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HEPATITIS B, C AND HIV TESTING IN DRUG USERS - SETTING UP A NEW SERVICE IN THE COMMUNITY

SUMMATIVE ASSESSMENT PROJECT

APRIL 2000

Contents

Introduction

Background

At the end of 1999 the Department of Health published revised guidelines on the management of drug misuse and dependence (1). These were intended for all doctors working with drug users. They make it clear that drug dependent patients have the same entitlement as the rest of the population to health services with respect to both their general health needs and drug-related problems, whether or not they are ready to withdraw from drugs. They highlight the increased risk of acquiring blood borne viral infections, in particular Hepatitis C, and they emphasise evidence based interventions such as Hepatitis B vaccinations, and providing harm minimisation advice when caring for drug users.

Previous research indicates that the provision of such services aimed at risk reduction in intravenous drug users (IVDU's) is poor. Farrell et al (2) noticed the limited availability of both screening for blood borne viral infections and vaccination in drug treatment clinics. Whilst Walter and Holmes (3) found testing limited, with doctors viewing it as an ineffective use of resources, NHS trusts unwilling to fund such a service, and some agencies who would only test if the client showed symptoms of liver disease or had abnormal liver function tests.

The consequences of poor service provision are extremely serious when considered alongside recent statistics regarding the prevalence of blood borne viral infections, most notably Hepatitis C, and the clinical consequences of such infections (see Appendix 1).

Existing Local Service Provision

During my vocational training I spent six months as an SHO in an innovative post based in the community working with both the homeless and drug dependent. Part of the job involved seeing many of the drug users attending the general practice where I am now a GP registrar. During this time I became concerned that these patients were not receiving the standard of care suggested in the DOH guidelines - specifically with regard to risk reduction and testing for blood borne viral infections. This was based on my own observations and also on a survey carried out by the team I was working with looking at the provision of care for drug users within the practice (4).

The practice is situated in a deprived part of South London and has a population of 14,500 patients. The survey, carried out in February 2000, identified 140 patients who were receiving help with drug dependency from the practice. 105 of those identified (75%) had been seen in the last 2 months and the vast majority (92%) were receiving substitute prescriptions of methadone for opiate dependency.

The transmission of viral infections such as Hepatitis B (HBV), Hepatitis C (HCV) and HIV was only documented as having been discussed with 53 patients (38%). Only 30 patients (21%) were recorded as having had a vaccination against hepatitis B, and the promotion of needle exchange and safer sex was only noted as having been discussed with 17 (12%) and 16 (11%) of drug using patients respectively.

Whilst these results may be partly explained by poor documentation, it is also possible that drug users may not have been receiving the quality of care recommended in the DOH Guidelines. In a more recent survey of general practice treatment for

substance misusers across Lambeth and South Southwark (5) only 49% of practices working with drug users claimed to be screening patients for HBV and HCV.

It was on the basis of this evidence that I felt there was a need to provide a community based testing service for HBV, HCV and HIV available to all local drug users.

The SHO post had, for many years, been offering a drop-in clinic one afternoon a week giving general medical advice to drug users attending a local drug project providing shared care with local GP's and pharmacists. Two years ago the clinic expanded to include a Hepatitis B vaccination service. During the first six months of this service being set up clients were counselled and invited to go to the local hospital for a blood test to confirm their HBV and HCV status prior to vaccination. The take up of this offer was virtually nil (6) and clients were, therefore, advised to seek screening from their GP. However, the results from the two surveys of local practice given previously would indicate that a significant number were probably never being tested. This, therefore, seemed like the ideal setting for a new testing service.

Aims

Aims of the Service

- To provide a confidential pre and post test consultation with a doctor.

  Not to dissuade or encourage a person to be tested, but to explain and discuss the implications and limitations of testing for hepatitis B and C and HIV, thus enabling the client to make an informed decision about whether to be tested or not.

- To provide an opportunity to discuss routes of transmission of HIV, hepatitis B and hepatitis C.

- To discuss the implications of both a positive and a negative result.

- Following a positive result to provide support and information regarding the disease, further diagnostic tests and examinations, and arrange appropriate referral.

- To explore harm reduction practices in the case of those who remain at risk of acquiring hepatitis B or C or HIV and to minimise the risk of transmitting or contracting any of these viruses in the future.

