



Viral Hepatitis Prevention Board

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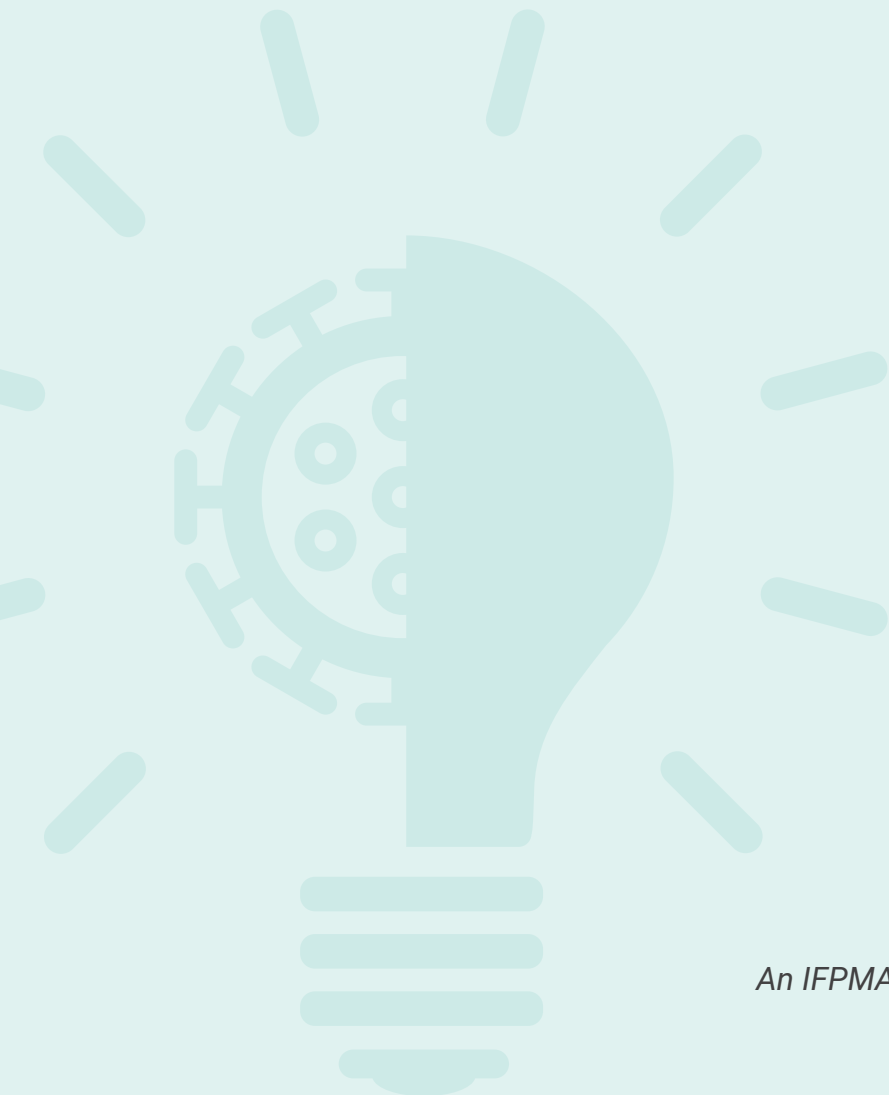
INNOVATIVE FINANCING INTO HEPATITIS B AND C PREVENTION AND TREATMENT IN LOW AND MIDDLE INCOME COUNTRIES



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LIST OF ABBREVIATIONS

ACT	Artemisinin-based Combination Therapy
ALS	Amyotrophic Lateral Sclerosis
AMC	Advance Market Commitments
AMFm	Affordable Medicines Facility – malaria
AU	African Union
AUSAID	Australian Agency for International Development
BMS	Bristol-Myers Squibb
CSR	Corporate Social Responsibility
DAA	Direct-Acting Antiviral Agents
DAH	Development Assistance for Health
ETS	European Trading System
EVPA	European Venture Philanthropy Association
FECECAM	Faïtière des Caisses d’Epargne et de Crédit Agricole Mutuel
GFATM	Global Fund to fight Aids Tuberculosis and Malaria
GAVI	Global Alliance for Vaccine and Immunization
GHE	Government Health Expenditure
GHIT	Global Health Innovative Technology Fund
HBV	Hepatitis B Virus
HC	Health Care
HCV	Hepatitis C Virus
HDHP	High-Deductible Health Plan
HIV/AIDS	Human Immunodeficiency Virus infection / Acquired Immune Deficiency Syndrome
HAS	Health Savings Account
IffIm	International Finance Facility for Immunization

IHME	Institute for Health Metrics and Evaluation
ILO	International Labour Office
LIC	Low-Income Countries
LMICs	Low- and Middle-Income Countries
MFI	Micro-finance Institutions
MIC	Middle-Income Countries
MPP	Medicines Patent Pool
NGO	Non-Governmental Organization
NRCMS	New Rural Cooperative Medical System
OECD	Organization for Economic Co-operation and Development
ODA	Official Development Aid
PAHO	Pan American Health Organization
PFI	Private Finance Initiatives
PPP	Public-Private Partnership
SIB	Social Impact Bond
SPV	Special Purpose Vehicle
TRIPS	Trade-Related Aspects of Intellectual Property
VH	Viral Hepatitis
VHPB	Viral Hepatitis Prevention Board
WHA	World Hepatitis Alliance
WHO	World Health Organization
UHC	Universal Health Coverage
UNICEF	United Nations Children’s Fund

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EXECUTIVE SUMMARY

Viral hepatitis (VH) is clearly moving up towards its deserved place on the international public health agenda, thanks to the combined efforts of international organisations, the academic world, the pharmaceutical industry, national governments and patient advocacy groups. Recent breakthroughs in the treatment of hepatitis C, together with the WHO resolution WHA67.6 and other initiatives of the global community to control VH, resulted in a renewed atmosphere of enthusiasm and opportunity, with a sense of urgency and recognition that have brought us to a watershed. Many stakeholders realise that investing today in hepatitis B and C prevention and treatment means a fundamental alleviation of the burden of disease for individuals and their families and socioeconomic costs to the State at present and in the future.

WHO PROPOSED TARGETS FOR VH CONTROL BY 2030

- ✓ A 30% reduction in new infections of hepatitis B and C by 2020, and a 90% reduction by 2030.
- ✓ A 10% reduction in deaths due to hepatitis B and C by 2020, and a 65% reduction by 2030.
- ✓ Increasing childhood hepatitis B vaccine coverage from 81% to 90% by 2020, and increase coverage of birth-dose hepatitis B vaccine or other interventions to prevent mother to child transmission of hepatitis B from 38% to 50% in 2020 and 90% in 2030.
- ✓ Increase the proportion of injections carried out safely worldwide from 5% today to 50% in 2020 and 90% in 2030.
- ✓ Treat 5 million people with hepatitis B by 2020 and provide treatment for 80% by 2030.
- ✓ Treat 3 million people with hepatitis C by 2020 and provide treatment for 80% by 2030.

Hepatitis B and C present a major public health concern. Low- and middle-income countries (LMICs) bear a particular burden, where some regions experience high endemicity, precarious prevention of transmission and low access to treatment. Both diseases may need a different approach. Unlike hepatitis C, available therapies cannot cure hepatitis B, but lifelong treatment could prevent cirrhosis and liver cancer among a majority of patients. On the other hand, hepatitis B can be prevented with safe and effective vaccination. Both the potential to prevent and the need for lifelong treatment make a compelling case to continue and consolidate hepatitis B prevention programmes. Unlike hepatitis B, no vaccine to protect against hepatitis exists. Increased access to high quality treatment (for hepatitis B and C) and high vaccination coverage (for HBV) will have a tremendous impact on individuals' quality of life and save society significant future costs by reducing the number of liver cancers, cirrhosis and as a consequence avoiding hospitalization, liver transplants or other costly treatments. Treatment will prevent invalidity due to viral hepatitis-caused liver diseases and as a consequence will decrease the loss of productive years, will improve the patient's social life and that of his/her personal network. Last but not least,

it will prevent further infections. It is evident that treating chronic viral hepatitis is not just about drug delivery to the patient.

Nevertheless, these new opportunities pose a new financial challenge. Though the

implementation of the WHO targets to control VH by the year 2030 is feasible, it requires an estimated yearly budget starting at \$2 billion in 2016 and going up to \$8 billion in 2020 globally. Pivotal steps need to be taken to mobilize resources if the global community wants to avert the human and financial consequences of the epidemic peaking by 2020–30.

Innovative funding mechanisms could play an increasing and essential role to tackle VH in LMICs, where both the burden of hepatitis B and C and out-of-pocket payments for healthcare are significantly higher than in high-income countries. A survey among funders shows they are increasingly interested in exploring its practicability. Our research identified 266 relevant organisations¹ that deal with (innovative) financing and/or health care (in general or viral hepatitis in particular) in LMICs. A telephone survey (34 participants) and online survey (27 participants) found that strong favourability emerged among the stakeholders towards becoming more deeply involved in health financing. Foundations and financial institutions especially have a high level of understanding about the applicability of innovative finance mechanisms in support of public health and universal treatment of hepatitis C. However, financial stakeholders still need a greater insight into the business rationale for financing the treatment of viral hepatitis. Similarly, government stakeholders surveyed reported low levels of information on these matters. Gaining further knowledge about their needs and aspirations can assist the hepatitis community in presenting a compelling case for action and secure the engagement of a critical new dimension in the elimination of this disease. Informing funders in a proactive way about the potential of innovative funding for health care in general and hepatitis treatment in particular, will encourage investment.

Since the financial crisis of 2008, an array of innovative funding mechanisms have come to light in various sectors globally. These could serve as inspiration to all stakeholders involved in increasing access to prevention and treatment of hepatitis B and C in LMICs. Innovative financing has considerable potential and its deployment in the health sector in LMICs is far from exhausted. This report explores a range of these mechanisms, their feasibility for deployment in the area of prevention and treatment of hepatitis B and C in LMICs and insights from funders herein:

Reallocation of existing funds towards hepatitis – in the past years, various factors have modified the funding landscape for health in LMICs. Countries depend less on Development Assistance for Health (DAH) and have increased the share of government expenditure. Within this context, the introduction of safe, new and effective treatments for hepatitis C raises an opportunity to assess the health economics of early treatment and to redirect funds that serve a less cost-efficient or cost-saving purpose. Reallocation of existing funds is fast to implement and has the advantage that no new resources are needed. Existing channels can be used to raise awareness. On the other hand, it remains a difficult decision to reduce the budget for other areas and to adopt priorities.

Side funds created within existing bodies that are engaged in other areas – existing agencies have extended experience in building up and managing the complex tasks of tackling a global, regional or national public health problem. For funding of HCV DAA

1 Appendix 1

treatments, tapping into these experiences would gain time and profit from the lessons learnt. Examples are the Revolving Fund for purchase of vaccines of the Pan American Health Organization's (PAHO) and the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM). The latter already funds treatment of hepatitis C virus infection only in HIV/HCV co-infections. This mechanism has the strength that it can build upon experience within the organisation that will be in charge of the implementation of the funds, a criterion that funders (whether the funding model is in the form of a grant or a loan) do take into account for investment.

Specific funding body for viral hepatitis – with the new DAAs and new DAA combinations being rapidly released on the market and with similar expectations in the near future for new treatments of chronic hepatitis B, it is worthwhile to increase the awareness of political leaders and the public on viral hepatitis. Knowledge about HBV/HCV is still low in the general population and among health professionals in LMICs. Despite the time-consuming process needed to set up a new body, its assets may give a boost to up-scaling VH on the public health agenda. Creating a specific funding body has had proven success in the past. Next to mobilizing a serious amount of resources through various channels, it reinforces global advocacy towards the particular concern. In addition, the creation of a specific body, e.g. a hepatitis fund, will facilitate other initiatives.

