

Report of the Director of Public Health: Blood-borne Viruses in NHS Greater Glasgow and Clyde

1. RECOMMENDATIONS:

The NHS Board is asked to receive and note the content of the report and in particular:

- Note the burden of blood-borne virus infections and the approaches adopted by the Board within the national policy context.
- Note the prevention interventions to limit the transmissions of these viruses and the evidence supporting these interventions.
- Note the treatment and care services currently available within the Board.

2. Background

Blood-borne viruses (BBVs) are those viruses that are transmitted from the blood of one person to the blood of another person (for example sharing of needles and other equipment by Injecting Drug Users (IDUs), needle stick injuries). Some of these viruses can also be transmitted through other means including sexual intercourse and from mother to child during birth. Of particular concern in Scotland and NHSGGC are Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV).

3. HIV

3.1 Although treatment advances have transformed human immunodeficiency virus (HIV) infection from a fatal disease into a long-term chronic condition, it remains one of the most important and serious communicable diseases in the UK, because of its potential for serious long term morbidity, premature loss of life, high treatment and care costs and psychosocial impact.

3.2 Cumulatively to 30 September 2011, a total of 1,974 GG&C residents have been diagnosed with HIV infection; of these, 854 are men who have sex with men (MSM), 819 heterosexual and 209 IDUs; the remaining 92 acquired HIV infection from other/undetermined exposures.

3.3 All adults diagnosed with HIV and living in NHSGGC attend for treatment and care at the Brownlee Centre for Infectious Diseases located on the main Gartnavel campus. Children infected with HIV attend the paediatric infectious diseases service at Yorkhill Hospital.

3.4 Prevention strategies adopted in NHSGGC are aimed at; preventing HIV acquisition by using a range of biomedical and behavioural approaches, early detection of those already infected by encouraging more testing among clinicians and managing established HIV infection to prevent serious complications and minimise the risk of onward transmission.

4. Hepatitis C (HCV)

4.1 Hepatitis C infection is caused by the hepatitis C virus (HCV) that is transmitted through blood-to-blood contact and primarily infects and affects the liver. Following infection, around 20% of cases are naturally resolved within the first six months, and the remainder develop chronic, lifelong infection.

4.2 At the end of 2011, almost 13,000 people were known to be living and ever infected with HCV in NHS GGC. Health Protection Scotland (HPS) recently estimated that more than half of all HCV cases in Scotland remains undiagnosed, suggesting that the local number of infected individuals in GGC exceeds 26,000.

4.3 Within GGC clinical management of HCV cases is provided from Depts. of Gastroenterology at the Gartnavel, Glasgow Royal, Southern, Victoria, Inverclyde Royal and Royal Alexandra Hospitals and the Dept. of Infectious Diseases at the Brownlee Centre. Various service developments enabled acute services to significantly increase the number of patients initiated onto antiviral treatment and by 2010, the number of patients starting HCV treatment had increased annually by 178% compared to the 2006 baseline exceeding the targets set in the HCV Action Plan by the Scottish Government.

4.4 Another key priority of the HCV Action Plan was to reduce the incidence of new infections through increased provision of sterile injecting equipment to IDUs. In 2006, 32 community pharmacies and 6 drug services provided sterile injecting equipment (IEP) to local injectors. Glasgow Addiction Services recruited 30 additional community pharmacies to the IEP scheme, predominately in areas with a high number of injectors but historically low levels of provision.

5. Hepatitis B (HBV)

5.1 Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). If infection is acquired peri-natally, over 90% will become chronic. HBV is uncommon in NHSGGC and approximately 200 new diagnoses (both acute and chronic) of HBV infection were made annually in NHSGGC during 2009 and 2010.

5.2 A vaccine against hepatitis B has been available since 1982. Groups targeted for hepatitis B vaccination in NHSGGC include babies born to infected mothers, current and former injecting drug users, close family contacts of those with chronic infection and NHS staff and others who are at occupational risk

5.3 Antiviral drugs are available for the treatment of HBV infection but the therapy simply suppresses the viral load rather than cure the infection. The number of patients currently on treatment are relatively small (approximately 20 patients) but this number is expected to increase significantly over the next few years in keeping with the aspirations of the National Framework.

Blood-borne Viruses in NHSGGC

1. Introduction

1.1 **BBVs:** blood-borne viruses (BBVs) are those viruses that are transmitted from the blood of one person to the blood of another person. Some of these viruses can also be transmitted through other means including sexual intercourse. Of particular concern in Scotland and NHSGGC are Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV).

1.2 In recognition of the serious public health challenges posed by these BBVs in Scotland, in August 2011 the Scottish Government (SG) published the Sexual Health and Blood-borne Viruses Framework 2011-2015. This Framework sets out the Scottish Government's agenda in relation to sexual health and BBVs for the next four years. The Framework brings together the four policy areas of HIV, HCV, HBV and sexual health for the first time in an overarching policy document. The Framework recognises the links and commonalities between the work strands and aims to focus delivery on realising five outcomes that are embedded in the Quality Strategy and the inequalities agenda.

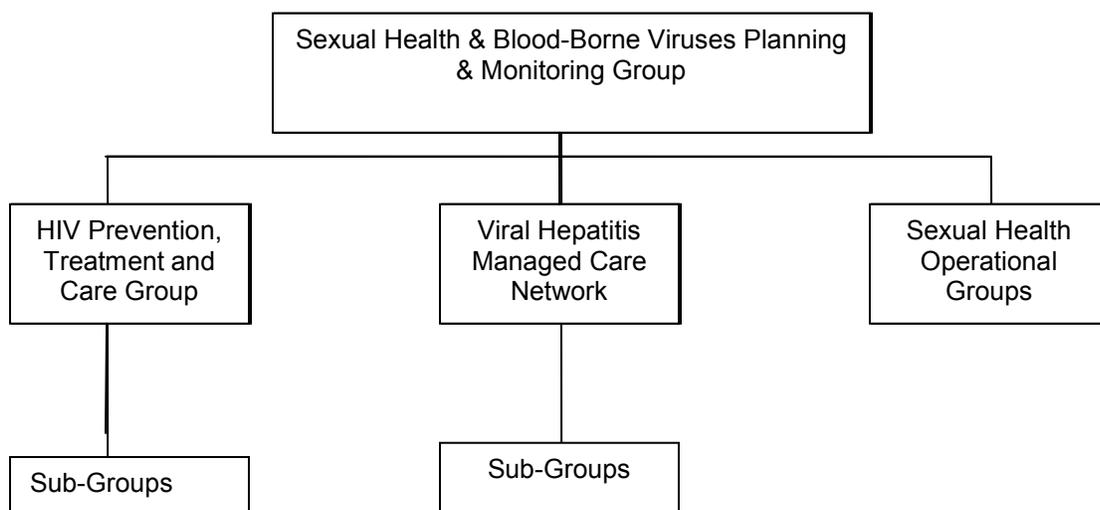
- Fewer newly acquired blood-borne viruses and STIs, fewer unintended pregnancies
- A reduction in the health inequalities gap in sexual health and blood-borne viruses
- People affected by blood-borne viruses lead longer, healthier lives
- Sexual relationships are free from coercion and harm
- A society whereby the attitudes of individuals, the public, professionals and the media in Scotland towards sexual health and blood-borne viruses are positive, non-stigmatising and supportive

Moreover, in progressing these outcomes, there is also an opportunity to link with other relevant policy areas including drugs and alcohol, Early Years, Curriculum for Excellence, Long Term conditions, and Equally Well.

1.3 In NHSGGC our planning structure for sexual health and blood-borne viruses was revised in 2011 to reflect and align with the National Framework so that effective communication is in place and constructive relationships are developed and maintained. The current BBV Planning and Performance Management arrangements are shown in Figure 1.

1.4 **Sexual Health and BBV Planning & Monitoring Group:** This group provides an overarching role, taking the long-term strategic view on local SH and BBV work plans, advises on whether these plans meet the aims and objectives of appropriate policy at both local and national level, in particular the Scottish Government SH and BBV Framework, and provides guidance on how SH and BBV work programme fits with and relates to the overall aims and objectives of NHS Greater Glasgow and Clyde and its partner agencies. In addition the group will also take cognisance of Statute and Scottish Government Guidance and Regulations.

Figure 1: Sexual Health and BBV Planning Structure



2. HIV in NHSGGC

2.1 **Introduction:** Although treatment advances have transformed human immunodeficiency virus (HIV) infection from a fatal disease into a long-term chronic condition, it remains one of the most important and serious communicable diseases in the UK, because of its potential for serious long term morbidity, premature loss of life, high treatment and care costs and psychosocial impact.

