 89 in 1996 to 270 in 2010. In addition to the deaths related to HCV, the HPA identified HCV as one of the top three reasons why people required a liver transplant, with about 15% of liver transplants in England occurring due to liver damage caused by chronic HCV infection.\textsuperscript{4} In England, the HPA reported that ‘the number of English residents with post-hepatitis C cirrhosis registering at NHS Blood and Transplant for a liver transplant increased from 42 registrations in 1996 to 107 registrations in 2010’.\textsuperscript{11} In addition, the number of first liver transplant performed in patients with hepatitis C-related disease increased from 43 in 1996 to 96 in 2010.\textsuperscript{11}

\begin{figure}
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\includegraphics[width=\textwidth]{figure1.png}
\caption{Deaths (per million) from liver disease: UK versus the rest of Europe}
\end{figure}

The HPA estimates that by 2020 there will be 15,840 people living with HCV related cirrhosis or HCC\textsuperscript{11} and if individuals remain undiagnosed and access to treatment does not increase, the future burden of HCV on the NHS is estimated to reach up to
£8 billion in the next 30 years. Charles Gore, chief executive of the Hepatitis C Trust believes that deaths and subsequent liver transplants resulting from HCV can be ameliorated by eradicating the virus. Mr Gore further stresses that, there needs to be clear direction on how to target the escalating burden of liver disease, which he hopes the National Liver Strategy, that will be published later this year will help address. The Liver National Plan suggests that with effective case identification and treatment, HCV disease burden may be largely eliminated by 2040.

3.0 Epidemiology of Hepatitis C in the United Kingdom

The true incidence, prevalence and epidemiology of people chronically infected with HCV in the UK are unknown, but it is estimated that 0.5% individuals are chronically infected with hepatitis C. According to the HPA this equates to approximately 216,000 people. However, the APPHG argues that this figure is much higher and suggest that there are between 250,000 - 466,000 people chronically infected with the virus. The possible reason for the differences between the HPA and the APPHG figures is the failure to incorporate prevalence rates of migrants from high prevalence countries into the modelling tool to project the prevalence of HCV in the UK. In spite of the discrepancy, rates of diagnostic testing and the number of newly diagnosed individuals with HCV have increased over the years, with 12,000 new cases being reported every year.

3.1 Local Epidemiology in Bedford

The prevalence of people chronically infected with HCV in Bedford varies between 730 to 987. However, Sivananthan believes that both these figures underestimated the prevalence of HCV in ethnic minorities including the South Asian, Eastern European, Italian and African communities. Although under-estimation and under-reporting of HCV infections is a national issue, the recorded local prevalence of HCV in Bedford remains low, as at risk groups were either not being offered a HCV test or declined testing.

According to Sivananthan, the number of current injecting drug users in Bedford is estimated as 741, of which 35% are estimated as being infected with HCV. In 2006,
Sheridan et al used the Hospital Episode Statistics (HES) and information from the number of requests made to Bedfordshire PCT for antiviral therapy to identify that only 20 patients were diagnosed with HCV.\textsuperscript{21} Between April 2009 and March 2010, a total of 27 patients were treated for HCV. From April 2010 to July 2011, a further 20 patients were treated. The Hepatology service at Bedford Hospital NHS Trust has seen an increase annually since 2009 in the number of individuals being referred for management of HCV. A total of 107 individuals have been referred and four individuals were Pakistani in origin.

Although Bedfordshire PCT has seen an increase in the number of people diagnosed with HCV since 2009 there is potentially a large pool of undiagnosed HCV in the community. The HPA believes that increasing the awareness, diagnosis and treatment will help reduce this substantial future burden of long term management of complications arising from end stage liver disease.\textsuperscript{4}

### 4.0 Hepatitis C Action Plan

In 2002 the Hepatitis C Strategy for England was published by DH, this guideline suggested how prevention, diagnosis and treatment could be improved in order to address the management of chronic HCV. This was followed by the Hepatitis C Action Plan for England in 2004 which was based on best practice. Its purpose was to serve as a broad framework for implementation of the Hepatitis C Strategy for England.\textsuperscript{13} The Hepatitis C Action Plan identified four key priorities for local action:

1. Improve surveillance and research so that trends in hepatitis C infection and the effectiveness of prevention measures can be monitored

2. Increase awareness and reduce the number of undiagnosed infections by promoting testing in a range of accessible clinical and community settings

3. Co-ordinate accessible high quality health and social care services for the assessment and treatment of all patients with hepatitis C infection across the country
4. Intensify prevention strategies to reduce the spread of hepatitis C infection among the ‘at risk’ groups

These four actions proposed require collaborative working from all agencies responsible for individuals at risk of HCV. According to the Hepatitis C Trust, the PCTs were responsible for implementing much of the Action Plan and the Strategic Health Authorities (SHAs) were tasked with having overall responsibility. However, no particular agency or organisation had responsibility to ensure that the actions were being implemented. Morris reported that some critics believed the plan had few outcome measures and no clear timetable or finances attached, therefore making it difficult to implement. The APPHG also questioned the governance arrangements, monitoring and evaluation. The Action Plan had not been implemented across 70% of SHAs, including Bedfordshire PCT, despite the fact, they were partly responsible for overseeing the four key actions.

4.1 Implementation of Action Plan 2: Increasing awareness and reducing undiagnosed infection across the UK and Bedford

The DH, estimate that five out of every six people with HCV are unaware of their infection. This required action by DH to increase awareness of HCV amongst health professionals, the public and high-risk groups as well as promoting testing in a range of accessible clinical and community settings. In England, the DH and non-government organizations (The Hepatitis C Trust and The British Liver Trust) have worked in collaboration on initiatives to increase the awareness of HCV among health professionals and public, launching campaigns such as FaCe It and Get Tested: Get Treated. They also ran advertising campaigns in national and regional newspapers, on regional radio stations and bar and pubs and professional journals such as the British Medical Journal, GP and Nursing Standard.

The awareness initiatives have been partially successful, as during the campaigns the Hepatitis C Trust identified a more than doubling of visits to their website (to 400,000), with high levels of calls (approximately 12,000) to their hepatitis C information line. The HPA also reported rising numbers of laboratory confirmed diagnoses and evidence of increased HCV testing in all settings (Table 2). These
campaigns focused primarily on the injecting drug user population. A direct consequence of this was that many from the South Asian community ignored the HCV campaigns, even though Mann et al identified that majority of them were found to be accessing treatment for HCV or dying of liver disease. This coupled with the data from Uddin et al suggesting that South Asians are at a greater risk of contracting the virus, led to the DH extending their campaigns to include the South Asian community.

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Although national awareness campaigns has been in progress since 2004, the specialist nurse observed enormous disparities between the levels of awareness between London (where she previously worked) compared with Bedford, because action to tackle the virus and knowledge about the virus among the health professionals and public widely differed. From professional experience the specialist nurse witnessed insufficient knowledge about HCV among the health professionals therefore very little testing was being done despite the DH guidelines. This became apparent as during the launch of the national awareness campaign there were approximately 40 confirmed diagnoses from an estimated prevalence of 987 in Bedfordshire.