Mechanisms that strengthen financial protection of individuals – though a common good in high-income countries, mechanisms addressing risk pooling and sharing are underused in LMICs. Micro-finance mechanisms destined for rural communities, poor people and people working in the informal sector (micro-health insurance, micro-loans and health savings accounts) have the benefit of strengthening the financial protection of patients. In line with WHO support for Universal Health Coverage (UHC), they are also a powerful tool for patient empowerment. Furthermore, they bring together, stakeholders – sometimes opposing – to reflect on the common goal to increase patients' access to health. Micro-finance is one of the better-known innovative funding mechanisms among funders surveyed. Given the existence of tiered pricing structures for hepatitis B and C treatment in a number of low- and middle-income countries, (the impact of) including hepatitis B and C treatment in national health insurance or in risk pooled schemes is worth studying.

Market oriented mechanisms – the pharmaceutical market uses various instruments to influence prices to the advantage of both consumers and producers. Most common are volume or tiered pricing, voluntary licensing and advance market commitments. Experience with vaccine tenders in low-income countries (e.g. the GAVI Alliance and hepatitis B vaccines, and PAHO's Revolving Fund for vaccines) has proven that pooling demand and purchasing activities are effective mechanisms to reduce prices through increasing the certainty of demand. The Medicines Patent Pool (MPP) is a particular example of voluntary licencing. Created by UNITAID in 2010, it is currently managing over 50 sub-licensing projects to help speed up access to medicines and decrease prices, specifically for new therapies and pipeline products. The pool was extended to hepatitis C treatment in 2015. The benefit of bringing together supply and demand has proven its efficacy with medicines. As with financial protection mechanisms, there is a strong focus on collaboration between stakeholders. Regional tables for price negotiation could be a forum to discuss the different

VH and health care context of countries within the same region, differential pricing between countries and streamline often complex contract issues.

Social impact investments – investing in a social purpose is a growing trend among private companies. Venture philanthropy, social impact bonds, social franchising, health cooperatives, and other forms of social impact investment alleviate the strain on government and may attract private sector capital that would otherwise not be used for social purposes. Social investment and philanthropy are well-known mechanisms among funders and reported to be the most-applied innovative funding mechanisms. Social impact investment differs from traditional types of investment in that it offers greater flexibility in repayment terms, lower interest rates, and the acceptance of greater risk than commercial lenders would normally consider. It also implies less government involvement and is often directed towards difficult-to-reach populations. On the other hand, the lack of government involvement may result in difficulties with monitoring the compliance with health guidelines, e.g. those of the World Health Organization (WHO) or a national health or in particular VH programme.

In LMICs the potential of involving local companies undertaking activities as part of their corporate responsibility to their employees is far from exhausted. In countries with high HBV/HCV endemicity, local companies could be convinced of the benefit of prevention and treatment for their employees and therefore on productivity. This may stimulate companies to e.g. introduce awareness raising activities on the work floor, co-pay treatment or facilitate in the issuance of micro-loans for employees.

Small contributions from multiple donors – collecting relatively small contributions from multiple donors is a growing fund-raising strategy in both the profit and non-profit sector. Examples of this strategy are crowdfunding, dedicated taxes on specific commodities and migrant remittances. All of them combine the advantage of pooling of resources with communication and campaigning on the topic for which the resources are mobilized. A relative insignificant donation collected from each donor (e.g. less than a euro), may result in an impressive total amount, as seen with the air levy from UNITAID. The action does not require a lot of effort from the donors and as the amount is so low, not giving may sometimes be more difficult than giving. Together with awareness raising, it also creates solidarity and social cohesion among donors.

Performance-based financing – with the growing pressure on donors to reduce resources and raise development effectiveness, performance-based financing is finding its way into the health sector. Many low-income countries have a health system where all functions are centralized. Performance-based financing initiates a radical shift herein, by giving substantial decision rights over resources to organizational units. Remunerating health facilities according to their outputs may be to the advantage of private hospitals and patients will vote 'with their feet', which will challenge the functioning of public healthcare. Therefore, it serves as a powerful tool to improve healthcare services, especially in combination with other patient-empowering mechanisms as health insurance or micro-finance. Financial institutions that value market return may be more attracted to investing in an innovative funding mechanism for VH, if financing includes performance-based

criteria. One thing to note on performance-based financing with the new HCV DAAs is that given the efficacy of the regimens, performance will depend significantly on programme effectiveness.

Public-private partnerships (PPP) – should be seen as the ‘red thread’ running through this report. Most innovative finance implies collaboration between various stakeholders which traditionally did not consider each other as business partners. PPPs are seen as the most suitable innovative finance mechanism for supporting public health by most respondents of our survey. Whereas in the past, private health initiatives faced image problems, funders surveyed agree that the private sector does have a role to play in universal health coverage.

In line with innovative finance in other areas, the introduction of new financing mechanisms for the prevention and treatment of VH will have the most success if embedded in PPPs that ensure:

- social impact with a focus on local outcomes, value of solution and community context;
- financial viability and financial sustainability;
- capacity-building support to healthcare providers in the area of VH control and prevention and in the area of innovative finance management.

Partnerships will encourage collaboration and will bring opponents together, striving for the same goal of controlling viral hepatitis B and C and improving the patients’ quality of life. Additionally, they will function as accelerators for the provision of services to develop and implement national, regional or local strategies for surveillance, prevention and control of hepatitis B and C combined with funding strategies for hepatitis B and C prevention and treatments.

Overall this project sets the stage for introducing innovative financing into the prevention and treatment of hepatitis B and C in LMICs. The Round Table in London (June 2015) provided the Viral Hepatitis Prevention Board (VHPB) the opportunity to debate the issue of funding the prevention and treatment of viral hepatitis and in particular the potential of innovative funding in VH. Since then, the VHPB has included the item as a recurrent theme on their meeting agendas. Furthermore, through the invitation to participate in the survey, over 200 organisations were contacted and informed about the tools available to eliminate the disease.

Even more than before, we are convinced that scaling up prevention and treatment of hepatitis B and C on a global level, and making use of innovative funding mechanisms, provides a unique opportunity for private investors, foundations, non-profit organizations and national governments to work together on a project with an extraordinary societal gain and possible return on investment.

The following five recommendations form the basis of a trend-setting approach towards prevention and treatment of hepatitis B and C in LMICs:

1

FIRST A PLAN, THEN A FUNDED CONTROL OF VIRAL HEPATITIS

The new DAAs make the WHO targets for VH control by 2030 feasible. But providing safe and curative therapy is only one element in a comprehensive public health approach. Countries can give a stronger signal to funders about their political will and commitment to control VH by developing a (national) control programme. Using the existence of a national VH control programme as criterion for funding priorities may encourage governments to take steps towards, or seek support for its development.

2

ACCESS IS PART OF A SUPPORT PLAN

There is no doubt that funding of DAAs improves access to treatment. New hepatitis C treatment has a relatively short treatment period (measured in weeks), but hepatitis B treatment is lifelong. This implies that funding should invest in all stages of the therapy cycle, including proper screening and patient identification, linkage to care, additional therapy compliance and support plans (e.g. peer support, directly observed therapy, text reminders, home visits, electronically monitored pill administration or blister packaging).

3

A MIXTURE OF FUNDING SYSTEMS MAY HAVE MOST EFFECT

There is no sole financing mechanism that is best. Three innovative funding mechanisms can pave the way to reach the WHO target to eliminate VH by 2030:

PPPs with a focus on non-infrastructure interventions – The global character of the VH epidemic and the need to treat millions of patients, urges for a robust design that involves public private partnerships, engages civil society and the private sector and encourages political will to control the disease. PPPs around initiatives with social impact create new dynamics and innovative forms of collaboration between stakeholders. Also, recent pilot projects with social impact bonds are an example of how to expand the reach from their

historical use in simple construction projects toward a more flexible means of outcomes-based funding. Our survey revealed that regional (development) banks have the potential to play a critical role in the process of creating partnerships at a regional level.

Shared value approaches – Health partnerships are increasingly viewed as a core component of business strategies by research based pharmaceutical companies. In parallel, local companies in LMICs could be encouraged to take initiatives (from VH awareness raising to treatment) among employees and appropriate support could be given by companies and financial institutions that successfully implement CSR activities. CSR in LMICs could be used as a springboard to connect major funding institutions with local implementers. These concrete initiatives also serve as tools to introduce current ideas focusing on e.g. responsible investment to advance public health and shared value creation.

Micro-finance – extend existing partnerships between local micro-finance providers and lending institutions in LMICs to health insurance, ensuring the coverage of hepatitis C treatment.

An adequate combination of funding mechanisms, adapted to the context of the country, payers and patients, can accurately target country-specific challenges. Issues at stake to be considered by country are:

- HBV/HCV prevalence and incidence rate
- the population affected
- the existence of a VH national programme
- the organisation of the healthcare system
- the patients' out-of-pocket share for health care

4

PARTNERSHIP IS THE WAY FORWARD

In line with innovative finance in other areas, the introduction of new financing mechanisms for the prevention and treatment of hepatitis B and C will have the most success if embedded in PPPs. Partnerships will encourage collaboration and will bring conflicting interests together, striving towards the same goal of controlling viral hepatitis B and C and improving the patients' quality of life. They could function as accelerators for the provision of services to develop and implement national, regional or local strategies for surveillance, prevention and control of hepatitis B and C combined with funding strategies for hepatitis B and C prevention and treatments.

6

DISCUSS INNOVATIVE FINANCING MECHANISMS WITH STAKEHOLDERS

Advocacy on how to use innovative finance to tackle viral hepatitis will increase interest in innovative finance in general and will raise awareness about viral hepatitis. Starting a dialogue between stakeholders is an excellent advocacy tool. An optimal dialogue should involve major stakeholders: health care providers, patients' organisations, pharmaceutical industry, financial institutions and governmental bodies. **Consequently, the urgency to mobilize resources for prevention and treatment of hepatitis B and C could be seen as an opportunity to bring together stakeholders.**

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INTRODUCTION: HBV/HCV SILENT BUT PREVENTABLE EPIDEMICS

The World Health Organization (WHO) views the hepatitis epidemic as a “viral time bomb”. Worldwide, one in twelve people are infected with either hepatitis B virus (HBV) or hepatitis C virus (HCV), a majority of them unaware of their illness. Because chronic HBV and HCV infections produce almost no symptoms before secondary and potentially lethal complications, such as end stage liver disease, liver cirrhosis or liver cancer development, experts speak of a ‘silent’ epidemic. Within the next 15 years liver cancer and cirrhosis secondary to chronic HCV will significantly increase overall costs to the health system – costs and related suffering that could be avoided if chronic infection is cured at an early stage. In addition, the clinical progression of HCV-related liver disease is accelerated in HIV/HCV co-infected patients. Modelling has suggested that the peak of the epidemic will be reached between 2020 and 2030.

...hence a silent time bomb.

Due to the progression of the disease, chronic hepatitis infections are a major public health concern, with HBV and HCV causing the death of approximately 1.4 million people every year globally, their toll comparable to that of HIV and tuberculosis. In the near future chronic hepatitis will be responsible for a considerable growth in the number of patients who suffer from end stage liver disease, liver cirrhosis or liver cancer, due to the ageing of the infected population cohorts.