This section describes changing patterns of HIV in NHS GG&C, the treatment and care services available, outlines our current programme of preventive interventions and demonstrates the vital contribution of a flexible, needs-driven and evidence informed HIV prevention programme to the population health in NHSGGC.

2.2 The population impact of HIV infection

2.2.1 **Transmission:** within the UK, HIV is most commonly acquired by sexual contact; other transmission routes include sharing injecting equipment, mother to child transmission and receiving donated blood, organs or injections with unsterilised needles in countries with inadequate screening procedures.

2.2.2 **Effects of HIV on human health:** HIV attacks cells of the immune system. Over a number of years the immune system 'weakens' so that the body cannot defend itself against infection. One of the important features of HIV infection is its prolonged 'silent' period during which it causes no symptoms but is infectious and can therefore be transmitted to others. Untreated HIV infection generally progresses to the condition known as acquired immunodeficiency syndrome (AIDS), characterised by life-threatening infections and cancers.

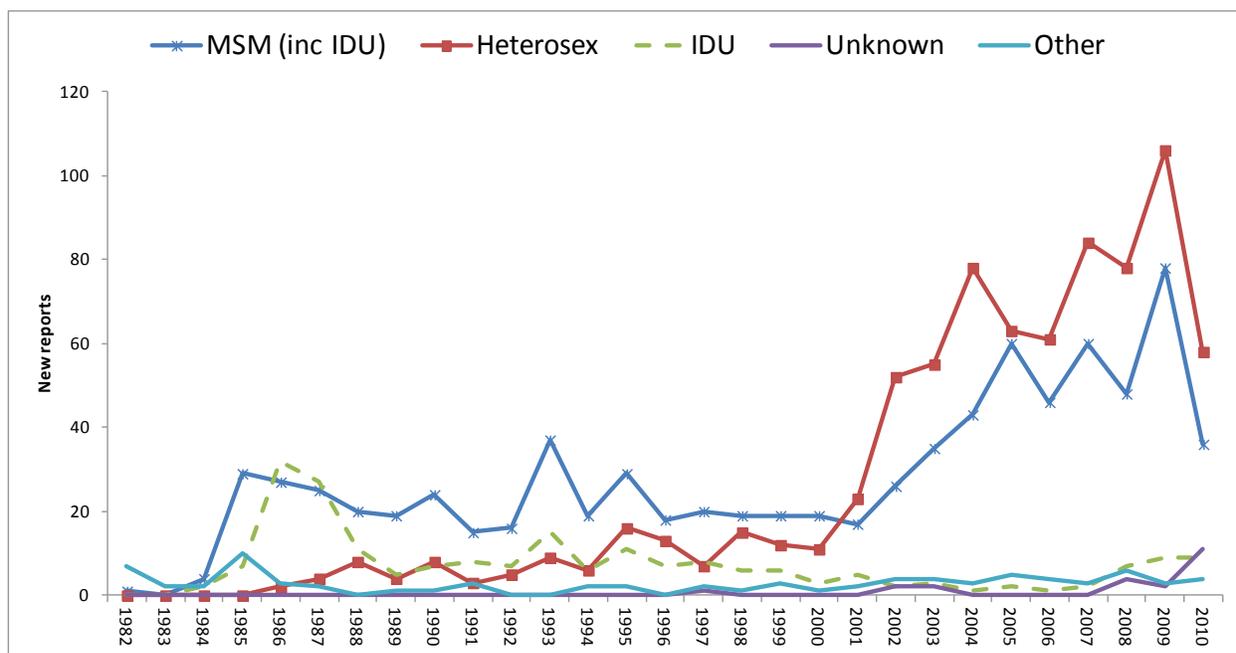
2.2.3 **International context:** in the 31 years that have elapsed since its initial recognition, AIDS is estimated to have killed over 25 million people. However, the latest epidemiological

data indicate that annual reports of new HIV cases peaked in 1996, with AIDS-related mortality peaking eight years later, in 2004. These impressive reductions have been achieved through coordinated deployment of evidence-based preventive interventions, including behaviour change amongst those at greatest risk; increased availability of condoms; wider access to antiretroviral therapy (ART); and, most importantly, committed public health leadership to ensure that investment in these interventions is appropriately balanced, regularly reviewed for its effectiveness and reaches those who need it.

2.2.4 National context: It is estimated that by the end of 2012, 100,000 people will be living in the UK with HIV-1 infection, around one quarter of whom will be unaware of their HIV status. In Scotland, the cumulative total of known HIV positive individuals is now 6,845, of whom 4907 (72%) are male and 1898 (28%) are female. 2826 (41%) of the total known cases are thought to have acquired their HIV infection out with Scotland.

2.2.5 GG&C: Cumulatively to 30 September 2011, a total of 1,974 GG&C residents have been diagnosed with HIV infection; of these, 854 are men who have sex with men (MSM), 819 heterosexual and 209 injecting drug users; the remaining 92 acquired HIV infection from other/undetermined exposures. The recent decline in annual number of new HIV cases has following a prolonged and substantial upsurge in new diagnoses (Figure 2). Over 85% of patients in the heterosexual risk category acquired their infection in sub-Saharan Africa.

Figure 2: New HIV diagnoses in NHS GG&C residents, by prevention group 1982-2010

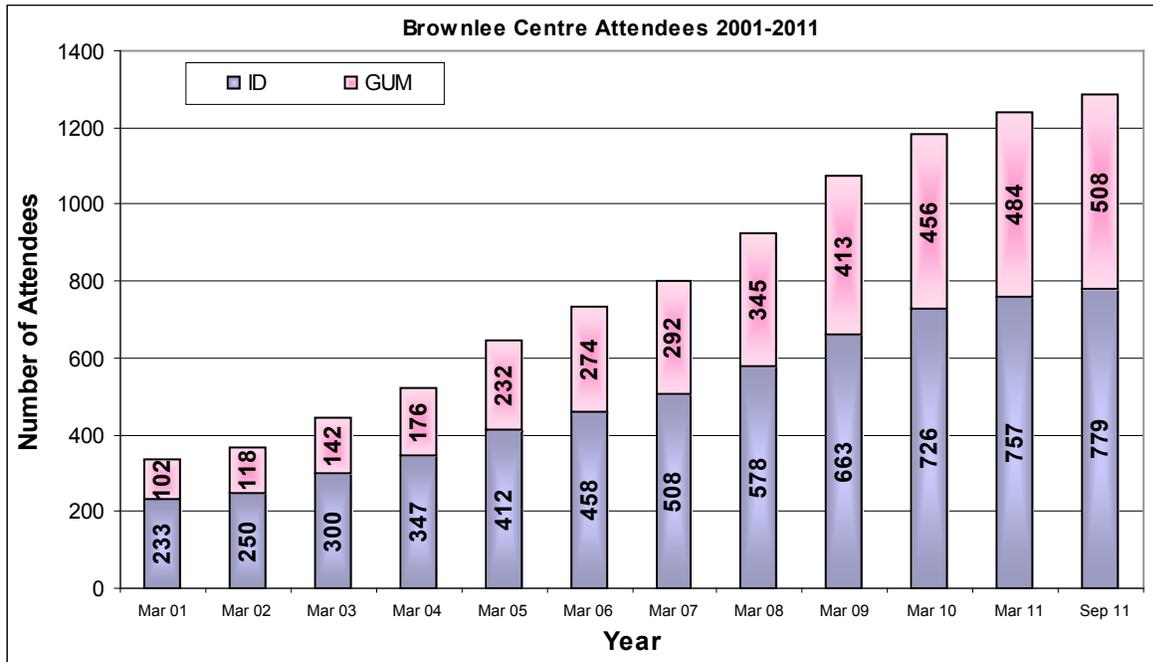


As at 30 June 2011, an estimated 1,084 HIV-positive GG&C residents were alive and attending for monitoring and treatment.

2.3 HIV Treatment and Care: All adults diagnosed with HIV and living in NHSGGC attend for treatment and care at the Brownlee Centre for Infectious Diseases located on the main Gartnavel campus. Patients are treated by both ID and GUM consultants. Children infected with HIV attend the paediatric infectious diseases service at Yorkhill Hospital.