Knowledge about HCV among the South Asian community varied as the Pakistani community had a little more knowledge about hepatitis C compared to the Indian and Bangladesh communities. Some Pakistani individuals had seen the DH information
through the Asian Network, others were educated while abroad by family members who either were infected with HCV or knew someone with the virus. However, the limited knowledge they had were filled with myths e.g. some individuals thought that water was the source of infection. Regardless of their knowledge, individuals were not coming forward to be tested, adding to the group of undiagnosed individuals with HCV. This further highlight the need for awareness raising in the South Asian community in Bedford since the national awareness campaigns seems to have failed to reach this community.

To reduce this wide variation in knowledge of HCV among the community, it was essential to ensure that healthcare professionals i.e. GPs, practice nurses, midwives, prison healthcare staff and drug services had adequate levels of knowledge of HCV to enable them to pass on the correct information to those at risk. Therefore, prior to the Mary Seacole project a number of initiatives to improve professional awareness of HCV began in 2009. However, in spite of these initiatives, the number of HCV tests performed at the general practices did not increase that year.

Awareness raising of HCV among the general public began in May 2010 when the viral hepatitis team at Bedford Hospital NHS Trust collaborated with the Hepatitis C Trust and brought the “Get Tested-Bus” to Bedford during the week of ‘World Hepatitis Day’. On the day, leaflets were handed out and individuals were offered free HCV oral swabs tests (provided free by Axis via the Hepatitis C Trust) to those individuals who had risk factors. A total of thirty-nine people were tested on the day with two testing positive for HCV antibody. This awareness raising proved to be successful as the public were receptive to the message and some individuals came forward for testing. The team learned that lack of information about HCV, the current testing facilities and opening times at testing facilities deterred individuals from accessing a HCV test.

4.2 Testing Facilities

In Bedford, HCV testing is only available for the community via the GPs, genitourinary medicine clinic (GUM) and Terrence Higgins Trust clinic, which many find difficulty in accessing. From networking and liaising with the South Asian community, many individual saw their GP surgery as a barrier to accessing testing,
as the relationship between some patients and GP surgeries was difficult. Accessing GUM clinic and Terrence Higgins clinic was seen as ‘taboo’ and often associated with stigma. In addition, opening times between 9-5 pm on Mondays to Fridays presented difficulties across all testing settings which dissuaded people who thought they may have been at risk from accessing testing, thus the low number of people coming forward.26

Uddin et al and Lewis et al both, successfully targeted the South Asian community by offering HCV testing outside these settings.5, 27 The first study by Uddin et al involved 5 areas; east and west London, as well as in Walsall and Sandwell in the Midlands and Bradford in West Yorkshire with large South Asian community.5 Screening involved 4,998 individuals using oral swab tests in mosques, community centers and individual homes. The Uddin study was pivotal as it added important data about the prevalence of HCV among the South Asian community as data was not available prior to this.

The second project reported by Lewis et al involved awareness raising for the Pakistani community in three mosques located in Newham27 but instead of offering oral swab tests which were seen as a popular screening method in the Uddin study, pre-printed blood forms were attached to the patient information leaflets and handed out to the community on the first day of the month long campaign. The study was not successful in getting the individuals to attend their GP for screening as Lewis et al reported that no new tests were performed since the awareness raising which was puzzling to the researchers.27 Lewis et al suggested that ‘multiple steps to achieve a test are less successful than an immediate testing such as oral swab’. Another possible suggestion for the study being unsuccessful was the lack of study members being present during the month long campaign apart from when the leaflets were distributed on the first day.

A more recent pilot study by the Hepatitis C Trust involving substance misuse clients proved successful in offering viral hepatitis screening outside the current facilities. This study was jointly funded by the Hepatitis C Trust in partnership with five PCTs; City & Hackney PCT, the Isle of Wight PCT, Nottinghamshire County PCT, Sandwell PCT, Tameside & Glossop PCT providing testing in pharmacies.26 Of note, although
the Hepatitis C Trust pilot study was 3 months involving substance misuse clients, it observed an increase in the uptake of the number of individuals coming forward and having a HCV test, similar to the Uddin study, emphasising the need for change to the current testing facilities available in the UK.

The South Asian community are identified as an ‘at risk group’, unaware of their risk and who experience difficulty accessing current HCV testing facilities, therefore, urgent action is needed by the Government to further increase awareness raising of HCV. In addition, providing greater choice of suitable testing facilities is recommended by the NHS White Paper: Liberating the NHS, The National Liver Strategy and the Hepatitis C Action Plan. Locally, Bedford Hospital NHS Trust via this project took action to increase awareness of HCV, to provide suitable testing facilities for its community and to reduce the inequalities in access to services and treatment for HCV among the South Asian community.

5.0 Aim

The aims of the project are three-fold and targeted at the South Asian Community in Bedford. They include:

1. Increasing awareness of HCV
2. Improving access to testing for HCV
3. Assessing the prevalence of HCV antibody by testing individuals to determine exposure to the virus

5.1 Objectives

The project will focus on three main objectives:

- To provide knowledge of HCV among the health professionals and the South Asian community
- To offer free HCV testing in different settings in the heart of the community
- To identify those that may be infected with HCV antibody and Hepatitis C ribonucleic acid (HCV RNA) and refer to Bedford Hospital NHS Trust for care and management
5.2 Methodology

Providing Health Education to the Health professionals

Knowledge about HCV in both the South Asian community and among healthcare professionals was lacking. Patients and their healthcare professionals were unaware of who was at risk from HCV and who should be tested and referred for treatment. Increasing awareness amongst healthcare professionals and the public has been shown to increase the number of people coming forward for HCV testing in the UK and has been important in reducing the number of undiagnosed infections.\textsuperscript{12} Even though awareness raising was already in progress by the Hepatology service in Bedford, considerable persistence is necessary to ensure the message is understood. Catt believes that it is essential to continue increasing the awareness and education among the health professionals and the public.\textsuperscript{29} Therefore it was essential to ensure that healthcare professionals, particular the GPs and practice nurses had adequate knowledge about HCV and this project. The specialist nurse also needed support from the voluntary sector and the leaders of the community for the project to succeed.

Educational sessions were provided to 87 primary and secondary health professionals to ensure they had adequate knowledge about HCV in order to inform individuals and carry out appropriate testing and referrals. The awareness raising started in November 2010 with an educational Hepatology evening sponsored by Merck Sharp and Dohme a pharmaceutical company that manufactures one type of pegylated interferon for the treatment of HCV. This was attended by a range of 78 health professionals including GPs, practice nurses, medical consultants and specialist nurses and students as well as people from voluntary services and service users. The evening provided an opportunity for health professionals to increase their knowledge about HCV and identify their patients who may be at risk of HCV. The health professionals and the specialist nurse were able to network among their peers and other guests to facilitate awareness raising and support for the forthcoming project.