Chronic HCV infection is among the most common causes of cirrhosis and hepatocellular carcinoma, and the most frequent indication for liver transplantation (1). Some 130–150 million people are chronically infected with hepatitis C virus (HCV), leading to 350,000–500,000 deaths a year from liver diseases related to that infection². Prevalence of hepatitis C varies across the world; it is estimated to be highest in Africa and the Middle East and lowest in major parts of Western Europe and the Americas. Overall seroprevalence rates for HCV infection in general populations in Asia are reportedly between 3% and 4%, but much higher rates are reported from some countries or regions of the continent (e.g. 11% in Mongolia and even 32% in parts of Punjab Province, Pakistan)(2). A recent meta-analysis(3) identified high prevalence rates of HCV infection in sub-Saharan Africa – overall 3%, but with variations between regions and groups. In people who inject drugs, seroprevalence rates are often higher than 50%.

An estimated 240 million people are chronically infected with hepatitis B virus, resulting in nearly 800,000 deaths each year from cirrhosis and liver cancer. The highest rates of hepatitis B are found in South-East Asia, Sub-Saharan Africa and parts of the Pacific Basin and Amazon Basin, where 70-90% of the population will be infected by the time they are 40

2 Some sources put the burden at more than 400 million people chronically infected with hepatitis B and C viruses, with some 1.4 million deaths a year; viral hepatitis ranks among the top 10 causes of death globally.

and many are infected under the age of five, increasing the likelihood of developing chronic infection, liver cancer and cirrhosis(4). In Western and Northern Europe, North America, some parts of South America and in Australia, prevalence rates are believed to be low.

The proportion of people with hepatitis B and hepatitis C can vary between, and within, countries. But even in areas of generally low prevalence, rates in certain sub-populations can be very high (5). Many cases of chronic hepatitis B and C are undetected, and thus the supporting data are poor; only a small minority of cases are diagnosed, but where cases are sought, they are found.

In view of the above, curing these chronic infections and preventing new infections will avoid the suffering and the future high costs of treatments related to advanced stage of liver disease, liver cirrhosis or liver cancer.

A vaccine against hepatitis B was introduced in 1982 and more than a decade later a hepatitis A vaccine was licensed. Recently a vaccine against hepatitis E has been approved and is commercially available in China. In 1992, the World Health Assembly adopted resolution WHA45.17 on immunization and vaccine quality, urging Member States to introduce routine hepatitis B vaccination. More than 90% of the WHO's 194 Member States have done so(6). These programmes have dramatically decreased the incidence of hepatitis B virus infection among infants, children and adolescents globally. Furthermore, according to a WHO analysis, investment in hepatitis B vaccination could prevent an estimated 4.8 million hepatitis B-related deaths over the 10-year period to 2020 in the 73 countries supported by the GAVI Alliance(7, 8).

The treatment of chronic hepatitis B is, as of today, hampered by a low cure rate (1–7%) and many years (lifelong) of necessary drug application. Large numbers of adults remain chronically infected with hepatitis B and are at risk for developing liver disease. For them, prolonged treatment is needed. Beside treatment, the major remaining challenges are to improve coverage of the neonatal dose of hepatitis B vaccine, and to design good prevention and control strategies for Viral Hepatitis (VH) in low- and middle-income countries (LMICs).

For hepatitis C the landscape is complex and rapidly changing. The epidemiology of, and responses to, hepatitis C are diverse. There is no vaccine, but recently discovered and developed direct-acting antiviral agents (DAAs) are a “technological breakthrough” offering public health gains, with a cure possible in up to 95% of cases in three months with apparently little risk of resistance or relapse. For the first time in history, a chronic viral disease can be cured. The treatment is oral, some regimens needing only one pill a day, and causes far fewer side effects than previous standard treatments. In addition, several new drugs are in the pipeline. Although barriers to treatment remain, including access to care and financial considerations (see below), there now exists no medical reason to withhold therapy. Successful treatment can improve liver fibrosis and cirrhosis, help prevent hepatocellular carcinoma and even clear the virus (Pearlman & Traub, 2011)(9). Treatment also contributes to disease prevention by reducing the reservoir of infected individuals who can transmit the virus (10).

Moreover, studies have demonstrated that HCV infection can be eliminated in the next 15–20 years with focused strategies to screen and cure current infections as well as prevent new infections (11). According to Alfaleh FZ, et al. (12), with a treatment rate of approximately 10% it may be feasible to eliminate HCV (defined as a >90% decline in total infections) by 2030. However, this will require a 3–5 fold increase in diagnosis and/or treatment.

PREVENTION AND CONTROL OF HEPATITIS B AND C, WHERE ARE WE NOW?

It is clear that the introduction of the new DAAs install a renewed atmosphere of enthusiasm and opportunity, with a sense of urgency and recognition that we are at a watershed. It is therefore timely to unite stakeholders in order to level up the fight against viral hepatitis. Many countries are now ready to take up the gauntlet. A study by the World Hepatitis Alliance (WHA) for the WHO among WHO member states reveals that about in 80% of countries the government considers hepatitis B and/or hepatitis C as an urgent public health issue and more low-income (96%) than high-income (66%) countries report that hepatitis B and/or hepatitis C is an urgent public health issue for their government (13).

Nevertheless a number of challenges hinder the widespread adoption of new treatments. The concern about pricing, based on the reported prices of treatment in high-income countries (14), may be obvious. There are indeed questions about programmatic budget requirements to fully implement treatment for all HCV-infected people with limited resources (both human and financial), especially at a time of austerity and shrinking budgets. But the situation has altered in the sense that, especially in LMICs, discounts have successfully been negotiated and tiered pricing has been introduced by pharmaceutical companies. Furthermore, countries are inclined to extract a budget for treatment. Survey data indicates that partial or total government funding is available for hepatitis treatment in 69% of countries worldwide and in more than 50% of countries in all WHO regions except the WHO African Region. On average 83% of high-income, 77% of middle- and 33% of low-income countries report full or part government funding for treatment of hepatitis B and/or hepatitis C (13).

Financial barriers, however, are not the only challenge. To begin with, surveillance of viral hepatitis varies widely from country to country and is, overall, inadequate. Countries lack solid published data on prevalence and burden of disease. Table 1 provides an overview of countries reporting disease surveillance (13), 82% of countries have hepatitis B and/or C surveillance measures in place, although the components of these differ considerably.

Table 1: Presence of disease surveillance for hepatitis B and/or C (N=133)

	Total countries	% of region
Africa	17	59
Americas	18	90
Eastern Mediterranean	12	100
Europe	43	98
South-East Asia	4	57
Western Pacific	15	71
World	109	82

Source: WHA (2011)

Even though a majority of the countries reports that disease surveillance is present, one in three countries has no prevalence data available and more than 75% would like assistance with surveillance. The lack of accurate prevalence data on hepatitis is commonly recognized as constraining more effective prevention and control.

Second, as mentioned earlier, many people are unaware that they are infected and public awareness is generally low. Table 2 illustrates that worldwide, less than half of the countries spend money on raising awareness. About 41% of countries report having funded a public awareness campaign on hepatitis B or C in the past five years prior to the survey (13).

Table 2: Presence of government-funded public awareness campaigns (N=131)

	Total countries	% of region
Africa	7	25
Americas	7	35
Eastern Mediterranean	4	36
Europe	20	45
South-East Asia	3	43
Western Pacific	13	62
World	54	41

Source: WHA (2011)

Third, approaches to control and prevention of viral hepatitis vary markedly across all countries, but none yet has a realistic financial model to promote complete programmes

for vaccination and disease elimination of hepatitis B and C. Approximately one in three countries has a national action plan to address hepatitis B and C. A survey among WHO member states notes 37% countries having a plan and 29% having a governmental unit dedicated to hepatitis prevention and control (15).

In some countries, political commitment and governmental leadership are evident, with written national plans and predominantly state funding for programmes. For example, in Pakistan the Prime Minister took responsibility for a national prevention and control programme and in Georgia the government has lead the way in tackling hepatitis C with the organisation of national workshops leading to a national programme with the support of the US CDC, and collaboration with Gilead Sciences (16). The company started a demonstration project in the country, offering free drugs to a select cohort of patients. Also, in some countries, the new DAAs have been introduced with donor support (Ukraine, Georgia and Macedonia e.g. received support from the Global Fund). Not all countries have national plans; in Latin America, for example, most countries in the region lack surveillance and monitoring plans, meaning that knowledge of the burden of disease is poor. The Pan American Health Organisation (PAHO), however, is developing a regional plan of action for the period 2016–19).

In Pakistan, the national health system is devolved, but weak at the basic and rural levels, and is barely coping. Some 60–70% of healthcare expenditure is paid for out of pocket and 70% of the 180 million total national population visits the private sector for health issues. It also has the highest rate of therapeutic injections in the world and widespread re-use of syringes, a fact that triggered the introduction of a viral hepatitis prevention and control programme. Responsibility for the programme has now been devolved to provincial level, where significant gaps and challenges such as security, funding and fragmentation of programmes exist.

In Mongolia (17), the health care system focuses on treatment rather than on prevention. It faces numerous obstacles in its health system, which is being transformed only slowly. Although the healthcare network covers the whole country, it lacks health professionals and equipment, health professionals are poorly trained, and the infrastructure is precarious. The country claims the highest mortality rate from liver cancer in the world (70/100,000 population) and prevalence rates of hepatitis B and C virus infection of about 11% for each. It aims to eliminate hepatitis C by 2020. However, there is a general lack of knowledge about viral hepatitis, laboratory tests are not standardized, and, above all, there is practically no funding for viral hepatitis (despite there being considerable funding for the small number of HIV/AIDS patients). The elimination programme has three pillars: prevention (including awareness raising and expanded vaccination against hepatitis B), screening and early diagnosis for hepatitis B and C virus infections, and treatment for both infections.

In Georgia, which has also adopted a strategy and action plan to eliminate hepatitis C (which has a high prevalence among the country's small population), the health ministry has responsibility for policy and strategy development, with surveillance, control and prevention devolved to a national centre for disease control and public health. Implementation lies with municipal public health centres and infectious disease hospitals, and civil society plays an

active role.

In many countries, the number and quality of health care professionals are often suboptimal, especially in rural areas, generally awareness of viral hepatitis is poor, and out-of-pocket payments are necessary and pose a heavy burden on poor populations.

Overall, the list of the main obstacles to prevention and control of viral hepatitis, and indeed, effective, strong and sustained health systems, is long. Challenges identified included funding (for testing and treatment), shortage and lack of training of healthcare workers, low levels of awareness (if any), poor infrastructure, weak data, inadequate infection control (including massive overuse of injections), inadequate supplies of equipment, lack of licensing of non-medical facilities, and difficulties in controlling the private health care delivery services. Examples given include the lack of a written national policy in Nigeria, the need to improve injection safety in Pakistan, the lack of follow-up of treatment after a testing and care programme in one province, and the disparity in funding between viral hepatitis and diseases with higher profiles (18).

At governmental and institutional levels, from the European Commission to governments of some LMICs, there is insufficient or absent stakeholder commitment to prevention and control of viral hepatitis, translating into a lack of political will and financial investment. Viral hepatitis specifically, and liver disease in general, have been underrepresented in health policies and funding. Yet, after years of neglect of viral hepatitis there are encouraging signs of movement: the disease is moving up towards its deserved place on the international public health agenda (18).