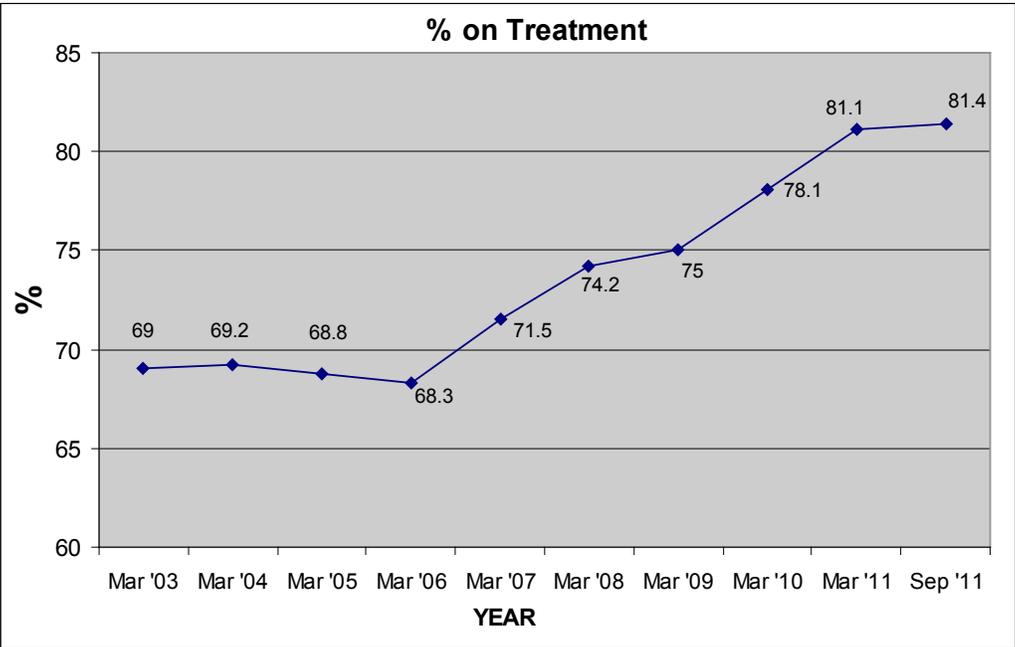
A total of **1287** patients were under the care of the HIV clinical teams by September 2011. This is a 3.7% rise as at 31 March 2011, and a 6.7% rise on the cohort at 30 September 2010. Figure 3 illustrates the increase in attendees from 2001 to 2011.

Figure 3: Brownlee Centre Attendees for HIV Care – 2001-2011



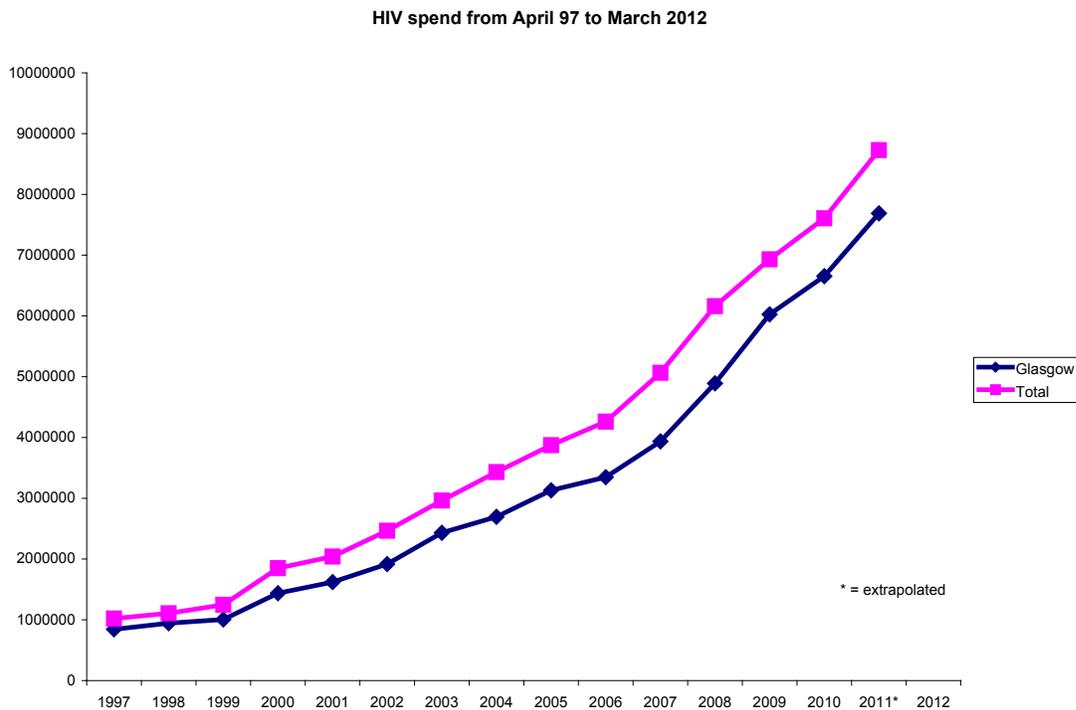
As at September 2011, there were **1047** patients (81.4%) on Antiretroviral therapy (ART). The total number of patients on therapy has increased by 16.5% since September 2010 when 899 were receiving therapy. Figure 4 describes the proportion of patients receiving ART.

Figure 4: Percentage of Cohort on Antiretroviral Therapy



Linked to this increasing cohort of patients on therapy is the increase in associated drug costs. A person diagnosed with HIV and accessing treatment and care, can expect to be on treatment for the rest of their life, with a lifetime of treatment estimated to cost between £280,000 and £360,000. Economic evaluation studies demonstrate that ART is highly cost effective, with an incremental cost-effectiveness ratio of £11,000 per quality adjusted life-year gained, well below the conventional NICE threshold of £30,000 for considering the cost effectiveness of pharmacological interventions. There is also evidence that initiating ART at a CD4 count of 500/mm³ is more cost effective than initiating therapy at 200/mm³. The more recent evidence on the public health benefits on reduction of transmission further strengthen the health economic case for early treatment. Figure 5 illustrates the HIV drug expenditure in NHS GGC from 1997 and extrapolated to the end of March 2012

Figure 5: HIV drug expenditure in NHS GGC 1997-2012



The expenditure in 2010/11 was £6.6 million pounds and is projected to reach £7.7 million by the end of March 2012.

2.4 Strategic components of HIV prevention: The highly dynamic nature of HIV epidemiology necessitates regular strategic review of HIV prevention activities, to ensure that they remain balanced, appropriate and effective at a whole system level. HIV prevention interventions act at three principal intervention points (Figure 6; Table 1).

- Preventing HIV acquisition, using a range of biomedical and behavioural approaches.
- Early HIV detection in the pre-symptomatic stage. This benefits both affected individuals (clinical outcomes are comparatively poorer in advanced HIV infection) and also reduces infectivity and thus the risk of onward transmission
- Managing established HIV infection to prevent serious life-threatening and disabling complications and minimise the risk of onward transmission to others

Figure 6: Intervention points for HIV prevention

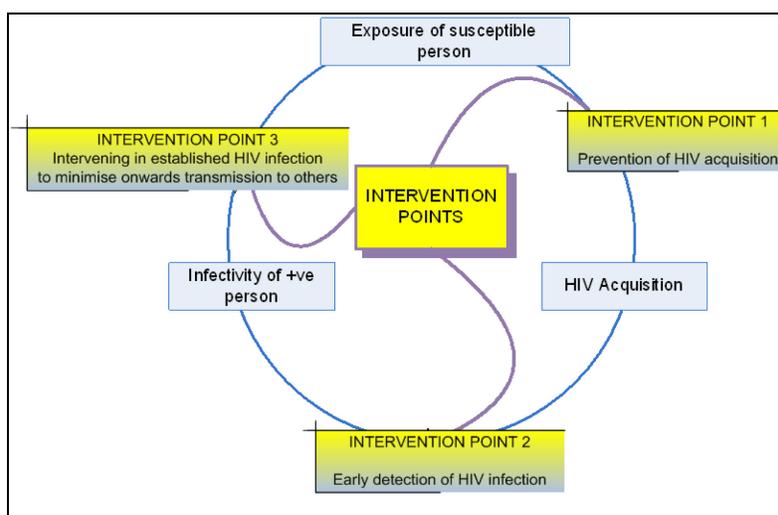


Table 1: Components of HIV Prevention Interventions

Intervention point 1 (Preventing HIV acquisition)	Intervention point 2 (Early HIV detection)	Intervention point 3 (Case management)
<i>Awareness raising</i> (Peer education; social marketing, community development)	<i>Promotion of testing</i>	<i>Antiretroviral therapy</i> (appropriate resources, adherence monitoring & support, supported self care)
<i>Condom provision</i>	<i>Accessible and appropriate HIV testing facilities</i>	<i>STI prevention, detection & Rx</i> (Regular STI screens)
<i>Information provision</i> (appropriate resources, peer education, social marketing)	<i>Partner notification</i>	<i>Psychosocial support</i>
<i>Behavioural interventions</i> (partner number reduction; risk reduction, HIV testing)	<i>Clinician education in non-specialist settings</i>	<i>Behavioural change interventions</i>
<i>Post exposure prophylaxis(PEPSE)</i>	<i>Opt-out HIV testing in sexual health services</i>	<i>Post exposure prophylaxis(PEPSE)</i>