The evening was evaluated by 58 (74\%) of the health professionals which including 10 GP and 4 specialist consultants. Overall, 68\% of respondents strongly agreed
that the programme met the stated educational objectives and 66% felt that the programme content was well balanced (Figure 2 and 3). All of the health professionals (100%) who responded felt that the programme content provided updated information regarding treatment and 94% expressed that the programme content was relevant to clinical practice. Finally, 71% of healthcare professionals strongly agreed that the information presented on the evening would assist them with future clinical management decisions.

**Figure 2: Hepatology Evening Evaluation**

![Pie chart showing the percentage of respondents who agree or disagree with the statement that today's programme met the stated educational objectives.](image)

**Figure 3: Hepatology Evening Evaluation**

![Pie chart showing the percentage of respondents who agree or disagree with the statement that the programme content was well balanced.](image)
The educational evening was pivotal in securing testing facilities for individuals to access free oral HCV testing as two GPs came forward and offered their support to the project. Between January and February 2011 the specialist nurse met with the GPs, to discuss how they can help raise awareness of HCV and to offer testing in both surgeries. A weekly drop in HCV testing service led by the specialist nurse were set up in the two surgeries offering free oral HCV antibody mouth swabs to the South Asian community. The specialist nurse distributed information leaflets and provided advice and information about HCV, its risk factors and the importance of having a test. All the information provided to the community was DH approved and in individuals' preferred language (Appendix 1). An interpreter was also provided when necessary.

It was essential to advertise the HCV testing service among the GPs. In February 2011 the specialist nurse contacted Horizon Health Commissioning Limited, a primary care- based commissioning group for GPs, to solicit their support in advertising the new HCV testing service. Arrangements were made for the specialist nurse to attend an educational meeting for GPs and practice nurses across Bedford to disseminate information about the project and hand out posters to advertise the two GP surgeries offering free oral testing for the South Asian community (Appendix 2 and Appendix 3). Although the message about the project and new service were advertised, patients were not referred to the HCV testing service by their GPs. Unfortunately the specialist nurse was unable to enquire from the GPs their reasons for not referring their patients for testing.

In January 2011, HCV awareness training was provided to the staff at a local government funded neighbourhood centre that provides support to families and children in the community. The message was well received as the staff had limited or no knowledge about HCV or its risks factors. As a result of this the specialist nurse was invited back to speak to the attendees of the centre about HCV.

**Educating the South Asian Community**

Gaining access to the community was the second priority for the specialist nurse as it would allow for awareness raising among the South Asian community. As there
was limited resources, the project leader decided to concentrate the awareness raising in Queen's Park, an area of Bedford with a large South Asian population, which has two mosques and a Sikh temple situated near the two GP surgeries where testing was being offered. Prior to raising awareness, it was crucial to gain access and support from the leaders of each community and knowledge of existing services involved in delivering of health care, to advise on the most effective ways to facilitate awareness raising within the community.

In December 2010 the Assistant Director of Research and Development at Bedford Hospital NHS Trust facilitated the arrangement for the specialist nurse to address worshippers at one of the mosque in Queen's Park. The HCV message (Appendix 4) was well received by approximately 1300 people (700 men at the mosque and 600 women listening via a radio link that goes directly into the homes so that women who do not attend the mosques could listen).

It was important to get the correct message to the worshippers; therefore, the specialist nurse was debriefed by a committee member of the mosque before addressing the worshippers. This was to ensure the message was accurate and informative without causing panic or alarm. After Friday prayers three men came forward enquiring about the HCV test and one gentleman attended the hospital to have a test the following week. Leaflets in Bengali and Urdu already endorsed by the DH (Appendix 1) and the Hepatitis C Trust (Appendix 5) were handed out to the worshippers in the language of choice for each individual.

In February 2011, with the support from one of the GP supporting the project, the specialist nurse and the hepatitis C health champion were invited to attend Friday prayers at a second mosque and set up a stall outside it. During Friday prayers an announcement by the GP about HCV and its risk factors was made encouraging male worshippers to attend the GP surgery for a test. After prayers, information leaflets were handed out about HCV and which detailed the opening times of the free testing service were provided (Appendix 2). It was important to keep the momentum going and to get the message across to as many individuals from the community as possible; therefore, a second visit to the first mosque was arranged by the GP in
March 2011. At this visit, the GP again addressed the worshippers informing them about HCV and a stall was set up to distribute the information. During December 2010-January 2011, access to the three main Gudwaras in Bedford was made possible through a senior member of the Sikh community. Leaflets information in English and Punjabi were left for the worshippers to read. From a meeting with one community leader in January 2011, an opportunity was given to the specialist nurse to attend the temple on the day of worship to raise awareness of HCV to between seventy to ninety people. The message was spoken in English by the specialist nurse and interpreted by the Punjabi speaking hepatitis C health champion, with a questions and answers session afterwards. At the end of this session seven worshippers came forward and had a HCV test on the day at the temple.

In February 2011, the specialist nurse, a hepatitis C health champion and two patients from the Pakistan community attended the Women’s Group at the neighbourhood centre to share their experiences of having HCV and successfully completing antiviral therapy to eradicate the virus. The Women’s Group was attended by twenty women from the community and who were mostly South Asian. Ten minutes were allocated for a brief HCV awareness raising and there were questions. Leaflets in Urdu and English were handed out to the attendees and one lady from the group had a test and a second lady telephoned her husband to attend the centre to have a test, which he did.

It was very important to get the message across to as many women of the community so this necessitated accessing the places they frequented such as; the neighbourhood centre and at a local mosque on a Friday night where Arabic classes are given. The specialist nurse and a hepatitis C health champion were given an opportunity to address approximately forty women. The message was well-received with most women having little or no knowledge about HCV. Many ladies requested a test but unfortunately the specialist nurse had no supply of the oral kits available for testing. This highlighted to the specialist nurse that she needed to have a supply of oral swabs at each awareness session. An invitation was extended to the specialist nurse to provide further awareness and testing when more oral swabs were
available. Unfortunately by the time the oral swabs were available the Women’s Group temporarily stopped so an opportunity was missed.

Once the awareness initiatives were fully underway it was clear the message was reaching the South Asian community as people were telephoning the GP surgeries and the specialist nurse for testing. Word of mouth was instrumental in getting the message across as individuals who were tested often sent family and friends to the surgeries to also get tested. Buttle agrees that word-of-mouth communication has been shown to influence awareness and getting the message across as it provides independent and honest information of the individual’s experiences of a particular service.30

Improving access to hepatitis C testing at two local GP surgeries for the South Asian community

It was important to improve access to individuals having a HCV test at two local surgeries and provide an alternative testing service to the South Asian community outside the GUM, Terrence Higgins centre and the GP surgeries. South Asian individuals accessing HCV testing at either GP surgery were initially offered oral swab tests as this is the most effective form of screening.5 As the oral swabs were fairly new to the specialist nurse, all individuals who came forward for testing were sent for a confirmed venous HCV antibody test at Bedford Hospital NHS Trust which enabled the validity of the oral testing kits to be assessed. In addition, a HBV test was performed with the volunteers consent as the risk factors for HBV are similar to HCV, thus ensuring all individuals at risk for viral hepatitis were screened according to the DH guidelines. However, as the number of oral swabs was limited during the opportunistic case finding some volunteers, were referred to the hospital for a blood test. This form of testing proved partially successful as 14 out of the 16 individuals did attend the hospital for testing.