NATIONAL ACTION PLANS AS A BASIS FOR PREVENTION, CONTROL, TREATMENT....AND FUNDRAISING

It is evident that treating chronic viral hepatitis is not just about drug delivery to the patient, but needs to be based on a national strategy and action plan, encompassing a number of fundamentals which serve as a basis to estimate cost-effectiveness for the best treatment options and the overall costs to the community. WHO presents a framework for global action with four components (19):

- Widespread media campaign informing the medical community about at-risk situations and raising awareness for the need for screening measures
- Implementation of free-of-charge programmes for testing and diagnosis
- Access to therapies and reimbursing the patients the cost of treatment
- Building of a national or regional network of Hepatology Reference Centres, which will guarantee recognized standards of quality, collection of data, monitoring and evaluation.

1. Raising Awareness, Promoting Partnerships and Resource Mobilization

Raising awareness and changing behaviours in the general population and of targeted groups at risk require careful collaborative planning along with sustained implementation and monitoring. Better-informed populations are expected to make better choices. The national viral hepatitis programme should work closely with communication and social

mobilization experts to deliver the right messages for the specific communities:

- Media campaigns informing the general public about at-risk situations, effective prevention measures, the need for screening, and the benefits of treatments resulting in the reduction of hepatocellular cancer and all-cause mortality.
- Engaging all stakeholders involved at the national level (e.g. people affected by HCV, political leaders, the pharmaceutical industry, all health care providers involved, policymakers, civil society).
- A national and/or regional strategy must be established.

2. Data for Policy and Action

To develop good prevention and control policies, it is essential to have adequate estimates of the burden of the disease at the national level. Because most patients with chronic HBV or HCV infection are symptomless for years, globally about half of them are unaware of it; it is estimated that 45% to 85% of all persons with chronic HCV infection do not know that they are infected. Consequently, it is difficult, if not impossible, to assess the disease burden, and, therefore, to evaluate correctly the costs of prevention and treatment at the public health level is hampered by great uncertainty. Without standardized and affordable prices, public health and private reimbursement institutions cannot correctly assess the impact of different policies. In conclusion, data are of paramount importance for the development of a national policy and plan of action.

3. Prevention of Transmission

Preventing new cases remains the basis of any national public health programme dealing with viral hepatitis, even in the presence of curative and accessible medications. Governments have the responsibility to prevent transmission of viral hepatitis infections to populations through all available means including provision of vaccination, ensuring safe injections and safe medical interventions, safe blood and blood products, tissues and organs. Hepatitis B vaccine remains one of

GLASGOW DECLARATION

Because there are 400 million people living with hepatitis B or hepatitis C infection with no country/region unaffected,

Because there is a lack of global awareness and most persons with hepatitis remain undiagnosed,

Because 1.4 million people die every year from complications of viral hepatitis yet most of these deaths can be prevented,

Because there are highly effective measures to prevent new hepatitis B and C infections and highly effective treatments that can suppress hepatitis B virus replication and cure hepatitis C infection,

Because universal access to prevention, diagnosis, care and treatment is a human right and promoting access to and affordability of these services is the responsibility of all stakeholders,

The participants of the inaugural World Hepatitis Summit believe it is possible and essential to set as a goal the elimination of both hepatitis B and C as public health concerns. We therefore call upon governments in all jurisdictions to develop and implement comprehensive, funded national hepatitis plans and programmes in partnership with all stakeholders and in line with the World Health Assembly Resolution 67.6 and, in collaboration with the World Health Organization, to define and agree on realistic yet aspirational global targets for prevention, testing, diagnosis, care and treatment.

<http://www.worldhepatitissummit.com/declaration/>

the most effective public health tools to prevent infection; it has already prevented millions of deaths since it has been implemented in public health programmes globally in 1992. By 2010, hepatitis B vaccination coverage among infants had reached an estimated 75% worldwide. This achievement was made possible through several developments, including removal of cost-related barriers. Throughout the 1990s, the cost of hepatitis B vaccine was \$3 to \$6 per dose; however, by 2010, the price dropped to \$0.185 to \$0.40 per dose. Additionally, the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunisation) was formed to provide targeted assistance for the countries with the lowest per capita gross national product.

By 2004, 50% of the low-income countries receiving GAVI Alliance support had included hepatitis B vaccines in their routine immunization programmes. China, India, and Indonesia, all of which received GAVI Alliance assistance, represented approximately one third of the global birth cohort. In China, GAVI Alliance collaborations resulted in administration of a birth dose of hepatitis B vaccine, free of charge, to more than 25 million new-borns living in the poorest and most remote provinces of western and central China; this initiative was expanded in 2002 to provide free hepatitis B vaccine to all new-borns born in China. In India, a country with 1.5 million new HBV infections in the annual birth cohort, GAVI Alliance funds have improved vaccine infrastructure (e.g., increased availability of auto-disposable syringes and vaccine) and supported hepatitis B vaccination in states with high-performing vaccination programmes (20). Similar collaborations have occurred worldwide. By the end of 2014, 184 countries have integrated hepatitis B vaccine into their national childhood immunization systems.

The demonstrated progress made in global hepatitis B prevention, much of which is attributable to implementation of infant immunization programmes, is commendable and can help inform policy and programming for other vaccine-preventable infections. However, the goal of hepatitis B elimination can be achieved only by overcoming known challenges to HBV vaccination and building and sustaining support for it particularly in developing countries with limited health resources.

To reach full potential as a public health intervention, hepatitis B vaccination must be more readily available to protect vulnerable populations, beginning with a birth dose of hepatitis B vaccine. Data from a mathematical model demonstrate that 90% coverage with a birth dose could prevent 225,000 (16%) deaths from chronic liver disease over the life of the 2000 global birth cohort (21); in 2006, only 27% of new-borns received a birth dose of hepatitis B vaccine (22). Currently a global coverage of 83% is reached for the three doses of hepatitis B vaccines in the universal HBV immunization programmes and is as high as 92% in the Western Pacific (23, 24). Perinatal transmission is one of the most efficient and devastating modes of transmitting hepatitis B virus; depending on the viral load of the pregnant mother (and HBeAg status) 15 to 90% of infected new-borns become chronic carriers of the virus. The main objective of maternal screening is to identify HB-carrier women and to prevent hepatitis B carriage in their infants; this can be achieved by screening all pregnant women for HBsAg and vaccinating new-borns of carrier mothers. Control of perinatal transmission can also be achieved by universal new-born vaccination starting at birth, as recommended by the WHO. Offering the birth dose within 24 hours is still an issue that needs to be solved in a

large number of developing countries (25).

4. Case Finding, Screening, Care and Treatment

Access to screening and diagnostic testing services is a prerequisite for scaling up hepatitis treatment. Routine free-of-charge screening programmes for large groups of potentially infected subjects should be developed to reduce the proportion of undiagnosed infections, with a special focus on neglected populations. It is necessary to identify infected subjects as soon as possible. As of today however, most countries have not implemented concrete measures and strategies to ensure efficient screening and adequate treatment is still not licensed or not reimbursed. In Europe, only France and Scotland have a well-functioning national screening strategy in place (26). Outside Europe only Egypt and the USA have developed a national action plan. This is of particular relevance, as case finding, screening, care and treatment can be developed, implemented and maintained only when targeted to the specific situation of a country.

Screening is of limited utility when the person who is diagnosed does not have adequate information about how to respond effectively. Efforts to expand access to, and uptake of, clinical assessment and antiviral treatment play a key role in determining equitable health outcomes for people affected by hepatitis. Diagnostic testing should provide a clear benefit to the person being tested. Mechanisms that link screening and diagnosis to treatment and care are essential. In addition, this measure will reduce the societal burden of infections causing severe liver disease and prevent transmission.

Consideration should be given to:

- Improved surveillance and screening policies and programmes to reduce the number of undiagnosed subjects.
- Easier access to therapies through hospitals and reimbursing the patients the cost for treatment.
- Expanded access by enabling the prescription and delivery of treatment in primary care settings.
- Clinical care and treatment should be delivered in line with evidence-based guidelines.
- Building a nationwide network of Hepatology Reference Centres, which will be responsible for the quality of the policies and delivered services and ensure regular updates.

At the occasion of the symposium in Antiviral Research on “Hepatitis C: next steps toward global eradication.”, Graham and Swan (2015) (27) proposed an action plan to improve hepatitis C treatment in LMICs (see box). The suggested interventions are inspired by HIV and tuberculosis programmes in LMICs.

ACTION PLAN TO IMPROVE HEPATITIS C CARE IN LMICS (27)

Summary of specific actions that can be taken by public and private organisations to improve the diagnosis and treatment of people living with HCV infection. Diagnostic companies to develop anti-HCV antibody assays that are rapid, point-of-care, and cost less than US\$1 and point-of-care HCV RNA assays or HCV core antigen tests that have a minimal acceptable viral detection threshold and cost less than US\$10.

- National and Global agency funding to perform population-level anti-HCV and HCV RNA surveillance in regions with limited data
- Global agency support to determine the country-level burden of advanced liver disease attributable to HCV infection as well as direct and indirect costs associated with infection
- Academic partnerships to develop country-specific models to estimate lifetime costs, quality-adjusted life expectancy, and incremental cost-effectiveness ratios of different screening and treatment strategies as well as comparison with no action
- National ministries of health to define a threshold for interventions to be cost effective/affordable in individual countries
- Countries to use TRIPS flexibilities to overcome patent barriers; these include compulsory licensing and parallel imports and patent oppositions
- Partnerships with pharmaceutical companies that support equitable pricing strategies through voluntary licenses that are transparent and do not have any restrictions limiting access in MICs; agreements to allow production of affordable generics; addition of patents to the Medicines Patent Pool
- The WHO should institute a pre-qualification programme for HCV diagnostics, biosimilars and DAAs (which should be added to the Essential Medicines List)
- Provide on-line training modules and telehealth support to expand the pool of effective HCV treaters
- Use best practices from antiretroviral roll-out programmes in HIV to provide adherence and adverse event management support, including peer support and other low cost community-based adherence interventions

PART 1: HEALTH SYSTEMS FINANCING IN LOW AND MIDDLE INCOME COUNTRIES

Health system financing varies across countries. Funding of health care systems in LMIC predominantly comes from government health expenditure (GHE), donor agencies (development assistance for health, DAH) and last but not least out-of-pocket payments³.

Table 4 provides an overview of the average spending on health care in low-income, lower-middle- and upper-middle-income countries. The percentage of foreign capital invested in national health care (delivery) decreases with the increase in welfare of the country. Low-income countries receive more foreign aid than lower-middle-income countries, which in turn receive more than upper-middle-income countries (table 4, column 2: average % domestic HC expenditure).

The average percentage of per capita HC expenditure (table 4, column 1) increases with the welfare state of the country, going from 40 US\$ low-income over 130 US\$ in lower-middle-income countries to 487 US\$ in upper-middle-income countries. The average percentage of out-of-pocket payment for health care is lower in upper-middle-income countries (30%) than in low-income (41%) and lower-middle-income countries (42%). However, this does not mean a lower out-of-pocket payment in upper-middle-income countries in real terms, as the average per capita HC expenditure is significantly higher in those countries. Furthermore, the range between countries within the three regions is very high.

Table 4: average spending on health care in low-income, lower-middle- and upper-middle-income countries, 2013

Region	Average per capita HC expenditure (US \$)	Average % domestic HC expenditure	Average % out-of-pocket expenditure (range)
Low-income- countries	41	68%	41% (6-74)
Lower-middle- income countries	130	87%	42 % (3-83)
Upper-middle- income countries	4871	96%	30% (0-71)

Source: WHO, own calculations.