2.5 Evidence supporting current prevention investment : Pursuit of value for money is a key priority for all health systems; the HIV prevention programme in NHS GG&C is no exception. Although assessing the value of investment in prevention is intrinsically challenging (because success is defined by an absence of events), high quality evidence is beginning to accumulate in several areas. The HIV Prevention Network is strongly committed to ensuring clear definition of the inputs, critical change components and outputs of all HIV prevention interventions in which it invests. NHS GG&C’s HIV Prevention Network conducts an annual stocktake of its preventive interventions, which ensures that each constituent component is

clearly defined and re-evaluated, against both changing research evidence and also the changing local epidemiological picture in NHS GG&C. In this section, we briefly summarise the evidence underpinning our current portfolio of HIV prevention activities at each intervention point.

2.5.1 Prevention of HIV acquisition: male latex condoms are the single most effective available technology for reduction of the sexual transmission of HIV; consistent condom use provides an overall protection of around 80-85% against HIV (estimated plausible range: 76 to 93%). There is also good evidence that behavioural interventions can reduce high risk sexual behaviour among MSM, with a progressive shift away from generic behavioural strategies towards more individualised, skills-based approaches tailored toward the known serostatus of both partners.

2.5.2 Early detection of HIV infection: HIV testing is a vital part of HIV prevention; as well as individual clinical benefits arising from earlier detection, HIV testing is highly cost effective at a population level, because earlier ART has such a powerful effect on reduction of transmission. For this reason, NHS GG&C is making considerable efforts to scale up HIV testing activity in a wider range of settings when particular clinical circumstances arise, which also helps to normalise and destigmatise HIV infection.

2.5.3 Case management & support in HIV positive people: since publication of randomised controlled trial evidence that ART can achieve a 96% reduction in HIV transmission, there has been a growing emphasis on 'treatment for prevention', i.e. ART for the explicit purpose of decreasing onward transmission of HIV at a population level. However, adherence to therapy is a key issue, and research continues to examine innovative real-time strategies to monitor and improve adherence to ART. The value of prevention with antiretroviral drugs highlights the overlap of treatment and prevention and the need for integrated strategies for HIV treatment and prevention.

2.5.4 Targeted HIV prevention interventions: The overall effectiveness and efficiency of our HIV prevention programme depends critically on the following factors:

- Evidence of the intervention's efficacy in clinical and/or public health trials
- Size of the target population and its proportionate contribution to current HIV incidence in the NHS GG&C population
- Achievable coverage in the GG&C target population

Accordingly, the majority of our current HIV prevention activity and expenditure is targeted to the two large subgroups most at risk of acquiring HIV; Black African subgroups and MSM (Figures 7 and 8 overleaf), however it also includes more generic activities and the crucial interface with the extensive and multifaceted programme of BBV prevention work with injecting drug users, which is fully described in the context of HCV prevention in the next section

Figure 7: HIV prevention targeting Black African subpopulation

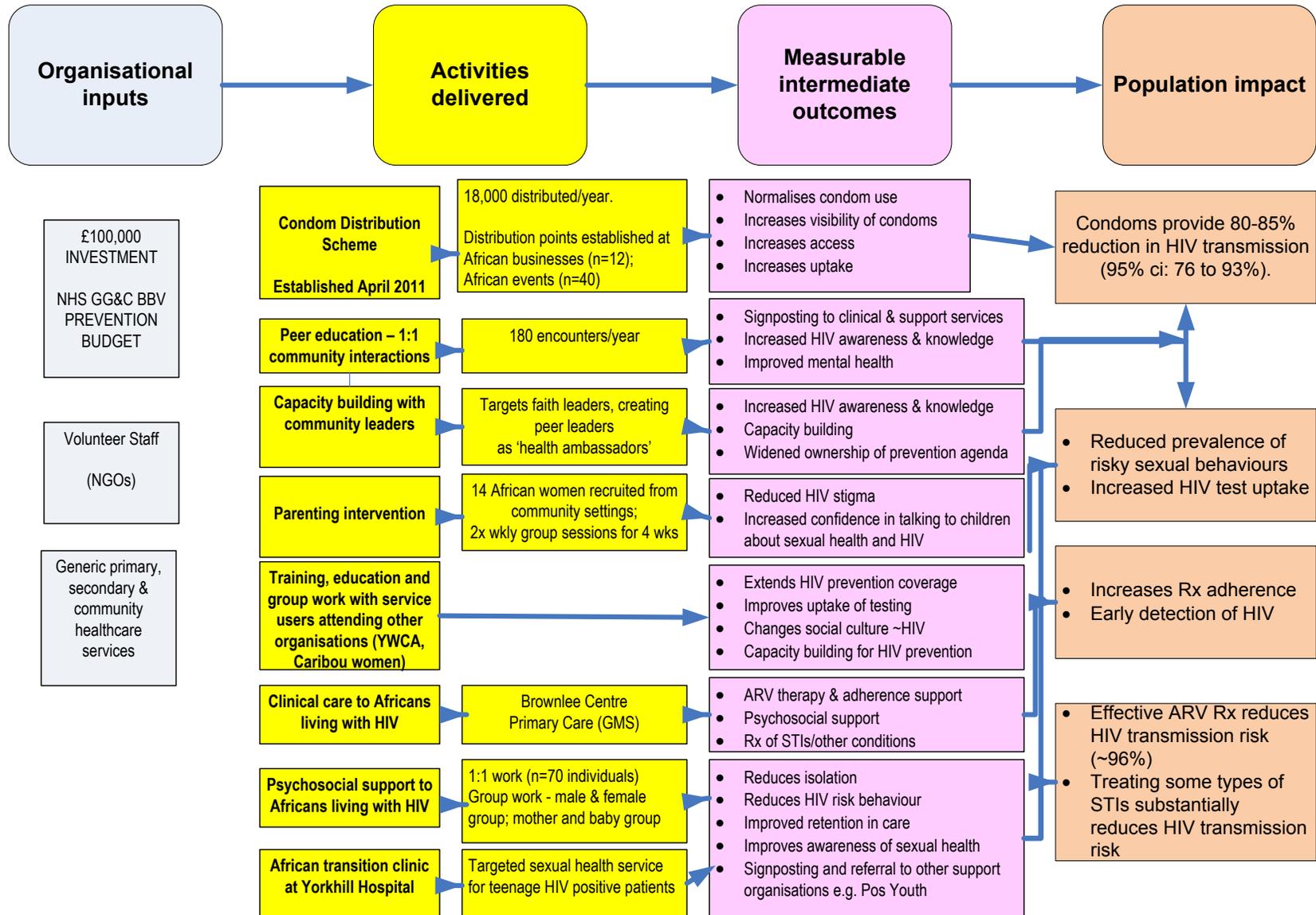


Figure 8: HIV prevention targeting men who have sex with men (MSM)