Those individuals who came forward for a HCV test that were not registered with a GP involved in the project had letters sent to their respective GPs to inform them of their patient’s HCV result and to request that their GP send them for a HBV and HCV test. This was to confirm the HCV oral swab test result and to rule out HBV exposure. However, only one of ten GPs managed to send his patients for viral
screening. The specialist nurse decided to find out from the remaining nine GPs why they failed to send their patients for testing. From the letters sent to the GPs, the specialist nurse received two letters; one GP said she did attempt to contact the patient but he failed to collect his blood forms and the second GP sent the results of the patient blood test. From the lack of GPs responses, the specialist nurse believes that further work is needed to increase awareness among the GPs as the GPs who failed to send their patients for blood test were the ones who did not attend the educational evening.

Contrary to reports which suggest that accessing a HCV test from GPs can dissuade people who think they are at risk coming forward for testing because of lack of confidentiality and opening times; the specialist nurse had fifty seven (57) individuals from the South Asian community come forward for a HCV test following the awareness raising at the GP surgeries. The extended opening times offered at the GP surgeries (3 -7 pm or 5-7 pm), supportive GPs, having a dedicated specialist nurse on site to offer advice and support; all improved the testing facilities offered at the GP surgery. One general practice was ideally situated in the heart of the community near both mosques where the awareness raising was being delivered making it easily accessible to worshippers. The testing service was a walk-in service with no appointments necessary and had a dedicated hepatitis C health champion acting as an interpreter with knowledge of hepatitis C.

**Provide an alternative testing service to the South Asian community outside the GUM clinic, the Terrence Higgins centre and GP surgeries**

HCV testing was offered to individuals wishing to have a test following the awareness campaigns. HCV testing took place at the neighbourhood centre and a Sikh Temple. As the mosque had no private facilities for the specialist nurse to offer testing, individuals were either directed to one of the GP surgery which was situated within walking distance of the mosques or asked to attend the hospital. Visiting venues such as Terrence Higgins centre and the GUM clinic were seen as stigmatising for this community.
The specialist nurse opted for using OraQuick HCV Rapid Antibody Test (Appendix 6) as it provided rapid results in 20 minutes. The OraQuick enabled patients to learn their HCV antibody status, receive counselling and information about their future treatment and care all in one visit. The test was simple and flexible and individuals could either have an oral swab, finger prick or blood sample taken. The oral swab was the preferred option and ideal for the project, as testing could be conducted in both clinical and non-clinical settings. This option was acceptable to the individuals as there were no needles involved. A total of seventeen individuals accessed testing outside the GP testing services; seven at the Temple; two at the neighbourhood centre and eight individuals came to Bedford Hospital NHS Trust to have a test.

**To refer those individuals that are both hepatitis C antibody and HCV RNA positive to the hepatologist at Bedford Hospital NHS Trust for appropriate follow up treatment and care**

**Results:**

Eighty-two South Asians came forward for HCV testing but seventy four of them were able to have a test, (38 males and 36 females) the hepatitis specialist nurse was unable to perform the test on four individuals due to time constraints on the day. Two individuals failed to attend the hospital for the HCV test and the specialist nurse felt that it was inappropriate to perform testing on one individual on the day (but requested that she seeks testing in the future) and declined testing another (Figure 4). Three individuals were identified as HCV antibody positive on oral swab and confirmed as HCV antibody and HCV RNA positive at the local laboratory (Figure 5). All three individuals have been referred to the Hepatology service at Bedford Hospital NHS Trust and one has commenced antiviral treatment. All three individuals who tested positive had no clinical symptoms.

All individuals who came forward for testing were advised to be tested for HBV and HCV. A total of 62 of 74 individuals attended the hospital to have this done. All the HCV test results were validated by the venous blood test at the laboratory. One individual who was negative for HCV antibody was identified with chronic HBV and is now receiving appropriate care and management at Bedford Hospital NHS Trust.
Fig 4: Hepatitis C Test Performed

**HCV Testing**
- Had HCV Test: 74
- Test not performed: 8

Fig 5: Results of Hepatitis C Oral Swab

**Hepatitis C Antibody on oral swab**
- Neg: 96%
- Pos: 4%
6.0 Conclusion

This project highlighted two main reasons for the low number of South Asians in Bedford presenting for HCV testing. Firstly, there is a lack of awareness of HCV across the community, resulting in a low number of individuals coming forward for HCV testing. Following the awareness campaigns across the community individuals came forward for testing.

Secondly, testing facilities at the GP surgeries, the GUM clinic and the Terrence Higgins Trust centre currently in place, are not appropriate for those at risk and deter the community from using the service. However, once the GP surgeries had an open access which was more client friendly with a dedicated specialist nurse and a hepatitis C health champion, more individuals accessed testing. The OraQuick testing device used to perform the test was also instrumental in getting individuals to have a test, as the results were rapid.

Pivotal to the success of the project were the links the hepatitis specialist nurse made with the community leaders, GPs, the hepatitis C health champions and other services already working with and caring for the community. This ensured the community were receptive to the specialist nurse and provided easy access to the community to allow the opportunistic case finding and voluntary testing to take place.

Although the project was on a small scale, it demonstrated that awareness raising and appropriate testing facilities can encourage those at risk to come forward for testing. This was apparent as other individuals from other ethnic groups came forward for testing following awareness raising at the GP practice. These individuals were HCV antibody negative on oral swab. The specialist nurse believes that Bedford PCT need to review their Hepatitis C Strategy and include the South Asian population as individuals at risk of HCV. The PCT also need to consider the cost implications if individuals with HCV are not identified early and progress to ESLD requiring complicated interventions such as liver transplants.
7.0 Project Achievements

Awareness raising helped increased knowledge of HCV among the health professionals and the South Asian community. The project helped improve access to HCV testing for the South Asian community at the GP surgeries and offered alternative HCV testing services at the temple, neighbourhood centre and Bedford Hospital, reducing stigma and the taboo associated with current testing facilities. The awareness raising and improved access to testing encouraged eighty two individuals to come forward for testing, which demonstrated that individuals from the ethnic minorities will access health services if they are given the information and have access to appropriate testing facilities.

Though the project primarily focused on the South Asian community three individuals from the African community and one individual from Afghanistan came forward to have a HCV test after hearing the message. HCV antibody was not detected on oral swab on these four individuals.

7.1 Project Limitations

The project was small scale and had limited staff working on it which meant a low number of individuals being tested. As the project was localised to the Queens Park area it placed restrictions on the number of individuals that could be tested and the areas that testing could take place. The specialist nurse had insufficient oral swabs for testing which caused the project to stop temporarily until funding was received for additional oral swabs test. The specialist nurse was also unable to influence the time taken for HCV RNA results. Long turnaround time increased anxiety for the individuals waiting for results. However this has been resolved as the turnaround time for the HCV RNA results have improved.
8.0 Recommendations

The following recommendations should be considered to reduce the inequalities in health within the South Asian community at risk of HCV:

1. Bedford PCT need to continue to raise the profile and increase awareness raising of HCV among health professionals through educational programmes for GPs and the South Asian community through road shows and awareness raising events.