The Institute for Health metrics and Evaluation (IHME) shows trends in financing health

³ Appendix 2 gives an overview of the health system financing for all LMICs in 2013.

in LMICS based on government expenditure and donor agencies. Funding from these sources grew significantly after 2000, when the United Nations established the Millennium Development Goals with a strong focus on health. After growing rapidly between 2000 and 2010, global health funding was stagnant until 2014 and decreased by 1.6% between 2013 and 2014 (28).

1. GOVERNMENT HEALTH EXPENDITURE (GHE)

At the Abuja summit in April 2001, heads of state of African Union (AU) countries committed to allocate at least 15% of their annual budget to improve the health sector in their country. Between the summit and 2011, AU Member States increased their health budget from 9% to 11% of public expenditures. Six countries reached the target (Liberia, Madagascar, Malawi, Rwanda, Togo and Zambia) and a number of others are within reach of the 15% allocation target. Most countries, however, have not met the commitment made (29). In 2012 governments of LMICS spent \$711.1 billion in 2012 (an increase of 9.7% against 2011). For every \$1 donors spend in global health, developing countries spend nearly \$20. In some low-income countries, it is estimated that the government spends one dollar for every dollar spent by donors (28).

2. DEVELOPMENT ASSISTANCE FOR HEALTH (DAH)

LMICS largely depend on international donors to finance their health care system. DAH, by definition, is provided by **governments** and **private organisations** in high-income countries to LMICS. Over the past years, the DAH funding landscape has made important shifts that reflect the delivery of healthcare. Even though governmental contributions still make up the vast majority of DAH, their share has decreased and other sources of funding have expanded. Non-governmental sources, such as corporate donations, foundations, and debt repayments make up only 23.5% of total DAH (28). In addition, donors have historically focused their funding on the direct delivery of health services without paying attention to assist the construction of sustainable financial and purchasing institutions inspired by core successes of richer countries (30).

Since the beginning of the millennium, **PPPs** have been established to streamline efforts to address a few key global health areas; examples are the **Global Alliance for Vaccine and Immunization** (GAVI) and the Global Fund to fight **Aids Tuberculosis and Malaria** (GAFTM). Beside focusing on a key global health area, their aim is also to improve the effectiveness of each DAH dollar. In 2013, the United States remained the largest source of funding of PPPs. The Bill & Melinda Gates Foundation is the largest private financing organisation. Funding by non-governmental institutions is on the increase. Sub-Saharan Africa continues to receive the largest part of development assistance on health through PPPs. Trends in PPP remain mixed, e.g. funding for GAVI rose, however contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria dropped (30).

Non-governmental organisations (NGOs) are major players in DAH in LMICs. NGOs are the channels through which funds from OECD countries are transferred to these countries and therefore play a crucial role in the health landscape in these countries. In recent years, the

share of private sources (financial and in-kind contributions from private companies, philanthropies, and individuals) to NGO DAH was larger than combined public funding. It is clear that NGOs mobilize an important amount of private funding to improve health in developing countries. In contrast with other channels that primarily rely on (shrinking) public funding, NGOs have succeeded in increasing their spending.

Last but not least, we note a new trend in funding to low-income countries, coming from middle-income countries as China, Turkey, South Africa, Brazil and India. Types of support from these countries are, next to the traditional DAH, transfer of technology, private investments and other forms of south-south cooperation. Data of the scope and magnitude of funding from middle-income to low-income countries is not available (28).

3. OUT-OF-POCKET PAYMENT

The above-described flows, however, do not include out-of-pocket payments, according to the WHO, a major source of payment(31) and constituting significant portions of household spending in those countries. Private financing in developing countries is largely synonymous with out-of-pocket spending or with contributions to small, voluntary and often highly fragmented pools. In contrast, public or mandatory private financing (from general taxation or from contributions to social security) in richer countries is always associated with prepayment and large pools (31).

Out-of-pocket payments in LMICs range from less than 10% to over 80% of the total national health expenditure (32). It is estimated that every year, around 44 million households throughout the world face catastrophic expenditure, and about 25 million households are pushed into poverty by the need to pay for services. Furthermore, many people decide not to use services because they cannot afford the cost(33).

4. RISK-POOLING MECHANISMS: UNDERUSED IN LMICS

One of the targets of the Sustainable Development Goal (SDG) 3 on good health and well-being is to achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, good-quality and affordable essential medicines and vaccines for all(34). Various initiatives paved the way for a larger coverage of the population by health insurance in LMICs. In the past decade, major international conferences have been held on social health insurance and social health protection in developing countries. The World Health Assembly passed a policy resolution whereby the WHO would advocate formally mandated social health insurance to mobilize more resources for health in low-income countries, pool risk, provide more equitable access to health care for the poor, and deliver better quality care(33).

Beside international conventions and calls for action from international agencies on financial risk protection, difficulties with traditional ways of health care financing, diversified consumer demand in the course of economic development, and intensified trade in the health-services sector (introducing foreign insurance providers to developing countries) have invigorated the development of private insurance mechanisms as a means to finance

health care in LMICs(35). Many studies can be found on the introduction of health insurance in developing countries, however figures about their general outreach are not available.

PART 2: INNOVATIVE FINANCING TO TACKLE HEPATITIS B AND C

Traditionally, in most countries with sufficient resources, public health pays for health prevention (e.g. screening, vaccines) and care related costs (e.g. treatments, surgical interventions) through taxpayers funding. This system, efficient in high-income countries, is less applicable in resource-limited countries. The experience with antiretroviral therapy against HIV/AIDS is a seminal example, in which advocacy by patient groups and NGOs played a major role in making access to antiretroviral therapy affordable for the payer. As a consequence, international agencies, in collaboration with newly created bodies, developed a model for the provision of HIV/AIDS antiretroviral therapy, based on differential pricing obtained in negotiation with the pharmaceutical manufacturers – ensuring that individuals in need would receive treatment, while guaranteeing sufficient income for future research and development.

Even though it is understandably difficult for public health decision-makers and the community to invest today in order to avoid future costs in the long term, the experience with HIV/AIDS demonstrates that a cure means the alleviation of socioeconomic costs to the state and families both in the present and future – undoubtedly a large gain for society. Thus, the time has come again for the international community to come up with new funding strategies that will be applicable in countries with very different hepatitis B and C epidemiology and non-comparable economic status. The introduction of safe, new and effective treatments for hepatitis C may raise a serious challenge, but also creates new opportunities for national public health spending.

In what follows, we present how innovation in finance mechanisms (including in traditional ways of funding) may pave the way for the elimination of hepatitis B and C by 2030. PPPs can be considered as the ‘red thread’ running through this report. Most innovative finance implies collaboration between various stakeholders which traditionally did not consider each other as business partners.

1. REALLOCATION OF EXISTING FUNDS TOWARDS HEPATITIS

The introduction of safe, new and effective treatments for hepatitis C raises the opportunity to assess the health economics of early treatment in order to ensure the best use of public health funds. This kind of investment may pay off for the whole national public health system by improving the overall scope of the national public health spending.

The current situation represents a unique opportunity to conduct an in-depth analysis of national public or private funding, which may reveal that switching resources may be a highly cost saving or cost-effective measure in the long term. It should be recalled that liver cancer and cirrhosis secondary to chronic HCV infection would significantly increase overall costs to the health system within the next 15 years. As an example, treating 10'000 patients at a treatment cost of 10,000 US\$ per patient would sum up to a total of 100 million US\$. Costs can be avoided if chronic HCV infection is cured at an early stage. In addition, the clinical progression of HCV-related liver disease is accelerated in HIV/HCV co-infected patients. For example, in Switzerland it was estimated that under historical standards of care, the annual economic burden of untreated viraemic infections was projected to reach about €96.8 million in 2030(36).

DEBT2HEALTH INITIATIVE

Debt2Health is an innovative financing initiative of the Global Fund. It helps channel the resources of developing countries away from debt repayment and toward life-saving investments in health. Under individually negotiated agreements, creditors relinquish a part of their rights to repayment of loans, on the condition that the beneficiary country invests the freed-up resources into programmes approved by the Global Fund. No new governance structure or administration for Debt2Health has been required, as counterpart funds are disbursed through the existing Global Fund performance-based system. Converted debt service amounts may be allocated to fight a particular disease and/or a particular country.

Reallocation of existing resources has the advantage that no new funds will be needed, because the existing budget of the institution will be used to finance the new DAA treatments for hepatitis C (e.g. an institution must develop and implement new security processes, such as installing new alarm devices or designating new security officers without receiving additional funds). This involves agreeing on new priorities and reallocating resources, often through negotiations and without harming existing or pledged services. The Debt2Health initiative⁴ (37, 38)(see box) from the Global Fund is an implementation of the principle of debt cancellation of a beneficiary country on the condition that an agreed-upon counterpart amount is invested in health. As an example, the board of GFFATM decided at its thirty-second meeting, in November 2014 that, as an interim measure and where there is a currently approved budget with an existing grant of the Fund, the Global Fund may continue to fund treatment of

hepatitis C virus infection and HIV/HCV co-infections in particular. It also encouraged partners to finance broader and additional hepatitis C treatment needs (39). The GAVI

⁴ The Debt2Health initiative is one of 8 innovative funding mechanisms described by the I-8 Group Leading Innovative Financing for Equity [L.I.F.E.]. Appendix 3 gives an overview of international initiatives on innovative finance.

Alliance(40) and UNITAID(41) have undertaken similar actions. Thus, the three bodies have proven that it is possible to raise or re-allocate funds for approaches that make a difference to ordinary people's lives. In all three cases, the organisations' mandates and priorities have been set some time ago and attempts to extend the remit have met with some resistance.

The European Trading System (ETS) for emission allowances (revenues from the carbon market) is an innovative funding mechanism to encourage countries to go along a low-carbon growth path(38). European governments in need for innovative sources to fund development assistance, have been reflecting upon redirecting these revenues towards development goals in order to fulfil their commitment to spend 0.7% of the GNP to Official Development Aid (ODA). In the same vein, revenues from the carbon market could be invested in supporting countries that want to tackle VH.

The challenges of this approach are twofold. Governments may not have the tools or expertise to analyse carefully their domestic situations, therefore provision of technical assistance through independent bodies funded by appropriate resources will be essential. Secondly, it is understandably demanding for public health decision-makers and the community to invest today in order to avoid future costs in the long term that are hard to calculate. Examples where this has been done for some chronic diseases (e.g. diabetes, cancer therapy for cancers that become chronic) and in particular for HIV, can be used as a model.

Applicability to hepatitis C treatment

Whether reallocation of existing funds can be applied to fund hepatitis treatment may depend on whether the source of funds available corresponds with the necessary national expenditure on HCV. The mechanism requires the government to critically assess expenditure patterns and to estimate cost of hepatitis treatment. Countries will only consider reallocating existing funds towards hepatitis treatment if the disease is perceived as a major public health issues by political decision makers and key opinion leaders.

In case of debt forgiveness, given the low cost of borrowing and low interest rates worldwide, paying down public debt may not currently be a high priority in LMICs. As with all transfers of funds from high-income to lower-income countries, the most likely recipients will be those with lowest income; middle-income countries (MICs) will find it hard to attract debt cancellation schemes unless their current spending priorities are judged to be a good use of national revenue (e.g., current spending on healthcare in contrast with expenditure on armed forces) and unless the process of gathering and spending national revenue is seen to be free of wastage or misappropriation.

Part 3 of this report shows that knowledge about debt forgiveness schemes is limited among organisations otherwise interested in the field of innovative finance, being reported by only four out of 27 organisations surveyed (graph 11).