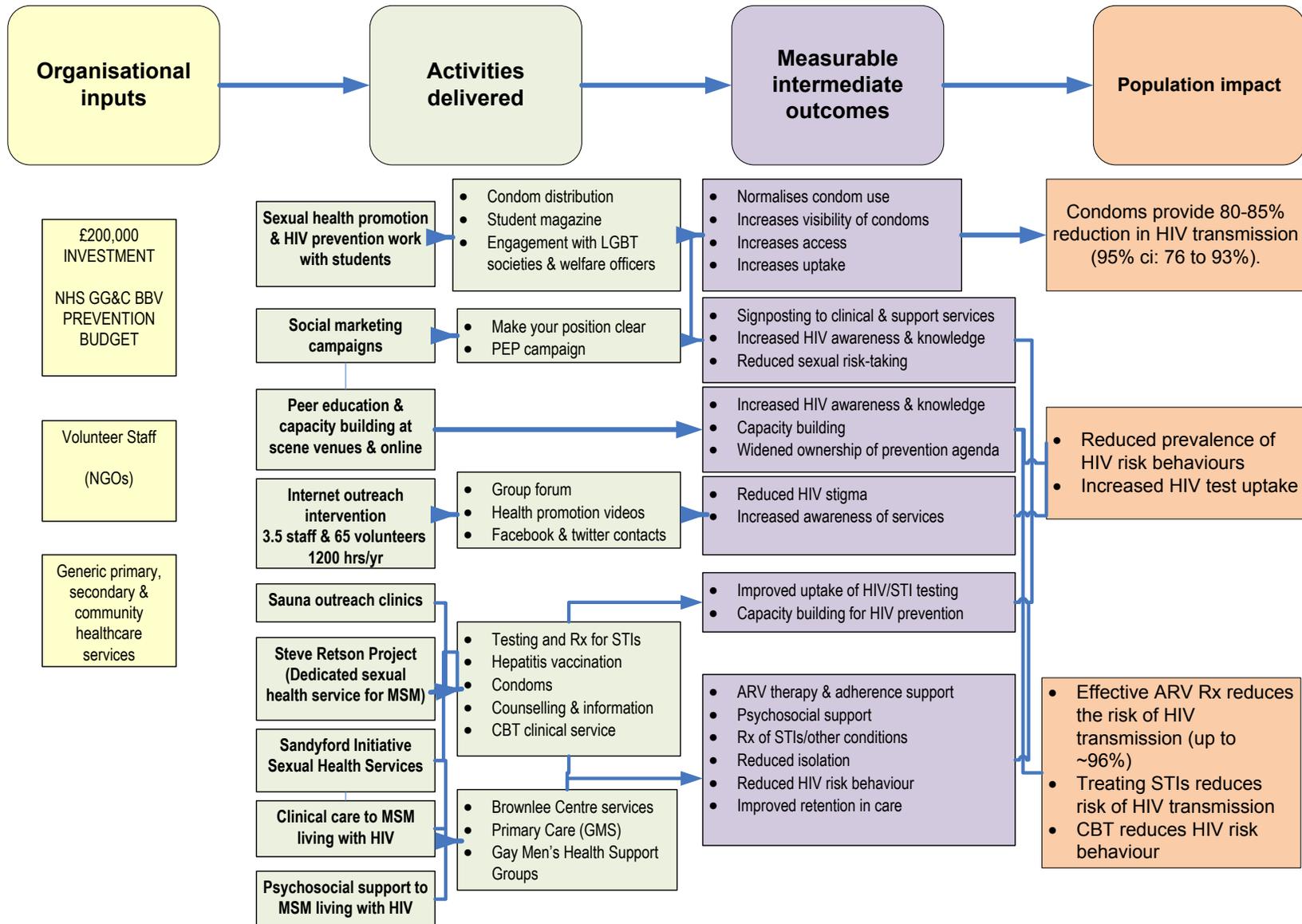
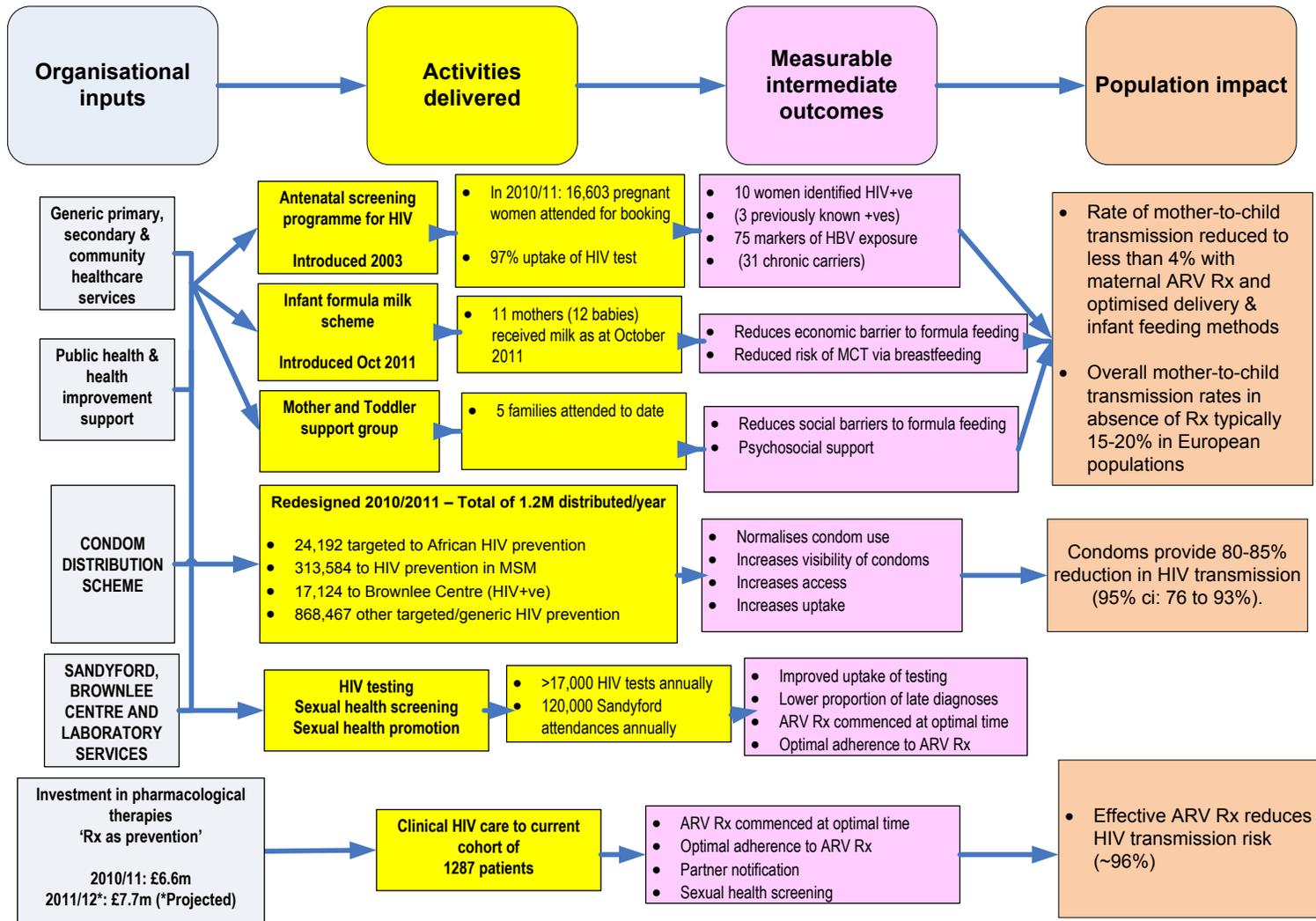


Figure 9: Generic HIV prevention activity and interface with targeted BBV prevention in injecting drug users



2.5.5 Generic HIV prevention interventions: Although HIV is generally concentrated within defined subpopulations in NHS GG&C there is a need to maintain proportionate investment in preventing HIV in the population as a whole, via standard sexual health and health improvement activities. All pregnant women are also offered screening for HIV in pregnancy because of the existence of highly effective interventions to reduce HIV transmission. In the absence of any intervention, an HIV-positive woman has a 15 to 30% chance of transmitting the virus to her baby during pregnancy and delivery. If she breastfeeds, there is an increased 5 to 20% risk of transmission. With ARV treatment, the risk of vertical transmission can be reduced to under 2%. Figure 9 summarises the current generic HIV prevention interventions and also details the range of interventions in place to prevent mother to child transmission in GG&C.

2.6 Summary and conclusion

HIV remains a substantial threat to public health in NHS GG&C because of its effect on healthy young people, potential for rapid transmission and high treatment and care costs. This paper demonstrates both its highly dynamic epidemiology and also the enormous advances that have been made in recent years in available HIV prevention interventions. NHS GG&C will maintain an annual stocktake of the preventive interventions it commissions, however the NHS Board members should note the key points/actions identified by the HIV Prevention and Treatment Group as follows:

- That the expanding range of effective and efficient prevention strategies now available for deployment at a population level
- That NHS GG&C plan to scale up HIV testing activity in a wider range of clinical settings and facilitate more HIV test requests in primary care
- That the recently redesigned condom distribution scheme shows continuing improvement in coverage and be supported, subject to its successful evaluation
- That progress has been made with community development initiatives among black African subgroups, which have substantially improved access to HIV prevention for this subpopulation at high risk of HIV infection

3. Hepatitis C in NHSGGC

3.1 Introduction: Hepatitis C infection is caused by the hepatitis C virus (HCV) that is transmitted through blood-to-blood contact and primarily infects and affects the liver. Following infection, around 20% of cases are naturally resolved within the first six months, and the remainder develop chronic, lifelong infection. One third of chronic cases are likely to develop cirrhosis of the liver within 20-30 years, of these around 7% will develop liver failure or primary liver cancer per year.