Personal Aims

My aim in setting up the service was to make a difference to a patient group that I felt required quality health care but were not receiving it - either because they found it difficult to access general medical services or because they were being ignored, possibly because of some of the difficulties that can arise in managing often complex and chaotic patients. Rather than simply immunising clients blindly against HBV, I wanted to provide an easily accessible testing service in the community linked to the needle exchange. This, I hoped, would be beneficial in both improving the health of the drug users attending the project and reducing further transmission of blood borne viruses. I also hoped that in the longer term, if we were successful, the service might provide a model for others working with drug users in primary care.

Setting Up the New Service

Having identified the need for a service locally, there seemed to be a number of key steps to be taken:

- Background research to inform the process of implementing change.
- Identify funding for the service.
- Arrange for the provision of laboratory services.
- Establish protocols and evaluation/outcome monitoring.
- Liase with other staff working with drug users attending the clinic.
- Identify sources of education, training and support.
- Develop pathways for referral and liason.
- Pilot the service.
- Evaluate the service.

Implementing Change

Prior to developing protocols I reviewed recommendations from the British Liver Trust (7) and looked at information from three other organisations that offered a similar service, one in Manchester, one in North London, and one in South London that had only recently extended its service in a very similar way to include Hepatitis B and C testing (8,9, 10).

None were exactly the same as the service we intended to provide, however, they were very useful in identifying the important steps involved in implementing change, avoiding potential pitfalls, and providing practical solutions to some of the problems that would arise.

What was most apparent in the literature regarding the implementation of change within any setting was the need to get individuals within the team on board. Bolman and Deal (11) urge leaders to articulate and communicate their vision to those people within the organisation, and it is clear that such involvement, participation and collaboration will aid service development. To this end the concept was discussed with the manager of the drug project who was very enthusiastic and was keen to be involved in developing the service protocol and, in particular, helped find solutions to many of the practical problems that arose. He also arranged training for other staff already working with drug users so that they could participate in the new service.

Funding

The provision of funding for the service was not as difficult to arrange as had first been envisaged, primarily because the testing was an extension of an already existing service. The general practice at which I was based was already providing the HBV vaccines and a grant of £1000 had been provided by the King's Fund to set up the vaccination service. The practice manager agreed with the partners that the practice would also bear the cost of the testing service. This had the added benefit that the practice already had a contract with the local hospital trust to provide laboratory services, so there was no need to set up a new account.

Laboratory Services

The practicalities of providing tests in the community requiring specialist laboratory services turned out to be more complicated than expected and significantly delayed the start of the service.

The -issue of confidentiality impinged on every aspect of setting up such a service. This will be discussed further with regard to the protocol but some practical aspects became clear early on with regard to the labelling of samples. As well as being identified as different from the usual samples sent from the general practice it was also decided that they should be entirely confidential. In this way the service would be more akin to that provided by a Genitourinary Medicine Clinic. However, it was essential that, whilst doing everything possible to maintain the client's confidentiality, there was no risk of results being mixed up. Advice was sought from local GUM clinics and the laboratory and it was decided that all samples would be labelled only with a unique eight character identifying number and the client's date of birth, sex and the first letter of their surname.

The transportation of samples was also problematic. It was felt important that they be picked up directly from the drug project. Refrigerated storage was already available and arrangements were made for courier collection as part of the local hospital service. This proved difficult as, initially, there were no funds available for extra collections. Fortunately, with a new financial year came extra funds, and the hospital was able to include the drug project in their schedule.

Developing the Protocol

Having ironed out some of the practical problems the next key stage was to develop a protocol for the service. This was developed in conjunction with the drug workers at the community project so as to involve them in the change, promote the new service, and obtain their advice and support.

The protocol needed to be as detailed as possible to provide structure and continuity for future SHOs working in the job, who would be changing every six months. Many would have had only limited exposure to working in the community and possibly no experience of testing for HBV, HCV, and HIV. It was important they could understand their role, the testing process, and had information on referral pathways and sources of support for them as well as the client. For this reason the protocol included very detailed guidance on pre and post-test consultations as well as a history taking check list (see Appendix 2), to serve as a reminder for the doctor during the consultation.