2. The Government should consider attaching a system incentive such as Quality and Outcomes Framework (QOF) for GPs to offer and screen those patients at risk for HBV and HCV at their surgeries.

3. Consider screening all new patients from countries with a high prevalence rate of HCV when registering with GPs across Bedford using a risk assessment tool for HCV.

4. Consideration should be given to having viral hepatitis specialist nurse/s and hepatitis C health champions attached to GP surgeries across Bedford to provide support and advice to practice nurses and individuals accessing or requiring testing.

5. Improve current testing facilities such as extended the opening times (including Saturday morning clinic) and providing alternative testing services to meet the community needs rather than just using the sexual health clinics which has stigma and taboos attached to it.

6. Consider offering quick test results such as OraQuick for initial antibody test and improve the turnaround for a HCV RNA result.
Appendix 1 Gujarati

Hepatitis C
The more you know the better

What is Hepatitis C?
Hepatitis C is a virus that can cause liver disease. Like hepatitis A and B, there is no vaccine to prevent against Hepatitis C infection, but we can stop spreading it.

Can I get Hepatitis C?
Hepatitis C can occur in a number of ways:

• By having sex with someone who has Hepatitis C.
• By having sex with someone who has Hepatitis C.
Appendix 1 Bengali

Hepatitis C

The more you know, the better.

বেগুনী হেপাটাইটিস C
অধিক জানান, কাছে থাকান।

What is hepatitis C?
Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). Most people don’t have symptoms, or the symptoms may not show up for years after they get infected. The symptoms can range from feeling sick for a few days to a long-term illness.

Mild symptoms:

• Feeling sick
• Fatigue
• Loss of appetite
• Nausea and vomiting

Severe symptoms:

• Fever
• Tender, swollen lymph nodes
• Jaundice

Treat your hepatitis C:

• Treatment for hepatitis C can cure the condition or control the virus. It is prescribed by your doctor after testing for hepatitis C.

• A course of treatment for hepatitis C may last for 3 to 6 months. It can include medication such as interferon and ribavirin.

• Depending on your treatment, you may have to undergo blood tests at regular intervals to track the effectiveness of the treatment.

• Follow-up appointments with your doctor are necessary to monitor the progress of the treatment.

• Treatment for hepatitis C is expensive, but it is not a lifetime commitment.

Information not required.

You can get more information on hepatitis C from the following resources:

Hepatitis C awareness week - www.hepaware.org
Hepatitis C support - www.hep.org.uk
NHS LIVER Unit - www.nhs.uk/liver

Information not required.

Opal Greyson-Mary Seacole Development Award
Appendix 2

Free Hepatitis C Testing

Hepatitis C is a blood borne virus that attacks and causes damage to the liver. Most people with Hepatitis C have no symptoms and five out of six people infected are unaware they have the virus.

If any of the below apply to you, you could be at risk of Hepatitis C:

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Prevention Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Born in Pakistan, Bangladesh, India, South America, Africa, Eastern Europe, Italy or the Middle East due to being vaccinated with contaminated needles</td>
<td>Shared toothbrushes, razors, cut throat razors, scissors, nail or hair clippers</td>
</tr>
<tr>
<td>Had blood transfusion or blood products abroad or in the UK before 1991.</td>
<td>Suffered occupational hazards such as needle stick injuries</td>
</tr>
<tr>
<td>Had a body/ear/nose piercing, tattoos or acupuncture with unsterile needles.</td>
<td>Have you had medical, surgical, dental treatment or multiple vaccines aboard</td>
</tr>
<tr>
<td>Shared notes, straws or pipes for drug use.</td>
<td>Injected anabolic steroids or injected drugs even once</td>
</tr>
</tbody>
</table>

A possibility that your mother was exposed to Hepatitis C whilst pregnant.

Get Tested, Get Treated

Free Hepatitis C Testing Service for the South Asian Community at
Dr Khokher Surgery
Queen Park Health Centre Friday pm 1:45-7pm
Or
Drs Agrawal and Agrawal Surgery
Ashburnham Road ~every Mondays 5-7 pm or
Wednesday am 10:00-13:00
Or at
Bedford Hospital call
Opal Greyson 0777 503 0970 or
email: opal.greyson@bedfordhospital.nhs.uk
Appendix 3

Opal Greyson- Developmental Award

Mary Seacole Award Project: To improve access to Hepatitis C Testing for the Sub Asian Community

Purpose of Project

- To improve access to testing and reduce the inequality of health among the Sub Asian community

- We intend to set up a weekly Hepatitis C testing service in the heart of the Asian community offering free hepatitis C testing to all individuals between ages of 18-70 years and offer appropriate follow up care where required.

Proposed Method of Project

The Hepatitis nurse and chosen health champions will display posters and give out leaflets about the risk factors to individuals from the community. Four weeks before testing the Hepatology service will launch a series of seminars, talks and Hepatitis C awareness days in the community by various speakers such as; leaders, viral hepatitis specialists and Hepatitis C patients who have previously undergone treatment prior to the screening programme. The information will be given in both English and their preferred language. Free Hepatitis C Antibody test (oral swab or dried blood test or venous bloods test will be offered to at risk individuals). All individuals will sign a consent form to demonstrate that they agree to the procedure and that they understand the process and what will happen with results and possible treatment pathway. Consent will also be given to pass information on to the registered General Practitioner (GP). Pre and Post test counselling will be given. Individuals who chose to have an oral swab or dried blood test will be notified about their results on the same day within 40 minutes. The venous blood sample individuals will return 2-4 weeks later to receive their results at the local hospital or at their GP surgery (whether positive or negative). All HCV antibody positive individuals will get a copy of their results and a letter to give to their GP about their test result. The results will also be sent by courier post to the registered GP. Once individuals are identified as having previous exposure to the Hepatitis C virus (HCV Antibody positive) they will be referred to the Hepatology Department at Bedford Hospital NHS Trust for appropriate follow up care, according to Department of Health (2004)

Frame of Reference


INTRODUCTION

Hello everyone

My name is Opal Greyson and I am the Hepatitis Nurse at Bedford Hospital NHS Trust. I would like to thank the……………………………………………………………for giving me the opportunity to come and talk to you today about Hepatitis C.

MESSAGE

- Hepatitis C is not caught from dirty water or food but it is caught from blood.
- In many cases your body cannot fight the virus and it becomes a chronic disease that could lead to liver scarring, cirrhosis and liver cancer as the virus attacks your liver.
- There is no vaccine to protect you from catching the virus
- But there is effective treatment to get rid of the virus
- Often if you are infected with the Hepatitis C virus you may not feel any symptoms but if you do have symptoms they may include:
  - Fatigue
  - Tiredness
  - Pain in the liver area
  - Night sweats
  - Digestion problems
  - Flu like symptoms
  - Depression
  - Difficult concentration
  - Joint and/ or muscle aches
If you were born in one of these areas: India, Bangladesh or Pakistan or go to visit there you may be at risk through:

- Medical injections even when you were young
- If you had a blood transfusion
- If you had an operation in hospital
- If you went to the dentist
- If you were circumcised
- Had dialysis or treatment there
- If you had a shaved from cut throat razor or razor
- Shared household equipments such as nail clippers, scissors or toothbrush
- Had ear or nose or body piercing under unsterilized conditions
- You could be at risk if one of your family especially if your mother has hepatitis C or any member of your family was diagnosed with hepatitis C, it is important to have a test

The virus can be hidden for many years so if you think you may have been at risk it is important to get tested.