In 2004, the Scottish Government recognised that “*hepatitis C is one of the most serious and significant public health risks of our generation*”ⁱ. By December 2006 HPS estimated that 50,000 persons in Scotland had been infected with the virus, and that 38,000 were chronic carriers.

Treatments are available that can clear the virus in 40-80% of those completing a course, according to genotype. HCV treatment is deemed cost-effective by NICE, Healthcare Improvement Scotland and the Scottish Intercollegiate Guidelines Network. However in 2006, HPS estimated that only 20% of chronic cases had ever attended specialist care, and only 5% had ever received treatment.

In response, the Scottish Government published the Hepatitis C Action Plan for Scotland in two phases, Phase I (Sep 2006-Aug 2008) and Phase II (May 2008-Mar 2011). These tasked Health Boards to significantly develop local services to make step-wise improvements in the prevention, detection and treatment of HCV. The Action Plan was supported by central funding of £4M in phase I and £43.2M in phase II.

Following completion of the Phase II HCV Action Plan, the Scottish Government incorporated hepatitis C into the new Sexual Health and Blood-borne Virus Framework (2011-15). This document defines outcomes and performance indicators for hepatitis B, C, HIV and Sexual Health, aligned to the government's spending cycle.

3.2 Epidemiology: At the end of 2011 almost 13,000 people were known to be living and ever infected with HCV in NHS GGC. Of these, around 20% (2,500/13,000) will have cleared the virus within 6 months of infection and 80% (10,500/13,000) will be chronically infected. In the Sexual Health and Blood-borne Virus Framework (2011) the Scottish Government note that more than half of HCV cases remain undiagnosed, suggesting that the total number of infected individuals in GGC exceeds 26,000.

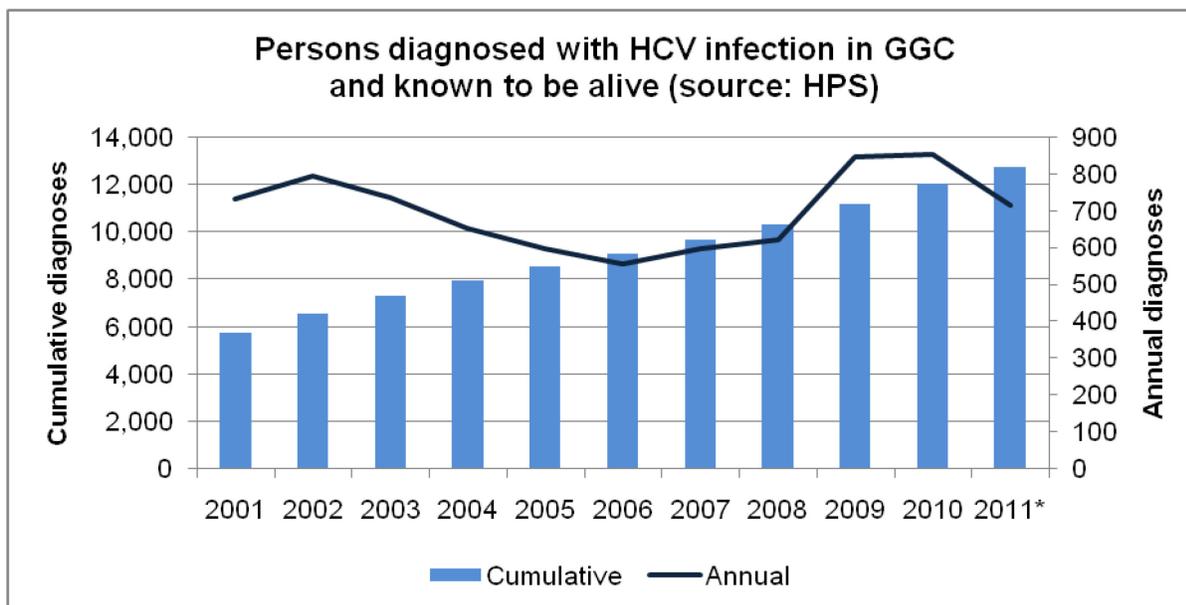
Where route of transmission is known 91% (7,791/8,818) of infections were acquired as a result of Injecting Drug Use. In Glasgow the incidence of HCV is steady at around 20-30 infections per 100 person years of injecting.

Almost three-quarters of individuals (9,134/12,709) were aged between 20-40 years at the time of infection. Audit data from GGC Acute centres show that 94% (5,010/5,351) of referred patients are of White ethnicity, and the remainder are predominately from Pakistani communities.

Figure 10: Persons diagnosed with HCV infection in NHSGGC and known to be alive (source: HPS)

Source data

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011*
Annual	733	794	734	652	597	556	596	623	846	852	714
Cumulative	5,745	6,539	7,273	7,925	8,522	9,078	9,674	10,297	11,143	11,995	12,709



3.3 Viral Hepatitis Managed Care Network (VH MCN): In 2006 the Hepatitis C MCN was formally constituted to provide a forum for the development of HCV care pathways, and to oversee the implementation of the testing, treatment, care and support elements of the National HCV Action Plan (Phases I & II).

Following publication of the Sexual Health and Blood-borne Virus Framework the MCN expanded to cover issues relating to hepatitis B, and was rebadged the Viral Hepatitis MCN.

The VH MCN addresses prevention, treatment, care and support issues for hepatitis C, and treatment, care and support issues for hepatitis B. In line with local epidemiology and service provision, Hepatitis B prevention will be discussed both at this group and also at the HIV Prevention and Treatment Group.

There are a small number of MCN subgroups that have been formed to address HCV prevention, develop local clinical management and treatment guidelines, produce public and patient information, and support the operational development of testing and referral services in localities.

3.4 Prevention: Over 90% of Scottish HCV cases are acquired as a result of Injecting Drug Use. A key priority of the Phase II HCV Action Plan was to reduce the incidence of new infections through increased provision of sterile injecting equipment to those at risk. The Action Plan tasked Boards to improve the quality, quantity and nature of injecting equipment provision (IEP), and to develop local HCV Prevention Networks to oversee this work.

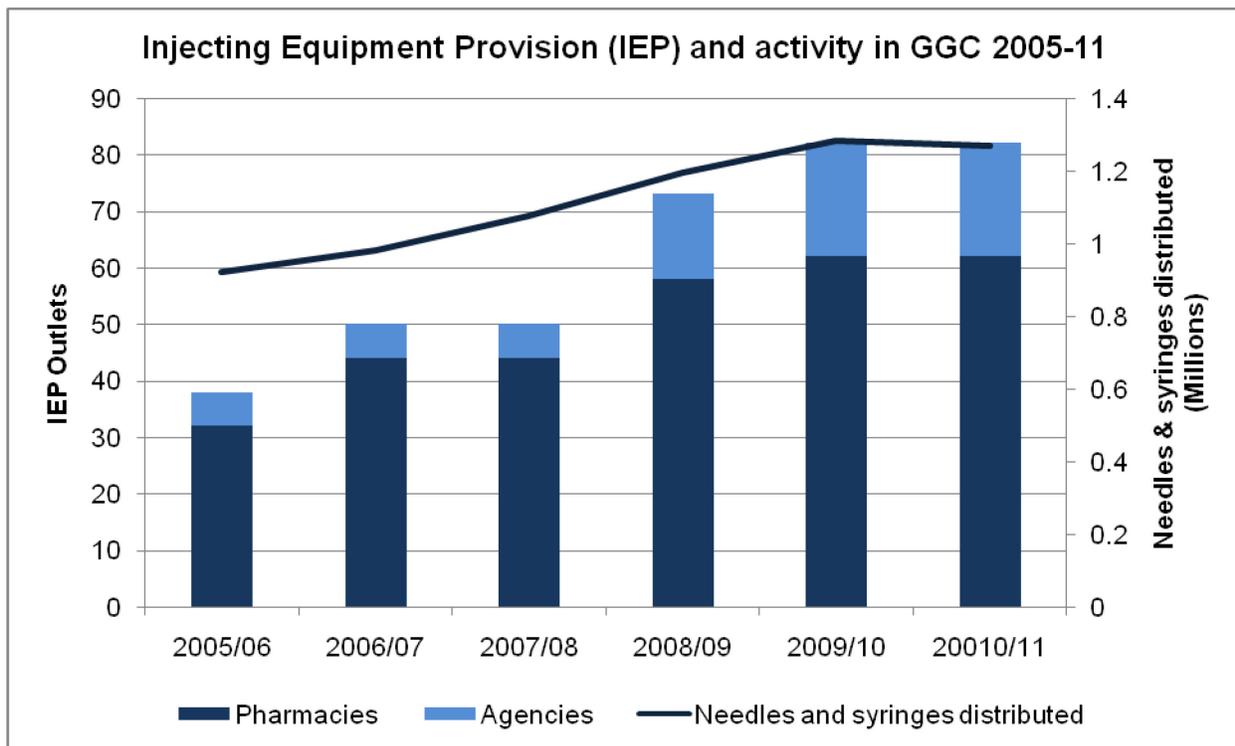
In 2006 a mapping exercise was conducted to review the number, type and geographical location of IEP services across GGC. At that time 32 community pharmacies and 6 drug