Confidentiality

The issue of confidentiality was central to the protocol. Only the doctor would have access to client's medical notes which were to be kept in a locked cabinet in the consulting room. No information would be communicated to others without the client's specific permission. Where there was a `need to know' situation which may benefit the client e.g. with agencies such as social services, informed consent had to be obtained before disclosure. It was, however, decided that it was important to discuss with the client the role of other health professionals with whom they were consulting, in particular their GP and drugs worker, and make them aware of

situations in which it may be advantageous for them to disclose their HIV, HBV or HCV status.

The client also needed to be aware of the limits of confidentiality and situations in which it may be necessary to breach confidentiality. It would be made clear, however, that, were such a situation to arise, for example where it was felt that a client was at risk of harming themselves or others, every *effort* would be made to discuss this with them first. The protocol contained clear guidance for the doctor with regard to circumstances in which a breach of confidentiality may be ethically justified according to the General Medical Council guidelines. In the unlikely event that there was felt to be a need to breach a client's confidentiality the protocol made clear that the rationale for disclosure should be fully documented in their notes.

A consent form was developed (see Appendix 3) requiring the client's signature prior to testing. The issue of uncollected results was of particular concern and it was decided that consent would be requested to inform the client's GP of their test results if they had not been to pick them up four weeks later. Consent was also requested to contact their GP in the event of a positive result.

In general it was deemed important for the GP to be as involved as possible if the client had a positive result as the drug project could make an initial referral for further care but could not provide continued clinical support for clients with positive results. This was emphasised to the clients but it was also made clear that if, for whatever reason, they decided that they did not want their GP involved then this wish would be

respected. A standard GP letter was developed to inform the doctors of those who consented to disclosure of their results (see Appendix 4).

Specialist Support and Referral

Local GUM clinics were extremely helpful with their advice in the early stages of setting up the service and strong links were made so that SHOs coming into the post would be able to obtain both theoretical and practical training and support from them.

Clear referral pathways to specialist units were essential to make the process as smooth and efficient as possible. Links were established with one of the local hospitals providing a specialist Liver Unit and referrals were then made direct to one of the consultants with a special interest in HCV. A good rapport was also developed with those providing specialist HIV services at the hospital, which ran a clinic specifically aimed at injecting drug users.

Initial Evaluation

Initial evaluation of the service at this stage is limited as it has only been running for six months and in that time there has been a change in the SHO running the clinic. This means that there have only been 21 clients who have had tests which is fewer than had originally been hoped. Of the 21 clients, 12 were men and 9 were women and they were aged between 18 and 46 years old. 14 of them returned for their, results and one was given her results over the telephone. One test was unable to be performed due to an insufficient sample being received by the laboratory and the client did not return for a repeat test. The results would, at this stage, indicate a slightly lower prevalence of HCV than expected in the clients tested with only 9 of 20 testing positive (45%). There were no positive tests for HIV and 4 clients tested positive for HBV, all of whom were also infected with HCV. 2 clients with a positive result did not re-attend for results. Of the 16 patients who would have benefited from Hepatitis B vaccination 12 were started on the course of three injections and, to date, 5 have completed the course.

"These are only preliminary results and cannot be considered in any way conclusive, they do, however, highlight some issues that could usefully be addressed in terms of service provision.

Strengths of the Service

The service provided at the drop in clinic is much more complete now that it includes testing. It is possible, and appropriate, to fully counsel clients about the risks of blood borne viruses and offer them a test rather than simply vaccinating them. There is then the opportunity to discuss the benefits of harm reduction in a way that is far more

relevant to the individual client. If the result of their test is negative, vaccination can be offered and, if they remain at risk of acquiring blood borne viruses through continued intravenous drug use, they can be offered advice on risk reduction. A negative result may also give them added impetus to get involved with other services offered by the drug project and the general practice such as the needle exchange, substitute prescribing, dependency to work programmes, and even detox regimes.

A positive result also has significant benefits to the client in terms of harm reduction - both by reducing the risk of transmission to others and by providing strategies to maximise the client's own health (e.g. by cutting down on alcohol if they have hepatitis). They can also be referred to secondary care for further treatment.

The other significant strength of the service is that it is based in the community at a centre already attended by some of the most chaotic drug users in the area, many of whom are homeless and some of whom are not registered with a GP or linked to substitute prescribing programmes. It is hoped that the accessibility and location of the service will lead to increased uptake.

From the doctors point of view I found the new service very rewarding. I was unable to prescribe and could only offer advice and testing - this made for a far more honest and interesting consultation. I was able to learn a lot more about the lifestyle many of the drug users were leading, what they were using, when and how, without the need to be constantly evaluating their requirements for substitute prescribing.