The test is FREE

You can either have an oral swab or a finger prick

The result is given to you in 20 minutes.

If the results indicate you may have been exposed to the virus the nurse will notify your GP on your behalf asking him or her to refer you to the hospital to see my consultant.

If you would like to be tested, leave you name with………. or we will be outside and take your details

Thank you for listening

Message adapted from Hepatitis C Trust Urdu information leaflet
Appendix 5 The Hepatitis C Trust Leaflet

Hepatitis
WHAT YOU NEED TO KNOW

Hepatitis A, B and C

There are three main forms of hepatitis: A, B and C.

Hepatitis A
Hepatitis A is usually caused by eating or drinking food or water contaminated with the hepatitis A virus. Symptoms usually appear two to six weeks after infection. Symptoms can include fever, headaches, fatigue, loss of appetite, stomach pain, nausea, vomiting and jaundice.

Hepatitis B
Hepatitis B is usually caused by sexual contact with an infected person or by sharing needles or other equipment used to inject drugs. Symptoms may not appear for several months after infection, or they may not appear at all. If symptoms do occur, they can include fever, loss of appetite, nausea, vomiting, stomach pain, and jaundice.

Hepatitis C
Hepatitis C is usually caused by sharing needles or other equipment used to inject drugs or by using contaminated needles at a tattoo or body piercing parlor. Symptoms can take up to six months to appear after infection. Symptoms can include fatigue, loss of appetite, nausea, vomiting, stomach pain, and jaundice.

Could you be at risk?

It is important to be aware of the risk factors for each form of hepatitis. The following risk factors may increase your risk of hepatitis C:

- Exposure to contaminated blood or tissue
- Injection drug use
- Transfusion of blood or blood products
- Sharing needles or other equipment used to inject drugs
- Exposure to contaminated needles at a tattoo or body piercing parlor

What should you do?

If you think you have been exposed to hepatitis C, you should contact your doctor or a health care provider. They can perform a blood test to determine if you have been infected with hepatitis C. If you have been infected, your doctor can provide you with information about how to manage your health.

What happens next?

If you have been infected with hepatitis C, your doctor will work with you to determine the best course of treatment. This may include medications to help you stay healthy or prevent complications. It may also include lifestyle changes such as eating a healthy diet and getting regular exercise.

This can save your life.
Appendix 6 OraQuick HCV Rapid Antibody Test

Read the Package Insert completely before using the product. Follow the instructions carefully when performing testing. Failure to do so may result in inaccurate test results.

INTENDED USE

For use by healthcare professionals only.

The OraQuick® HCV Rapid Antibody Test is a single-use, anti-HCV assay. It is an immunosassay for the qualitative detection of immunoglobulin G (IgG) antibodies to hepatitis C virus (HCV) in oral fluid, fingertip whole blood, venipuncture whole blood, plasma specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate), and serum (serum separator tube [SST]), and from individuals 11 years or older. The OraQuick® HCV Rapid Antibody Test assay results may be used to provide presumptive evidence of infection with HCV in individuals with signs and symptoms of hepatitis and in individuals at risk for hepatitis C infection.

Warnings: Not intended for use in screening whole blood, plasma, or tissue donors. The effectiveness of the OraQuick® HCV Rapid Antibody Test for use in screening whole blood, plasma, or tissue donors has not been established.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV) is the causative agent for most, if not all, non-A, non-B hepatitis. The presence of antibodies to HCV indicates that the individual may be currently infected and capable of transmitting the virus.

PRINCIPLES OF THE TEST

The OraQuick® HCV Rapid Test is a manually performed, visually read, 20-minute immunosassay for the qualitative detection of HCV antibodies. The assay test strip contains synthetic peptides and recombinant proteins from the NS3, NS4, and NS5 regions of the HCV genome (test lane) and a goat anti-human IgG (control line) immobilized onto a nitrocellulose membrane.

MATERIALS PROVIDED (REF 1001-0270 25 TESTS, REF 1001-0274 100 TESTS)

- Divided pouch contains OraQuick® HCV Rapid Antibody Test plus Absorbent Packet and OraQuick® HCV Developer Solution: Val containing 0.75 mL phosphate buffered saline solution containing polymers and an antifoam agent.
- Reusable test strips
- Collection loops
- Package insert

MATERIALS REQUIRED, AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick® HCV Rapid Antibody Test Kit Controls (REF 1001-0278)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer capable of timing 20 to 40 minutes
- Biohazard waste container
- Additional items required for Fingerstick and Venipuncture Specimens
- Antipsychotic, vasopressin, sterile lancet or venipuncture supplies, disposable gloves (optional for oral fluid testing), sterile gauge pads, centrifuge

WARNINGS

For In vitro Diagnostics Use. For use by healthcare professionals only.

- Read the Package Insert completely before using the product.
- Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test. Failure to do so may cause an inaccurate test result.
- Thawing the kit has been approved for use with oral fluid, fingerstick whole blood, venipuncture whole blood, serum and plasma specimen only. Use with other specimen types may cause inaccurate results.
- This test kit is not intended to be used for individuals who are undergoing treatment.
- If the test kit is exposed to temperatures outside of the recommended storage temperature (2°C-30°C), do not use the Kit Controls to ensure performance of the test. 

PRECAUTIONS

- Handle specimen and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- Use of gloves for oral fluid testing is recommended as any biologic specimen should be treated as potentially infectious. Test administrators with breaks in the skin (cuts, abrasions, or dermabrasion) should wear gloves when performing oral fluid testing. Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
- Do not reuse specimen collection loops, test devices, or developer solution. Disposable of these components properly. Reuse of these components is capable of transmitting infectious agents.
- Do not use the test beyond the expiration date printed on the pouch.

STORAGE

- Store unused OraQuick® HCV Rapid Antibody Test unopened at 2°C-8°C.
- Do not open the pouch until you are ready to perform a test.

SPECIMEN HANDLING

- Oral Fluid: Ensure prior to testing that the subject has not had anything to eat, drink, or chew gum for at least 15 minutes. Have the subject wait at least 30 minutes prior to testing if they have used any oral care products. Collect specimen and place in Developer Solution immediately.
- Whole Blood, plasma or serum: Invert the test device into the Developer Solution within 60 minutes of adding the sample.
- Serum or plasma: Centrifuge at 3000-10,000 g for approximately 5 minutes.
- Serum and plasma specimens stored frozen at -20°C may have up to 3 freeze-thaw cycles.