Table 4: reallocation of existing funds towards hepatitis: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ No new resources are needed. ✓ Fast to implement. ✓ Use of existing channels to raise awareness. 	<ul style="list-style-type: none"> ⚠ Difficult to decide on budget reduction in other areas. ⚠ No guarantee for a long term commitment. ⚠ MICs may not benefit from this mechanism.

2. SIDE FUNDS CREATED WITHIN EXISTING BODIES ENGAGED IN OTHER AREAS

Existing agencies have extensive experience in building up and managing the complex tasks of tackling a global, regional or national public health problem. For HCV DAA treatments, tapping into these experiences would gain time and profit from the lessons learnt.

Mega-funds have often been set up through large international agencies building upon private-public initiatives, thereby engaging in new ways of public health funding including research and development. Global and regional funds (mega-funds⁵) have been set up in the past to generate funding for resource-limited settings. Examples include PAHO’s Revolving Fund for purchase of vaccines, and initiatives for the prevention and control of disease such as AIDS, tuberculosis and malaria through the provision of treatment for HIV/AIDS and tuberculosis (e.g. directly observed treatment regimens), medicines, and prevention tools for malaria (e.g. bed nets). Other initiatives have tackled poliomyelitis, rare diseases and many other conditions. Zakat – the mandatory charitable contribution from Muslims’ savings and wealth directed to poor and deserving people – is an example of a trusted institution already engaged in health-care finance, where a drug-delivery side fund could be hosted.

Starting a fund within a larger body has several advantages. They have experienced failures and setbacks, thereby gaining an appreciable amount of solid experience in implementation and monitoring. Funding agencies have gained significant expertise over time in funding and oversight of large and complex public health programmes. Overlapping concerns may be identified, such as HCV/HIV co-infection, where HCV is killing the patient while his or her HIV disease is well controlled with the currently recommended triple therapies. As a consequence, HIV funding bodies are highly interested in funding treatments for HCV in HCV/HIV co-infected subjects, but only in these subjects and not in the absence of HCV/HIV co-infection.

Applicability to hepatitis C treatment

⁵ A megafund is an extremely large pool of money set up by a private body for the purposes of investing in health. The amount invested by private investors in a megafund is usually over \$5 billion US\$.

Existing funding bodies are already heavily burdened by their current activities and bound by their set priorities and commitments to deliver in their specified fields, making it thus necessary to secure funding not only for hepatitis C treatment but also to ensure that the additional tasks are being properly managed with adequate manpower. It may however be an option among funding bodies within a country. E.g. in a country where efficient HIV therapy resulted in an increased quality of life for HIV patients, but who are now suffering more from hepatitis B or C symptoms.

It is unlikely that mega-fund bodies will spontaneously engage in fund-raising unless they have a major incentive or remit to do so. In order to capture their interest, it is essential to search for additional resources that can be offered to them as an extra package.

Table 5: side funds created for hepatitis treatment in an existing body: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ Extended experience in set up & management. ✓ Network in place. 	<ul style="list-style-type: none"> ⚠ Existing bodies are already heavily burdened by their current activities and bound by their commitments to deliver in their specified fields. ⚠ New fund raising remains needed, who will take responsibility? ⚠ Fear for stigma that patients will be associated with other diseases. ⚠ Resistance from the existing institution. ⚠ Misleading relation between the disease for which the existing fund was created and VH.

3. SPECIFIC FUNDING BODY FOR VIRAL HEPATITIS

With the new DAAs and new DAA combinations being rapidly released on the market and with similar expectations in the near future for new treatments of chronic HBV infection, it is worthwhile increasing the awareness of political leaders and the public on hepatitis. A global and/or regional mega-fund (also called vertical fund/initiative⁶) for viral hepatitis with multibillion-dollar annual investments from public and private funding bodies is a major strategy for agenda setting, as seen in the past with similar initiatives for AIDS, tuberculosis and malaria, or poliomyelitis. Along these lines the setup of a dementia-discovery fund at the request of the British Government is another approach, where the J.P. Morgan bank has put together a fund of US\$ 100 million of venture capital with contributions from the

⁶ Global programme funded by different stakeholders that provides earmarked funding for a specific purpose.

UK Department of Health (US\$ 22 million), GlaxoSmithKline (US\$ 25 million), Johnson & Johnson, Eli Lilly, Pfizer and Biogen. Other models are: Médecins sans Frontières' Access Campaign (in the Democratic Republic of the Congo, the Manipur province in India, Myanmar and Pakistan), the Clinton Health Access Initiative (which aims to develop self-sustaining global markets for medicines and diagnostics, providing low-cost, high-quality care), the International Decision Support Initiative (which aims to guide decision makers in LMICs to effective and efficient resource allocation strategies for improving people's health) or the Global Health Innovative Technology Fund (GHIT Fund headquartered in Japan, the first public-private partnership (PPP) fund to involve a national government, a United Nations agency, a consortium of pharmaceutical companies, and an international philanthropic foundation), which aims to tackle some of the world's most neglected diseases. The creation of many platforms targeting small and/or remote communities is another complementary approach.

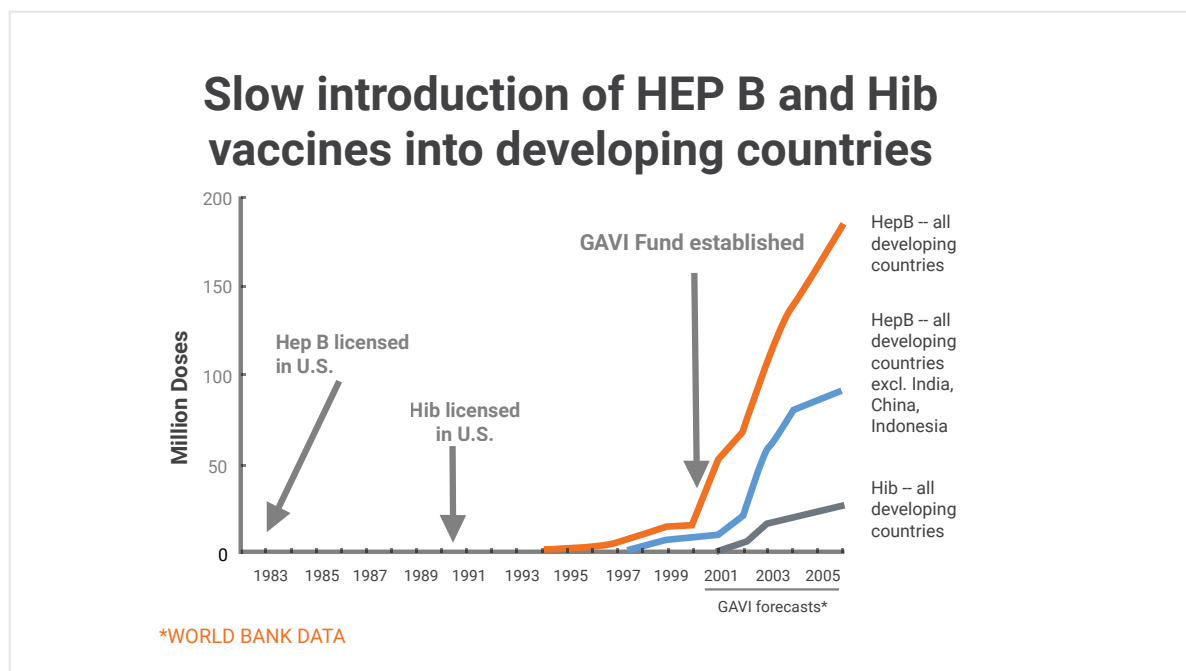
Beside its (international) agenda-setting role, a separate Hepatitis Fund would have no strings attached, funds would be dedicated to viral hepatitis only, and the use of funds would be decided without competing hindrances. Such a mega-fund could be devised as a revolving fund.

Creating a new body is a time-consuming process, and, without a rapid set-up, patients may globally protest if years pass by with slow progress being made. Difficulties may arise from finding the appropriate and efficient managerial structure that ensures adequate distribution of funds, sustainability (through mitigation of donor fatigue), and feedback while assuaging the public fear of misuse.

Keeping in mind that the problem is global and millions of patients need and will need treatment, the creation of the new body may have a serious role to play in creating PPPs, engaging civil society at a high level and encouraging political will (necessary for the development of national hepatitis action plans) in order to control the disease.

However, the sole creation of a (funding) body that tries to focus the international agenda on the topic does not guarantee a successful outcome. The robustness of the architecture also determines the outcome(42). Graph 1 illustrates the influence of the intervention from GAVI in the exponential growth in vaccination coverage in developing countries(43). Its success lies in the combination of financing the introduction of the vaccine as well as the infrastructure to support vaccination(42).

Graph 1: Introduction of HBV and Hib vaccines in developing countries



Applicability to hepatitis C treatment

Mega-funds may be global, regional or national. As an example of a national fund, the Imam Khomeini Relief Foundation (Komiteh Emdad) was founded in Iran in March 1979 as a charitable organisation to provide support for poor families. As well as receiving various forms of Islamic almsgiving, the foundation has collection boxes installed in city streets across the country. This example also illustrates the drawbacks of national/religious funds; the use of funds to support foreign policy aims and internal political activism has aroused international controversy and public suspicion.(44-48)

Regional funds such as the PAHO Revolving Fund have had a major effect on vaccination programmes, not only through the improved bargaining power that comes with bulk tendering but also because PAHO insists that member states should have a 5-year plan of action, a line item in the national budget for the procurement of vaccines and other supplies, and a specific entity responsible for running the programme. The fund is still, however, a mechanism in which member states have to invest as much as they receive, and any states with a greater need for vaccines will have to invest proportionately more funds(49).

Global funds are a mechanism which may potentially assist LMICs which are short of funds to invest in public health. Vaccine bonds in particular have shown that social investment can tap large amounts of investment from both wholesale and retail markets, but this also underlines the dependence of bonds on the credit rating of the issuer. Vaccination for children in the developing world is, of course, an aim that attracts sponsors as well as popular support, and the economic gains from the improved health outcomes are rapid and comparatively easy to demonstrate. There may be extra challenges involved in funding treatment for less popular causes and demonstrating long-term outcomes benefits. The example of the International Finance Facility for Immunisation (IFFIm), which sells

“vaccine bonds” to raise funds for the GAVI Alliance, demonstrates that large and diverse sources of funds may be tapped with dramatic effect (a 2011 report (50) claimed that 2.1 million lives had been saved as a result of its programmes). However, higher interest rates have had to be offered since the IFFIm was downgraded by Standard & Poor’s in January 2012. France guarantees a quarter of IFFIm’s debt and other guarantors include Italy and Spain; IFFIm’s dependence on Eurozone credit ratings means that it may have less money to spend on vaccines as a result.

Mega-funds have demonstrated that targeted large-scale funding can be attracted from both public and private funders in order to tackle long-term and widespread health needs, though measuring their impact remains difficult. It should also be noted that no risk, except the minor risk of national debt default, is transferred to investors.

The varieties of ‘mega-fund’ considered so far, whether global or not, have been not-for-profit organisations. The possibility of using regional financial institutions to manage and disburse large-scale funds may also be considered, given their existing connections to a variety of possible implementers.

Part 3 of this report shows that knowledge about ‘mega-fund’ schemes such as vaccine bonds is limited among organisations otherwise interested in the field of innovative finance, being reported by only one out of 27 organisations surveyed (Graph 10).

Table 6: specific funding body for viral hepatitis: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ Powerful international agenda setting tool. ✓ Funds are dedicated to hepatitis only. ✓ Facilitates other (local) initiatives. 	<ul style="list-style-type: none"> ⚠ Formal creation of a new agency is time-consuming.