Weaknesses of the Service

Many of the weaknesses of the service are related to its limited availability. The drop in clinic is provided by only one doctor and is open one afternoon a week. Due to the chaotic lifestyle of many of the clients it would be preferable to provide the service whenever the drug project is open, as many of them will forget to return for testing. There would obviously be significant resource implications if a doctor were required to work permanently at the project, and it is unlikely that that sort of expenditure could be justified.

However, during the initial piloting of this service, the manager of the drug project arranged for all the workers to attend a training day on HIV, HBV and HCV. It was then arranged for two workers to attend a course aimed at enabling them to provide pre and post-test counselling. This may, in the future, significantly reduce the workload for the doctor running the clinic and enable him/her to test many more clients.

Many of the other weaknesses with the service revolve around the giving of results. It was initially hoped that these could be given within a week. It was only when we piloted the service that it became apparent HCV results would take longer than this. This was because, following an initial positive test for HCV, a confirmatory test was required. This was only run once a week, too late to access the results in time for the next clinic. It was, therefore, decided that clients would have to be advised to re-attend two weeks after the sample was sent. It is not clear what effect this may have on the service, but it may contribute to people not re-attending and prolong what is often a very anxious time waiting for results.

The number of clients not coming back for results is of particular concern - particularly where the result is positive, as was the case for two people during the pilot period. This issue was discussed when writing the initial protocol as, by its very nature, the service would be unable to chase up many of the clients attending for testing. It was decided that this was a risk worth taking but that, as a back up, clients would be asked for their consent to communicate their results to their GP if they did not re-attend. In this way the service differs from most GUM clinics who do not divulge results to a patient's GP.

Finally, the procedure of taking blood also proved difficult as venous access was near ¡mpossible for many clients. On occasion the femoral vein had to be used to obtain a blood sample, a procedure that obviously requires a greater degree of competence by the doctor and is associated with a greater degree of risk. Further, whilst many of the clients were already using their femoral vein for drug injecting, there is the potential for negative modelling in those who had previously limited themselves to peripheral venous access. We have, therefore, started looking at possible alternatives for obtaining samples. There is increasing evidence from the USA with regard to Oral Mucosal Transudate testing (OMT), for which a swab simply needs to be placed between the cheek and the gum for two minutes. This technology would provide great benefits in terms of ease of testing, eliminating the risk of needlestick injury and may even mean that the service could be offered by trained staff without a medical or nursing background. The biggest issue is that of resources and, for the time being at least, there is not the funding available to introduce this.

What I Have Learned

I very much enjoyed doing this project. I found it very rewarding to be involved in setting up a new service that really does seem to make a difference to a group of patients with enormous needs but who often remain neglected. Seeing the `finished product' is very satisfying but, one of the most important lessons I have learned is that, in fact, there is no such thing. What I helped create is simply another facet in a continually changing and evolving service that needs constant re-evaluation and adjustment. I have come to realise the importance of involving other people in any change, and it was only through the enthusiasm and support of the other members of the team working at the drug project that I was able to get the service extended and iron out so many of the practical problems that arose. The value of careful planning and a detailed protocol has also become evident with the changing of doctors running the clinic. New doctors have been able to come in and feel safe and supported in continuing to provide the service. In this way I hope that it will grow and develop, providing an increasing standard of care for the drug users in the local area.

Word Count - 3,200 words.

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Appendix 1 - Hepatitis B, C and HIV

HIV (Human Immunodeficiency Virus) is transmitted both parenterally and sexually. Transmission most commonly occurs following vaginal or anal intercourse or as the result of blood to blood contact, including sharing blood contaminated needles and other injecting equipment used by intravenous drug users. The prevalence of HIV infection amongst injecting drug users attending specialist agencies in London in 1998 was 1 in 36 for both men and women, and 1 in 250 in men outside London, no infections were detected in women tested outside London in 1998 (12).

There is currently no immunisation against the HIV virus and no cure available for those who are infected. Current treatment methods involve a combination of antiretroviral drugs that, it is hoped, will slow or halt the destruction of the body's immune system by the HIV virus and the consequent progression to AIDS (Aquired Immune Deficiency Syndrome).