DIRECTIONS FOR USE

GENERAL TEST PREPARATION

- Allow all components to come to operating temperature (15°C-37°C).
- Place the Reusable Test Stand on your work space. Use only the stand provided with the OraQuick® HCV Kit.
- Do not open the pouch until you are ready to perform a test. Check the pouch for damage or holes. Discard the pouch if it is damaged.
- After opening the pouch, check for 30 minutes prior to testing. If it is not present or appears damaged, discard the pouch and open a new one.
- Hold the OraQuick® HCV Developer Solution very firmly in your hand. Remove the cap by residence it back forth while pulling it off. Set the cap aside. Stir the solution into the top of one of the tubes on the Reusable Test Stand.
- DO NOT cover the 2 holes on the back of the test with labels or other materials. Blocking the holes may cause an invalid result.
1. SAMPLE COLLECTION

1a. Oral Fluid
   • Ensure prior to testing that the subject has not had anything to eat, drink, or chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.
   • Remove the OneQuick® HCV Rapid Antibody Test strip from the pouch. DO NOT touch the Flat Pool.
   • Swab completely around the lower and upper outer gums ONE TIME. DO NOT swab the roof of the mouth, cheeks or tongue.

1b. Fingerstick Whole Blood
   • Clean finger. Air dry.
   • Puncture finger with a sterile lancet. Wipe away the first drop of blood with a sterile gauze. Hold the finger downward and apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed.
   • Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with the Loop.
   • If the Loop is dropped or contacts any other surface, discard it. Use a new Loop to collect the blood.

1c. Venipuncture Whole Blood
   • Collect the specimen using standard phlebotomy procedures into a tube containing EDTA, sodium heparin, lithium heparin, or sodium citrate. Other anticoagulants have not been tested and may cause an incorrect result.
   • Mix the blood by inversion. Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with the Loop.

1d. Serum or Plasma
   • Plasma: Collect the specimen using standard phlebotomy procedures into a tube containing EDTA, sodium heparin, lithium heparin, or sodium citrate. Serum: Collect into 10X tube. Other anticoagulants have not been tested and may cause an incorrect result.
   • Centrifuge at 1000-1200 x g for approximately 5 minutes.
   • Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with Loop.

2. RUN TEST
   • Insert the Test Device into the Developer Solution Vial.
   • Set the timer for 20 to 40 minutes.

TEST RESULT AND INTERPRETATION
Refer to the Result Window on the Test Device.

NON-REACTIVE
A test is Non-Reactive if a line appears in the C Zone and NO line appears in the T Zone. A Non-Reactive test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.

REACTIVE
A test is Reactive if a line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines appear. A Reactive test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV.

Follow appropriate guidelines for supplemental testing.

INVALID
A test is Invalid if:

- No line(s) in C Zone
- Test background measurable
- Read outside time limit of 30 minutes

An Invalid test result means that there was a problem running the test either related to the specimen or to the Test Device. An Invalid result cannot be interpreted. Repeat the test with a new Pouch and a new specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.

GENERAL TEST CLEAN-UP
1. Dispose of the unused test material and gloves in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

QUALITY CONTROL
The OneQuick® HCV Rapid Antibody Test has a built-in procedural control. A line in the C Zone after 20 minutes indicates assay validity. External controls are available separately. Run OneQuick® HCV Rapid Antibody Test QC Controls according to the quality assurance policy of the facility.

LIMITATIONS OF THE TEST
1. The OneQuick® HCV Rapid Antibody Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Results are valid for 20 minutes. After this period, the results may not be reliable.
3. Clinical data has not been collected to demonstrate the performance of the OneQuick® HCV Rapid Antibody Test in individuals under 11 years of age.
4. A reactive result using the OneQuick® HCV Rapid Antibody Test suggests the presence of HCV antibodies in the specimen, and the intensity of the test line does not necessarily correlate with the HCV antibody titer in the specimen. The OneQuick® HCV Rapid Antibody Test is intended as an aid in the diagnosis of HCV infection.
5. A non-reactive result does not exclude the possibility of exposure to HCV or infection with HCV. An antibody response to recent exposure may take several months to reach detectable levels.
6. A person who has HCV antibodies is presumed to be infected with the virus. Additional testing and medical evaluation is required to determine if that state or associated disease.

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PERFORMANCE CHARACTERISTICS

SENSITIVITY

The sensitivity of OneQuick® HCV Rapid Antibody Test was assessed in asymptomatic and/or at-risk individuals determined to be HCV infected. Sensitivity for each of the five specimen matrices was calculated by dividing the number of OneQuick® HCV Rapid Antibody Test reactive results by the total number of specimens tested from HCV infected individuals (N). Results with the 95% confidence intervals (CI) for all five specimen matrices are summarized in the table below.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Reactive</th>
<th>Total N</th>
<th>Sensitivity</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Fluid</td>
<td>739</td>
<td>753</td>
<td>98.1%</td>
<td>96.9-99.3%</td>
</tr>
<tr>
<td>Fingerstick WB</td>
<td>752</td>
<td>754</td>
<td>99.7%</td>
<td>99.5-100.0%</td>
</tr>
<tr>
<td>Venipuncture WB</td>
<td>753</td>
<td>755</td>
<td>99.7%</td>
<td>99.5-100.0%</td>
</tr>
<tr>
<td>Plasma</td>
<td>755</td>
<td>756</td>
<td>99.9%</td>
<td>99.5-100.0%</td>
</tr>
<tr>
<td>Serum</td>
<td>756</td>
<td>757</td>
<td>99.9%</td>
<td>99.5-100.0%</td>
</tr>
</tbody>
</table>

SPECIFICITY

Specificity of the OneQuick® HCV Rapid Antibody Test was assessed in asymptomatic and/or at-risk individuals who were determined not to be HCV infected. The percent specificity of the OneQuick® HCV Rapid Antibody Test for each of the five specimen matrices was calculated by dividing the number of OneQuick® HCV Rapid Antibody Test non-reactive results by the total number of specimens tested that were derived from subjects determined not to be HCV infected (N). Results with the 95% confidence intervals (CI) for all five specimen matrices are summarized in the table below.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Non-Reactive</th>
<th>Total N</th>
<th>Specificity</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Fluid</td>
<td>1418</td>
<td>1423</td>
<td>99.6%</td>
<td>99.2-99.9%</td>
</tr>
<tr>
<td>Fingerstick WB</td>
<td>1421</td>
<td>1422</td>
<td>99.5%</td>
<td>99.2-100.0%</td>
</tr>
<tr>
<td>Venipuncture WB</td>
<td>1423</td>
<td>1423</td>
<td>99.5%</td>
<td>99.1-100.0%</td>
</tr>
<tr>
<td>Plasma</td>
<td>1420</td>
<td>1422</td>
<td>99.0%</td>
<td>98.5-100.0%</td>
</tr>
<tr>
<td>Serum</td>
<td>1422</td>
<td>1423</td>
<td>99.0%</td>
<td>98.6-100.0%</td>
</tr>
</tbody>
</table>

REACTIVITY WITH HCV SEROCONVERSION PAIRES

Thirty panels containing sequential plasma specimens from individuals undergoing seroconversion as a result of HCV infection were evaluated with the OneQuick® HCV Rapid Antibody Test and compared with a CE approved anti-HCV EIA test. The sensitivity of the OneQuick® HCV Rapid Antibody Test to detect seroconversion was similar to that of the CE approved EIA. The OneQuick® HCV Rapid Antibody Test detected anti-HCV antibodies to HCV 6.6 days (95% CI 0.1 to 1.4) before the EIA test at the 20-minute read time and the OneQuick® HCV Rapid Antibody Test detected antibodies to HCV 9.9 days (95% CI 0.3 to 1.8) before the EIA test at the 40-minute read time.