services provided sterile injecting equipment to local injectors. Glasgow Addiction Services recruited 30 additional community pharmacies to the IEP scheme, predominately in areas with a high number of injectors but historically low levels of provision. The number of non-pharmacy outlets was increased from 6 to 20. Addiction services, Sandyford Sexual Health sites, and police stations offered a Needle Replacement service, providing an initial set of sterile equipment to persons in need, and signposting them to regular needle exchange outlets.

Between 2005-11, there was a 116% increase in the number of IEP outlets (Figure 11). A map of IEP services was developed by Glasgow Addiction Services, showing the location, opening hours and types of provision in each CHP. This map was circulated by IEP services, and others working with clients at increased risk of injecting drug use.

Over the same period there was a 38% increase in number of sets of sterile needles and syringes provided to injectors, from 0.92M sets in 2005/06 to 1.28M in 2010/11. This increase in activity closely matched developments in the number of outlets. Activity data showed a 1.0% decrease in activity between 2009/10 and 2010/11. This experience was reflected in other Health Boards, and is associated with a decrease in the availability of heroin in Scotland, and a reduction in persons choosing to inject following a cluster of IDU-related anthrax cases in 2010.

Figure 11: Injecting equipment provision (IEP) and activity in NHSGGC 2005-11



3.5 Diagnostic testing and referral: The Phase II Action Plan noted that “*the majority of persons infected with HCV remain undiagnosed [and that] the uptake of HCV testing among past and current IDUs is sub-optimal following test offer.*” In response, the HCV Managed Care Network sought to increase testing activity in a range of settings, with specific focus on Addiction services and Primary Care providers engaging with people with a history of injecting drug use.

Following validation by the West of Scotland Specialist Virology Lab, a new method of sample collection was adopted locally. Dried Blood Spot testing allowed testing to be conducted on small blood spots that involved a finger-prick. This avoided the need for venepuncture, which was often a barrier to persons whose peripheral veins were damaged as a result of injecting drug use.

Diagnostic testing activity has significantly increased in the Health Board area since the national Action Plan was introduced. Data from HPS indicate that from 2006-11 an average of 670 HCV antibody positive cases are first diagnosed each year. Of these, around 80% will have chronic infection and require referral to specialist care.

Table 2: Persons reported to be HCV antibody positive by source of referral and year of first positive specimen. Source: HPS, 2011

<i>Source of referral</i>	Pre-2006	2006	2007	2008	2009	2010	2011 proj.	Total	%
<i>GP</i>	1913	186	209	170	217	149	150	2,994	24%
<i>Acute</i>	3,131	183	194	224	202	178	128	4,240	33%
<i>GUM</i>	436	37	32	50	59	50	26	690	5%
<i>Prison</i>	629	8	20	22	22	34	32	767	6%
<i>Drug Service</i>	8	0	4	2	149	291	220	674	5%
<i>Other</i>	1,796	60	59	59	52	31	16	2,073	16%
<i>Not Known</i>	609	82	78	96	145	119	142	1,271	10%
Total	8,522	556	596	623	846	852	714	12,709	100%

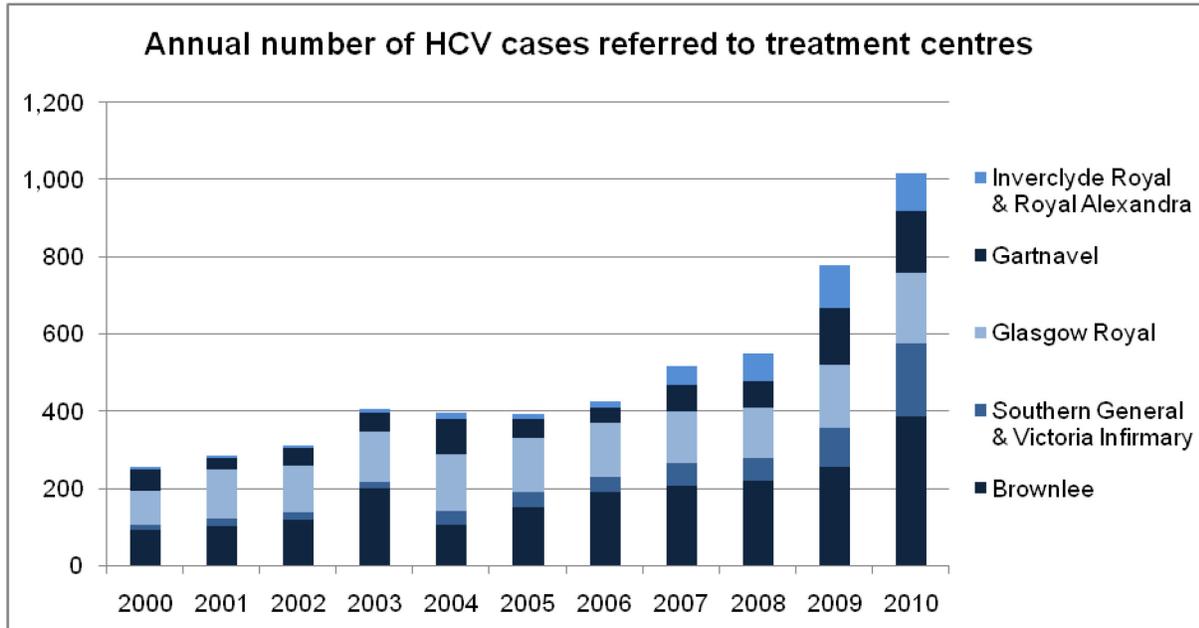
N.B. The classification of referral sources was revised the Phase II Action Plan, which accounts for the sudden increase in the number of samples attributed to Drug Services from 2009.

3.6 Specialist Care: A key priority of the Phase II Action Plan was to increase the number of infected persons who clear their infection and thus reduce the number of infected persons who develop severe hepatitis C-related liver disease. Each Health Board was tasked to increase the number of infected individuals attending for clinical assessment, and targets were set for treatment activity in each Board area.

Within GGC clinical management of HCV cases is provided from Depts. of Gastroenterology at the Gartnavel, Glasgow Royal, Southern, Victoria, Inverclyde Royal and Royal Alexandra Hospitals and the Dept. of Infectious Diseases at the Brownlee Centre.

3.6.1 Clinical capacity: In line with developments in diagnostic testing activity, the annual number of referrals increased from an average of 343 patients/year pre-Action Plan, to 1019 patients in 2010 (Figure 12).

Figure 12: Annual number of HCV cases referred to treatment centres



In order to effectively manage the increased workload, additional clinical capacity was resourced from Action Plan funds. As a result of this investment, the number of consultant sessions devoted to management of HCV was doubled, and Specialist Nursing capacity increased by a factor of 3.5.

HCV Clinic Staffing (wte)	Pre-2006	HCV Funded	Current
Consultants	1.8	2	3.8
Clinical Nurse Specialists	2.7	7	9.7

As well as support the increased workload in HCV outpatient clinics, this additional capacity enabled centres to deliver clinical assessment and treatment in other community settings.

3.6.2 Outreach model of care: The majority of HCV patients are from areas of high social deprivation, with a history of injecting drug use. These individuals are more likely to have concomitant health and social care needs including recovery from addiction, low household income, mental health problems, and alcohol excess; consequently, the default rate for first outpatient appointment was historically high at 20-70% across Scotland. This resulted in missed opportunities to assess and treat diagnosed individuals, and suboptimal utilisation of clinical resources.