Hepatitis B is similarly transmitted both parenterally and sexually, although there is about a ten-fold increase in the risk of acquiring the virus through a needle-stick injury than acquiring HIV (and a further ten-fold increase in risk of acquiring Hepatitis C in the same way). Approximately 5% of infections result in chronic carriage of the virus and these individuals are at further risk of developing chronic hepatitis, cirrhosis and hepatocellular carcinoma.

Whilst there is no cure available for individuals infected with the HBV hepatitis B vaccine is effective in preventing infection in those who produce antibodies to

hepatitis B surface antigen. Immunisation requiring a course of at least three doses of vaccine is, therefore, recommended for all those who inject drugs and are not already immune or infected, and for close contacts of drug misusers already infected.

Hepatitis C virus was first identified in 1989, prior to this it was referred to as non A-non B hepatitis. It is thought to be mainly transmitted through blood, although it has been found to be in other body fluids such as saliva, semen and vaginal fluids. The commonest route of transmission of hepatitis C in the UK is by sharing blood-contaminated needles or injecting equipment during intravenous drug misuse.

Studies vary in their estimates of the prevalence of Hepatitis C infection in injecting drug users from 50 to 80 percent being infected. In the UK there are estimated to be 250-500,000 people infected with the virus (13). Amongst intravenous drug users the prevalence is estimated to be 57% in England (71% in London), 77% in Scotland and 48% in Wales, although it is generally agreed that these figures are likely to underestimate the extent of the problem.

There is currently no immunisation available to prevent the acquisition of Hepatitis C. The clinical course of the infection is variable with the majority of people infected showing few signs of the disease and jaundice developing only infrequently. Hepatitis C infection results in 60-80% of individuals developing chronic infection, with a risk of approximately 20% developing cirrhosis as a result of progressive hepatitis, and a 10-15% risk of hepatocellular carcinoma in those with cirrhosis (14,15,16).

Management of Hepatitis C infection usually involves initial investigations (including liver function tests, an ultrasound scan and a liver biopsy) to assess the severity of liver damage. Treatment with alfa-interferons is available but is limited in its efficacy to particular genotypes of the virus. It involves a subcutaneous injection three times a week and can have significant side effects varying from a flu like illness to significant haematological effects such as thrombocytopenia, neutropenia and anaemia. People who do not respond by the three month period can have the dose increased, but a proportion will still fail to respond. Only 20-25% are long term responders (although this may be improved by combining interferon treatment with another anti-viral agent such as Ribavirin) (17).

Appendix 2 - History taking check list

CONFIDENTIAL

CDP - Pre-Test Consultation For Hepatitis B Hepatitis C and HIV Testing

Name.....

Date of Birth.....

Address. .. . .

Identifying Number.....

Indications/risk assessment	hepatitis B hepatitis C HIV	
Previous tests	when/where/results	
About the tests	blood tests for antibody	
Possible results	hepatitis B - negative/immune/ carrier/active hepatitis C - negative/positive HIV - negative/equivocal/reactive	
Window period	test/retest/wait	
Implications	Positive result - practical personal support coping strategies Negative result - risk reduction	
Confidentiality		
Post consultation appointment		
Consent		

Appendix 3 - Consent form for testing for hepatitis B, hepatitis C and HIV

Please read all three parts.

I.....

am satisfied with the information that I have been given and wish to have the test for (please tick):

0 Hepatitis B

0 Hepatitis C

0 HIV

I understand that I have to return in person to obtain my results and an appointment has been made for me to receive my results and have a post-test discussion with the doctor.

Signed - client..... CDP doctor .....

Date.....

If I am unable to return for my results in person within a four week period from the above date, I give my consent for my blood test results to be sent to my GP.

Dr.....

Address.....

Signed (client).....

Date.....

In the event of a positive result I do/do not give my permission for my GP to be informed (delete as appropriate).

Signed (client).....

Date.....

Appendix 4 - GP Letter

Date:

Dear Dr

Re:

The above named client attended for a:

Hepatitis B test on:

Hepatitis C test on:

HIV test on:

The results were:

HBV -

HCV -

HIV -

Hepatitis B vaccinations were/were not commenced on..... with a follow up vaccination appointment for.....

Referral has/has not been made to the * * * * * * * * * at * * * * * * * * Hospital.

Referral has/has not been made to the * *** * * * * * * at * * * * * * * * * * * * Hospital.

If you require any further information then please do not hesitate to contact me.

Yours sincerely

CDP Doctor