4. MECHANISMS THAT STRENGTHEN FINANCIAL PROTECTION OF INDIVIDUALS

Health insurance: intensifying risk-pooling in low and middle income countries

Health insurance, a common good and not an innovative tool in rich countries, still has unquestionable market possibilities in LMICs, where such a system often does not exist at all or is only offered to a few more privileged citizens. The purpose of health insurance is threefold: increase access and use by making health services more affordable, improve health status through increased access and use, and mitigate the financial consequences of ill health by distributing the costs of health care across all members of a risk pool(30).

Insurance is a formal risk management mechanism that complements other financial

services, namely credit and savings. It provides financial protection against specific perils, such as sickness or injury, in exchange for regular premium payments proportionate to the likelihood and cost of the risk involved. Various types of health insurance exist, from private insurance, over company driven to compulsory and inclusive health insurance.

According to the WHO Health Report(31), raising funds through required prepayment is the most efficient and equitable base for increasing population coverage. Experience shows this approach works best when prepayment comes from a large number of people, with subsequent pooling of funds to cover everyone's healthcare costs. Insurance allows pooling of health risks so that healthy people (the majority) subsidize sick people (the minority). Moreover, health insurance has the particular advantage (over other funding schemes) that it spreads costs over the life-cycle: members pay contributions when they are young and healthy and draw on them in the event of illness later in life(31). Government-sponsored insurance programmes can promote equity whereby the rich subsidize the poor, directly by progressively set contributions and less directly through income and other taxes.

Though health insurance has a proven track record in high-income countries, the system faces different challenges in LMICs. Determining what is covered under insurance benefit plans (including prevention and treatment of hepatitis) is not an easy task as it is driven by people, politics, fiscal space, and evidence – an exercise for which LMICs may lack experience. Health insurance products cater to catastrophic, episodic illnesses rather than prevention. Voluntary health insurance schemes do not work for all population groups, for a variety of reasons including adverse selection and low demand and affordability. Existing models struggle to manage administrative costs, especially if high-frequency outpatient services are included. Medical cost inflation, moral hazard (insured people, or providers treating insured patients, acting differently than they do in the absence of insurance) and fraud are challenges to manage claims costs.

In order to introduce or expand health insurance in LMIC, though, strengthening (management) capacities of governmental structures involved in regulations and procurement of health care and delivery is necessary. Different areas, in which support could be given, are:

- actuarial and cost-benefit studies in specific countries
- testing benefit plans that introduce coverage for viral hepatitis
- health insurance systems that target local communities
- encouraging partnership between the insurance industry, private healthcare providers, technology providers and government institutions, in order to debate risk-sharing and population coverage
- negotiations to include HCV DAA treatments (at least partially) in the reimbursement scheme
- exploration of sources of financing for the risk pool

In some countries, we notice an increased interest among insurance companies to offer **disease- or condition-specific insurance products**. Disease-specific insurance products may incorporate a disease management model and specific requirements to monitor the

disease. Caution is warranted with this model in order to avoid restrictive policies. Therapy compliance may be a prerequisite for benefits. Examples are the 'Extended Health Benefits programme'⁷ in Canada and All Life⁸ in South Africa. Funding agencies could support a **hepatitis-related insurance as a bridge to regular insurance products**.

Risk pooling is a strategy that combines and therefore increases access to health care and financial protection. Various innovative programmes demonstrate how the living conditions and health of poor people have improved through the installation of a health insurance system. Furthermore these programmes strengthen community awareness on risk pooling, promote high quality health-seeking behaviour and the development of tools to measure the impact of interventions and, last but not least, reduced out-of-pocket expenditures for health (51). Often, these programmes **combine different risk-pooling strategies** in order to reach a larger population, including poor people, and **maximize risk-sharing**. Initiatives are characterized by **building upon existing networks and services** to launch their innovation. Examples are (51):

- Grameen Kalyan Health Programme (GK) (Bangladesh: linking health micro insurance to microcredit services (www.grameenkalyan.org))
- Micro Insurance Academy (India): community-wide risk-pooling; context-specific microinsurance schemes and innovative tools for developing benefits packages (www.microinsuranceacademy.org)
- Yehasvini Cooperative Farmers Health Care Scheme (India): making use of the existing social network (in this case, a farmers' cooperative) to extend health insurance and making use of underutilized private providers (www.yeshasvini.org)
- Microcare (Uganda): combining custom product design with product tangibility and a sophisticated information technology platform (to reduce fraud) (www.microcare.co.ug)

Despite possible pitfalls, facilitating the introduction and further coverage of health insurance schemes in LMICs can be an innovative way of funding hepatitis C treatment. Promoting the combination of universal basic health coverage with compulsory insurance subsidized by taxes and a more extensive supply of additional (voluntary, micro, company or cooperative driven...) health insurance systems (e.g. consisting of different packages at different prices), can be an interesting strategy that combines risk sharing, prevention (health education), reimbursement of treatment and sensitization. According to WHO, to improve fairness and financial risk protection, a high level of prepayment is necessary and it is obviously necessary to spread risk (through cross-subsidies from low to high health risk) and to avoid fragmentation of pools. Subsidizing the poor should be encouraged (through cross-subsidies from high to low income)(31).

Amortization

⁷ to provide non-Native and Métis residents of the Northwest Territories who have specified disease conditions with certain benefits not covered by hospital and medical care insurance (<http://www.hss.gov.nt.ca/health/nwt-health-care-plan/extended-health-benefits-specified-disease-conditions>, consulted online on 29/10/2015)

⁸ where people with HIV/AIDS or diabetes who control their disease and demonstrate near-normal risk, can obtain health insurance (alllife.co.za).

Amortization (due to the flexibility in repayment terms) is another approach that can relieve payers from the enormous initial cost. If treatment could be paid for over a period of 5 or even 10 years, the immediate health budget impact would be dramatically reduced. For pharmaceutical companies, signing up for a therapy now, even with deferred payment, ensures that they maximize sales before new competition enters the market. At the same time, cooperative purchasing under an amortization scheme allows for hedging of risk across multiple payers (governments or insurance companies) so that interest rates for the hedged investment would be quite favourable.

Micro-financing

As opposed to rich people, poor people rather save in informal ways. In LMICs, they invest in assets that they can easily exchange for cash, such as gold, jewellery, domestic animals, building materials. A widespread informal form of saving and micro-financing⁹ in West Africa, is the 'tontine', an informal savings group where everyone contributes a small amount of cash each day, week, or month, and is successively awarded the pot on a rotating basis. Sometimes members of the group are allowed to borrow from the pot (52).

Even though the system of micro-financing has existed for centuries, its modern version is credited to Dr. Mohammed Younes (founder of the Grameen Bank and Nobel Prize winner). Micro-finance is a well-known mechanism to finance small business opportunities in the informal (or semi-formal) sector in LMICs. The system is also used to provide micro-loans for educational purposes and healthcare. Numerous micro-finance institutions issue micro-loans, ranging from (inter)national non-profit organisations to commercial banks (52).

Studies have confirmed that micro-finance helps very poor households meet basic needs and protect against risks, improving their resilience. Most donor interventions have concentrated on the provision of microcredit. Experience has taught that micro-finance is not always the best option¹⁰, but over the past two decades substantial progress has been made in developing techniques to deliver financial services to the poor on a sustainable basis and guarding against the risk of indebtedness already vulnerable people. The mechanism is more difficult to operate with success in countries with hyperinflation, absence of law and order or when laws and regulations create serious obstructions to the sustainability of micro-finance providers (52).

Micro-finance institutions (MFIs) occasionally include non-financial services, e.g. health education and information sessions on preventive measures in their credit schemes. A few have added innovative micro-finance strategies (health savings account (see below) and emergency health loans) to facilitate access to health service products and providers. A MFI-organized and managed alternate healthcare financing scheme provides access to preventive and curative health services as well as financing in the form of health savings plans and emergency health loans.

9 Supply of loans, savings, and other basic financial services in small amounts to the poor.

10 It may for instance be inappropriate among geographically dispersed or nomadic populations or among populations with a high incidence of debilitating illnesses (e.g., HIV/AIDS).

According to Ofori-Adjei (53) integrating healthcare financing into a MFI is an opportunity to soften financial risks associated with poor health. A MFI-managed alternate health financing scheme is a form of collective pooling of health risks with the double outcome of decreasing the cost of health care for poor people and increasing access to health care services.

Health savings account

A health savings account (HSA) is a tax-advantaged medical savings account (owned by an individual) available to taxpayers who are enrolled in a high-deductible health plan (HDHP). At the time of deposit, the funds contributed to an account are not subject to federal income tax. Funds roll over and accumulate year to year if they are not spent. A HSA may encourage saving for future health care expenses, allow the patient to receive needed care without a gatekeeper to determine what benefits are allowed, and make consumers more responsible for their own health care choices.

Applicability to hepatitis C treatment

While expanding health coverage in LMICs is an important goal for the future, it should be noted that all insurance is a means of pooling risk, and therefore any insurance market will function better insofar as the participants are unaware of their own individual level of risk. For this reason, only universal and compulsory insurance will cover those who are already suffering from chronic conditions, or who are at high risk. The appetite for risk-pooling will therefore depend on public perception of the generalisability of risk; either high (for example if there is a widespread fear of infections at barbers' shops) or low (if HCV prevalence is seen as applying to a particular generation, such as those infected by past vaccination programmes, or high-risk and socially un-esteemed groups such as prisoners or those injecting drugs).

Amortization, as with any form of lending, carries an opportunity cost in terms of the return that would have been made on a five- or ten-year loan had the money been invested at a market rate during that time. Amortization, if it involves the funding of hepatitis C treatment by pharmaceutical manufacturers, must therefore either feature interest being added to the repayments, or involve what is in effect a price discount being offered; possibly some mixture of the two. The price discount would, in addition, be hard to quantify as the alternative return on investment would depend on various factors such as interest rates. Manufacturers would alternatively be faced with an unexpected role as lenders to LMICs, a role which is likely to attract negative publicity in any case; they would additionally need to consider how payment of debts would be enforced upon defaulters, and how such a process would affect their public image.

Micro-financing is a mechanism with direct applicability to HCV. For instance, in Ghana in 2014 about 1,000 people in the Nandom District were offered the opportunity to be screened for Hepatitis B and Hepatitis C through a free programme organised by DKM Diamond Micro-Finance Ltd (54). The exercise, carried out in collaboration with the local

District Health Directorate, ensured that those tested positive were offered counselling and referred to the district hospital for treatment. A variety of similar schemes have been piloted in LMICs and these could potentially be scaled up to national level with the backing of larger national or regional banks. However, while screening and counselling on the avoidance of re-transmission is important, the financial model for these schemes is different from ordinary micro-finance (in which individuals take out small personal loans at what is often a reduced rate of interest).

The likelihood of individuals participating in loan-based screening programmes, rather than free screening schemes, is hard to ascertain, although as a means of providing free access to screening it may be attractive to use the infrastructure of micro-finance providers in order to connect with 'hard to reach' groups. As a means of financing more expensive interventions such as hepatitis C treatment, the use of micro-finance firms could be an attractive means of developing local implementation partnerships (as would collaboration with NGOs involved in healthcare and vaccination) although this does not provide an answer to the basic funding challenge.

Health saving plans, like micro-finance, allow those with low incomes to invest in their future. Although useful in themselves they do not, without a connection to other funding mechanisms, provide risk-sharing or redistribution of funds of the type needed to provide relatively expensive hepatitis C treatment to those currently infected with HCV.