In response to these factors, the MCN developed an Outreach approach to initial clinical assessment and, where appropriate, treatment of infected persons. Effective working links were developed between treatment centres, addiction services and prison establishments. Clients with chronic HCV were offered the opportunity to see specialist nurses in a setting that they

were familiar with, and were more likely to attend. This provided an opportunity to address their information and support needs, provide accurate information on their condition, promote the benefits of antiviral treatment, and conduct initial clinical assessment.

Medic-led treatment services were developed in partnership with HMPs Barlinnie and Greenock providing opportunities for prisoners to be treated in prison, and at Leven Addiction Service, where previously clients were required to travel to the Gartnavel campus, with high default rates.

3.6.3 Treatment numbers and outcomes: These developments enabled Acute centres to significantly increase the number of patients initiated onto antiviral treatment. By 2010 the number of people starting HCV treatment had increased by 178% compared to the 2006 baseline. Local treatment activity (Table 3) exceeded the targets set by the Scottish Government during the Phase I and II Action Plans.

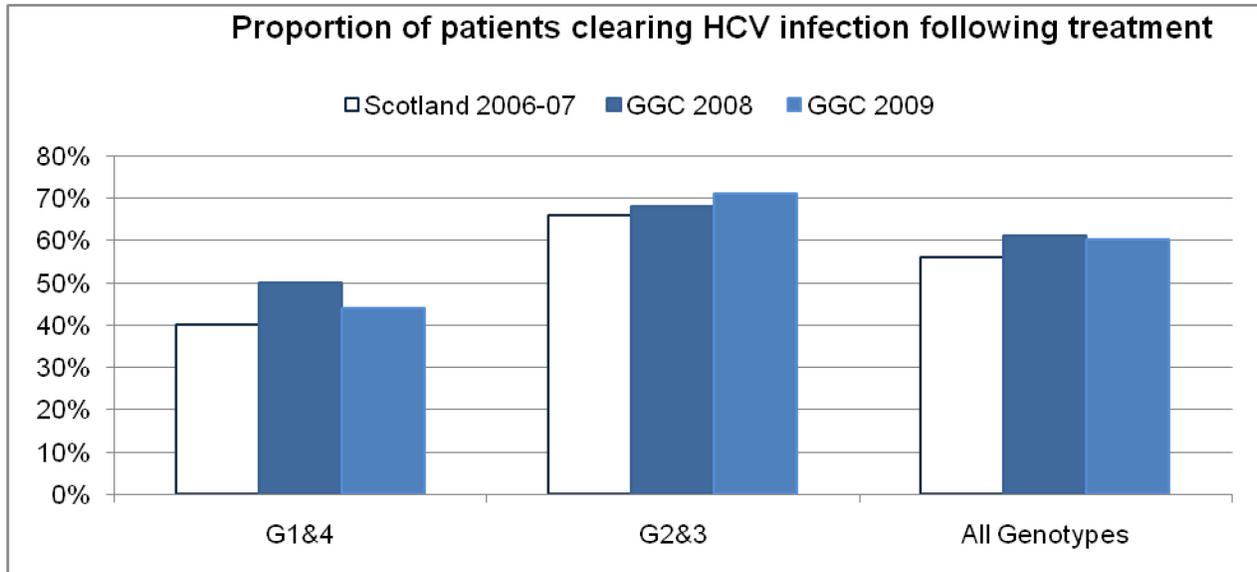
Table 3: Treatment activity

	2006	2007	2008	2009	2010
Brownlee Centre	41	59	82	93	157
Glasgow Royal	30	39	51	77	92
Gartnavel General	36	46	41	54	70
Southern & Victoria	18	21	22	34	40
Inverclyde Royal	18	21	13	14	19
Royal Alexandra	0	1	2	8	10
GGC	143	187	211	280	398
Scottish Govt. target	n/a	n/a	169	253	337
<i>Comparison with 2006 baseline</i>	n	44	68	137	255
	%	31%	48%	96%	178%

Patient response to treatment depends on a number of factors including the type of HCV they are infected with, their age at infection, gender and their adherence to therapy. Most important of these is the type of virus they have known as genotype (G). The goal of anti-HCV therapy is Sustained Viral Response (SVR) defined as the absence of viral DNA at 6 months following the end of treatment.

Patients infected with G1 and G4 HCV require a longer duration of treatment (48-72 weeks) and have a lower chance of achieving a SVR ~40%. Treatment duration for G2 and G3 patients is shorter at 24 weeks, with a higher chance of clearing the virus ~67%. Following clinical audit of treatment activity and outcomes, local cure rates compare well with those across Scotland, and have remained relatively consistent between 2008 and 2009.

Figure 13: Proportion of patients clearing HIV infection following treatment



3.6.4 Protease Inhibitors

Towards the end of 2011, a new class of drugs, HCV Protease Inhibitors, came to market. These two new treatments are suitable for G1 patients and, taken alongside the current standard of care therapy, increase SVR rates to 80-90%.

Following SMC approval these drugs have been considered by the local ADTC and are due to receive formulary approval in mid-February 2012. As well as increasing the number of persons who successfully clear their HCV infection following treatment, there will be associated cost implications. The MCN is working closely with colleagues in Acute, Pharmacy, and Finance to monitor prescribing activity, spend, and treatment outcomes.

4. Hepatitis B (HBV) in NHS GGC

4.1 Introduction: Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). Many new infections are sub-clinical or may have a flu-like illness and only a small proportion of cases may present with jaundice. Like the previous two BBVs, HBV is transmitted by exposure to infected blood or body fluid through vaginal or anal intercourse, blood-to-blood contact, (for example sharing of needles and other equipment by injecting drug users, needlestick injuries), or transmission from mother to child during birth.

In adults, most acute HBV infections occur among the high risk groups due to their lifestyle. Most recover from infection without any treatment and any long term sequelae. However, in a small proportion of these cases (approximately 5-10%) the infection will become chronic. If infection is acquired peri-natally, over 90% will become chronic. Cirrhosis occurs in up to 40%

of chronic infections acquired in childhood vs 20% of adult acquired infections. Up to 9% of them may go on to develop hepatocellular carcinoma.

4.2 Epidemiology: The World Health Organisation (WHO) has estimated that over 350 million people worldwide are chronically infected with HBV. The WHO has categorised countries based upon the prevalence of chronic infection into high (more than 8% of the population), intermediate (2 to 8%) and low (less than 2%) endemicity countries. High prevalence regions include sub-Saharan Africa and most of Asia whereas most of Western Europe and North America are low prevalence countries.

HBV is uncommon in NHS GGC and in Scotland and at the moment reported data in Scotland does not discriminate between cases of acute or chronic infections. Anecdotally however, there is evidence that the number of cases have been increasing over recent years. Most of these cases are diagnosed among those people who were born outside the UK and were probably infected at birth. Approximately 200 new diagnoses (both acute and chronic) of HBV infection were made annually in NHS GGC during 2009 and 2010. Around half of these were diagnosed in general practice and the antenatal clinic settings as part of the routine screening of all pregnant women for this infection.

4.3 Prevention: A vaccine against hepatitis B has been available since 1982. It is an extremely effective vaccine in preventing HBV infection and its chronic consequences and is the first vaccine against a human cancer. Based on the WHO recommendation, by 2009; 177 countries had included the hepatitis B vaccine into their national infant immunisation programme. However, in the UK, this vaccine is not included in the routine childhood immunisation programme but instead the UK adopted a policy of vaccination based on lifestyle and occupational risks. Groups targeted for hepatitis B vaccination in NHS GGC include:

- Babies born to infected mothers – all pregnant women are offered screening for HBV infection and if positive arrangements are in place to vaccinate their babies at birth. Approximately 70-75 mothers are identified every year in NHS GGC as being infected.
- Current and former injecting drug users – arrangements are in place to offer the vaccine in prison, in addiction services and shared care GP services
- Close family contacts of those with chronic infection through primary care
- NHS staff and others who are at occupational risk

Other prevention work targeted at those at risk of HIV (safer sex) and HCV (safer injecting) infections will also prevent the transmission of HBV infection.

4.4 Clinical management of cases: Antiviral drugs are available for the treatment of HBV infection but the therapy simply suppresses the viral load rather than cure the infection. Over the last decade, the treatment available has expanded with new and more potent antiviral agents becoming available. In NHS GGC, the Hepatitis MCN produced a guideline on the assessment and management of patients with HBV infection and all newly diagnosed (acute and chronic) infections are recommended to be referred to a specialist unit for assessment and treatment. The number of patients currently on treatment are relatively small (approximately 20

patients) but this number is expected to increase significantly over the next few years in keeping with the aspirations of the National Framework.