REACTIVITY WITH HCV SPECIMENS FROM VARIOUS GENOTYPES AND SUBTYPES

The ability of the OneQuick® HCV Rapid Antibody Test to detect infection derived from various genotypes and subtypes was assessed using two commercially available Worldwide HCV Performance panels. Thirty-two HCV positive plasma specimens derived from multiple geographies, representing six genotypes and eleven subtypes (1a, 1b, 2a, 2b, 3a, 3b, 4a, 4b, 4c, 5a, 5b, 6a, and 6e) were tested. All specimens were reactive with the OneQuick® HCV Rapid Antibody Test. Three HCV negative samples were included in the panel and all were non-reactive with the OneQuick® HCV Rapid Antibody Test.

MEDICAL CONDITIONS UNRELATED TO HCV INFECTION

The performance of the OneQuick® HCV Rapid Antibody Test was evaluated with commercially available HCV negative plasma and serum specimens derived from twenty-one medical conditions unrelated to HCV infection. Results are summarized in the table below.

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>N</th>
<th>Non-Reactive (%)</th>
<th>Reactive (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malignant Disease</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Scleroderma</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Systemic Lupus Erythematosus (SLE)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Other Medical Conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza Vaccination</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Hepatitis A Virus (HAV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Hepatitis B Virus (HBV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Hepatitis C Virus (HCV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Human T-Cell Lymphotropic Virus (HTLV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Epstein-Barr Virus (EBV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Cytomegalovirus (CMV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Herpes Simplex Virus (HSV)</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Parvovirus B19</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Typhoid</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
<td>10(100)</td>
<td>0(0)</td>
</tr>
</tbody>
</table>

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Of the twenty-one unrelated conditions tested, six produced a consistently reactive result with the OraQuick HCV Rapid Antibody Test that were not due to an HCV co-infection (Sideropenia, IgA deficiency Syndrome, Hepatitis A, Hepatitis B, HTLV, and HIV). Each of these unrelated medical conditions produced only a single reactive result in the twenty-six aliquots from patients with that condition. None of the medical conditions tested produced an unacceptably high rate of false positive results in the OraQuick HCV Rapid Antibody Test device.

INTERFERING SUBSTANCES
The OraQuick HCV Rapid Antibody Test was evaluated with the following interfering substance. None of these interfering substances had any impact on the OraQuick HCV Rapid Antibody Test assay performance at the concentrations listed.

<table>
<thead>
<tr>
<th>Interfering Substances</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>10 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Lipid (Triglycerol)</td>
<td>3500 mg/dL</td>
</tr>
<tr>
<td>Protein</td>
<td>12 mg/dL</td>
</tr>
</tbody>
</table>

In addition, a study was performed to assess the potential effect of anticoagulants on assay performance. Venipuncture whole blood specimens were collected from fifty HCV negative subjects and tested for eleven (11) conditions that consisted of three (3) sample types: whole blood, plasma, and serum; two (2) tube types: glass and plastic; and four (4) anticoagulant types: EDTA, Lithium heparin, sodium citrate, and sodium heparin, as well as serum in SST. Each of the sample types was aliquoted into vials marked positive and negative and then the positive aliquots were split with an HCV positive specimen. The aliquoted tubes were then stored either refrigerated (2-8°C) or at room temperature (20°C ± 3°C). Serum and plasma aliquots were also stored frozen at (-10°C to -20°C) for up to three (3) freeze thaw cycles. There was no anticoagulant-specific effect observed on assay performance with samples held up to 7 days at 2-8°C, 3 days at 30°C ± 3°C and up to 3 freeze thaw cycles at -10°C to -20°C.

ORAL INTERFERENCE
The OraQuick HCV Rapid Antibody Test was evaluated with the following interfering substance: Gingivitis, Denture, Tobacco (Smoked), Food & Beverages (Standardized Food, Acidic Beverage, Carbonated Beverage, Basic Beverage, Alcoholic Beverages), Oral Care Products (Toothbrushing, mouthwash, tooth whitening), and Medications (Aspirin, Warfarin/Coumadin/Plavix). None of these interfering substances had any impact on the OraQuick HCV Rapid Antibody Test assay performance with a wait period of 15 minutes for food and drink and 30 minutes for oral care products.

REPRODUCIBILITY
The reproducibility of the OraQuick HCV Rapid Antibody Test was tested at 3 sites using 3 lots of Test Devices on 5 different days with 9 operators (3 per site). A blinded panel was tested that consisted of 3 plasma specimens (1 negative, 1 low positive, and 1 moderate positive). Overall concordance across operators, sites, and device lots was 100% (95% CI 99.5-100%) for the negative specimen, 99.9% (95% CI 99.9-100%) for the low positive specimen and 99.9% (95% CI 99.9-100%) for the moderate positive specimen.

BIBLIOGRAPHY
### Explanation of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use by</td>
<td>Negative HCV Control</td>
</tr>
<tr>
<td>Ref.</td>
<td>Positive HCV Control</td>
</tr>
<tr>
<td>Lot</td>
<td>Package Insert</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>5 μl Loops</td>
</tr>
<tr>
<td>Consult Instructions for Use</td>
<td>Absorbent Packet</td>
</tr>
<tr>
<td>Caution, Consult Accompanying Documents</td>
<td>Developer Solution Vial</td>
</tr>
<tr>
<td>Contents</td>
<td>Test Stand</td>
</tr>
<tr>
<td>Kit Control</td>
<td></td>
</tr>
</tbody>
</table>

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**Opal Greyson-Mary Seacole Development Award**

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Belgium
Our Ref: ALD/PM

29 October 2010

Opal Greyson
Hepatitis Nurse Specialist
Bedford Hospital

Dear Opal

Publicising hep C testing and providing testing in community facilities

Thank you for coming to see me in connection with your application for a Mary Seacole award. I enjoyed meeting you and hearing your enthusiasm for this project.

I confirm that the activities you outlined, of publicising hep C testing and providing testing in community facilities is a service activity and not research, as the diagnostic process involved is proven and accepted. What is unique in the project is the innovative setting in which the testing is offered.

I hope this answers your queries.

Best wishes with the project.

Yours sincerely

Alan Dickinson
Trust Board Secretary
10.0 References


25. NHS Choice (2009). Hepatitis C- The more you know the better. Available at : http://www.nhs.uk/hepatitisc/southasian/Pages/default.aspx


11.0 Bibliography