Part 3 of this report (graph 11) shows that knowledge about health insurance schemes is widespread among organisations otherwise interested in the field of innovative finance, being reported by eight out of 27 organisations surveyed. Knowledge of micro-finance as a funding mechanism is even more extensive, being reported by 11 organisations. One regional investment group that responded to the telephone survey explained its involvement: "We raise money through funds and then we invest capital from those funds into these institutions. So we'll make a loan for, let's say, \$3 million to \$5 million to an institution in Cambodia, and that financial institution will then lend to micro-entrepreneurs or SMEs in that region."

Local and regional banks in LMICs will often have experience of partnership with micro-finance providers, and these will often link up major commercial sources of funding with smaller NGOs and not-for-profit projects. The recommendation section of this report will therefore suggest using the network of contacts developed through the operation of micro-finance projects, together with the local knowledge of project managers, as a way of connecting major funding institutions with local implementers able to deliver services to 'hard to reach' groups. The central role of local or regional financial institutions in these networks would build upon both commercial experience and the experience of interaction with micro-finance providers as part of their Corporate Social Responsibility (CSR) schemes.

Considering the low cost of hepatitis B and C treatment in a number of low- and middle-income countries, including hepatitis B and C treatment in the health insurance basket may be of added value to the risk-pooling scheme.

Table 7: Mechanisms that strengthen financial protection of individuals: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ Pooling and spreading of risk. ✓ Powerful tool to empower patients. ✓ In line with WHO support to Universal Health Coverage (UHC). 	<ul style="list-style-type: none"> ⚠ Coverage of expensive medicines remains problematic.

5. MARKET ORIENTED MECHANISMS

Volume or tiered pricing

Past experience with vaccine tenders in low-income countries (e.g. the GAVI Alliance and hepatitis B vaccines, and PAHO’s Revolving Fund for vaccines) has proven that pooling demand and purchasing activities are effective mechanisms to reduce prices through increasing the certainty of demand. The forecasting of the strategic demand and the use of long-term commitments have increased the certainty of vaccine demand, enabling manufacturers to plan production more effectively, which in turn allows lower prices to be obtained. In low-income countries, HBV vaccine prices decreased within 10 years from US\$ 30 per dose to about US\$ 0.50 per dose. The fundamental underlying conditions are that timely, transparent and accurate information on demand, supply dynamics and pricing is shared. Some middle- and high-income countries (e.g. France, Switzerland, and the UK) have negotiated significant price reductions for DAAs through this approach. Setting a lower price for hepatitis C treatment by increasing competition between manufacturers (through national or regional tenders, by pooling demands and purchases using volume or tiered pricing) is possible, but may take too much time in some settings.

Voluntary licensing

A pharmaceutical company that holds patents on a product (patentee) can offer of its own accord a licence to a third party (generally a generic producer) to produce, market and distribute the patented product. The patentee might in return request a royalty on the net sales gained by the licensee and often impose certain restrictions, such as geographical and pricing restrictions (55). For the past decade, pharmaceutical companies have increasingly used voluntary licences to allow generic production of patented antiretroviral drugs (ARVs) for HIV/AIDS patients in LMICs. Voluntary licensing can create generic competition that enables affordable prices and therefore better access to patients in LMICs (56).

As part of a ‘comprehensive access approach’, Gilead has entered into licensing agreements with generic pharmaceutical manufacturers to create a sustainable, market-based model for broadening access to HIV, hepatitis B and C medicines in the developing world. Hitherto, Gilead granted voluntary licences for manufacturing generic versions of

hepatitis C medicine to the governments of Egypt, Pakistan and India. Eleven international partners of Gilead produce generic hepatitis C medicine for 101 low-income countries and three in-country partners produce generic hepatitis C medicine for their home country (57).

Voluntary licence agreements relate to only one medicine; each new one will need a new contract. The example of Egypt, however, is encouraging, as the Government was able to initiate an effective treatment programme¹¹ based on a carefully developed national strategy using the best national and international expertise.

Medicines patent pool

The Medicines Patent Pool (MPP) (58) is a particular example of voluntary licensing. The MPP, created in 2010 by UNITAID, is a United Nations-backed organisation offering a public-health driven business model with the goal of lowering the prices of, and facilitating the development of better-adapted HIV medicines. The MPP is a PPP between communities of people living with HIV, governments, industry and international organisations, bringing together (sometimes opposing) stakeholders. The MPP offers a model that fits all stakeholders, by negotiating for public-health driven licenses with patent holders. This way, patent holders can share innovative products in resource-poor settings and may be compensated by a fair royalty. As a consequence, low-cost companies produce affordable new medicines in a rapid and easy way. Donors and developing country governments from their side, stretch their budgets in order to treat more people. As a result, the MPP ensures faster access to quality, life-saving treatments.

MPP's first licence with a pharmaceutical company was Gilead Sciences. The licence contributed to creating a generic market for tenofovir, the leading WHO recommended ARV for both HIV and now for hepatitis B patients (59).

In November 2015 the pool was extended to hepatitis C treatment, when the MPP and Bristol-Myers Squibb (BMS) signed a licensing agreement for daclatasvir, a novel direct-acting antiviral that is proven to help cure multiple genotypes of the HCV virus. The royalty-free licence enables generic manufacture of daclatasvir for sale in 112 LMICs, 76 of which are World Bank classified middle-income nations. Nearly 75% of all patients living with hepatitis C in the LMICs reside in the regions covered by the agreement (60). To date (February 2016) four sublicences have been signed with generic manufacturers.

Compulsory licensing and patent challenges

Some governments or nongovernmental organisations (NGOs) are trying to lower the prices of medicine by challenging patents or seeking compulsory licensing by exploiting flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)¹². The TRIPS Agreement allows the issuing of a compulsory licence to address public health

¹¹ *Plan of Action for the Prevention, Care & Treatment of Viral Hepatitis, Egypt 2014-2018. Egypt's Ministry of Health and Population (MOHP).*

¹² *For instance Argentina, Brazil, China, Morocco, the Russian Federation, Ukraine and Médecins du Monde are currently challenging the patent applications for sofosbuvir.*

needs without the authorization of the patent holder. Article 31 of the TRIPS Agreement stipulates that production of medicines under compulsory licencing should primarily be for the domestic market. Local production, though, requires not only appropriate technical knowledge and production capacity, but also access to a reliable source of active ingredients.

This approach, even if it is successful, is also hampered by several disadvantages:

- middle- and high-income countries with strict legal frameworks may not benefit;
- it goes against the fruitful past experience with vaccines, where high-income countries often paid higher prices in order to allow access to resource-limited countries at a lower price;
- it gives the wrong signal to the pharmaceutical industry by lowering the incentives to pursue research into new drugs and vaccines;
- the rapid development of new DAAs and new DAA combinations renders the procedures of signing multiple contracts or fighting through courts time-consuming and prone to rapid obsolescence.

In light of the above, before engaging into this approach, a careful balancing of the pros and cons is warranted. Advocacy and activism by pressure groups and interested parties have opened the way to policy changes and significant price reductions, particularly in the field of HIV/AIDS.

Advance Market Commitments (AMC)

In an AMC, funding agencies and pharmaceutical companies engage in a partnership for research on a disease that affects poor countries. Donors ensure predictable and liquid demand once research is completed. Companies commit contractually to conducting the necessary research. Pharmaceutical companies guarantee the distribution of medicines at affordable prices for the target population on the market in recipient countries once the research is completed. Unlike most other funding mechanisms, AMC motivates innovative research on neglected diseases. Therefore it is an interesting complement to financing research on medicines in the pipeline. On the other hand, the mechanism has two challenges: the partners have engaged in a long-term commitment, and the uncertainty generated when demand is not liquid in country markets, restrains pharmaceutical companies in doing research. Research efforts in the pharmaceutical sector imply expensive and important risks, which the sector is more willing to take when a price and a demand is guaranteed. The GAVI Alliance used AMC to accelerate global rollout of the pneumococcal vaccine (see box) (61). In this case, AMC was used to bring a vaccine developed and commercialised in high-income countries, to low- and middle income countries (or in other words as a strategy to bring an innovation from the developed world to those who could benefit in developing countries).

Private sector co-payment

Private sector co-payment is based on three components: price discounts, subsidies to

the manufacturers and supporting interventions towards the product (62). The mechanism is used in the Affordable Medicines Facility – malaria (AMFm) (63), a pilot project funded by UNITAID and hosted by the Global Fund. The project provides affordable and quality-assured artemisinin-based combination therapies (ACTs) for the public and private sectors in malaria-endemic countries. By reducing the price paid by end-users in these pilot countries, the AMFm uses competition to eliminate the ineffective medicines sold in shops and pharmacies in these countries. The AMFm seeks to shift the business model for ACTs from “low-volume, high-margin” to “high-volume, low-margin”. Its strategy is to first negotiate a discounted price for ACTs with manufacturers, ensuring that the price is the same for importers from the public sector and private sector. The AMFm then pays a proportion of this reduced price directly to manufacturers (as a form of subsidy or “co-payment”). Afterwards, importers of ACTs pay the remainder of the sales price. The reduced prices are passed on to private wholesalers and then to retailers such as pharmacies and stores (63).

Creating regional tables for price negotiation

The initiative of EURORDIS, a European non-governmental patient-driven alliance of patient organisations representing 695 rare disease patient organisations, and the European Patient Forum (EPF), towards increasing patients access to orphan medicines may inspire LMICs to reflect on similar actions increasing patients’ access to expensive medicine. EURORDIS and EPF call upon European authorities to create a roundtable for price negotiation involving all stakeholders, and enabling national authorities to take a collaborative approach to negotiating the prices of medicines with pharmaceutical companies (64). Such a negotiating table on pricing should be based on value assessment, volume and post-marketing evidence generation. Advantages of such an initiative are its focus on collaboration between industry and payers (64). The tables could be grouped by income-level of the country.

Applicability to hepatitis C treatment

Tiered pricing allows pharmaceutical manufacturers to provide a discount on patented products to lower-income countries. It cannot guaranty funding, though it gives a signal to funders that affordable products will be available and that funding will be sustainable as it could go across a wide population. However, since roughly 73% of those with chronic HCV infection live in middle-income countries as opposed to 12% in low-income countries (65), this is likely to form only one part of the solution to the HCV crisis. The same must be said of voluntary licensing. Licensing, neither patent opposition guarantee funding for a discounted or generic product in lower- or even middle-income countries, although it may be popular in middle-income countries which have their own generics manufacturers.

The use of a medicines patent pool is expected to have a major impact since the first round of sub-licences for the generic production of daclatasvir were announced in January 2016 (66).

The pricing schemes outlined above may appeal to patent-holders by offering “low-volume, high-margin” business as a substitute for “high-volume, low-margin”. The applicability to

hepatitis C would depend on whether the lower prices were still affordable in the context of widespread HCV infection. It should be noted that variable pricing models expose manufacturers to criticism from countries who benefit less than others, and others who may object to uneven access. Tiered pricing also involves the risk of parallel imports, and so (for instance) the distribution of hepatitis C treatment in Egypt will involve either re-packaging, or a controlled distribution scheme in which the recipient must break the seal of a tablet container and take the first dose in the presence of a pharmacist. This is not necessarily a problem, although it might restrict access to treatment by the less mobile.

It may be noted that this kind of mechanism, whose costs are mainly borne by patent-holding manufacturers, has the corresponding attraction of demonstrating a very visible policy of corporate social responsibility (CSR) on the part of the same firms. The process may allow industry to form partnerships with the governmental sector, having the joint aim of expanding access. It may be that other corporations, national and regional as opposed to multi-national, may be inspired to add hepatitis C treatment to their own list of developing CSR interests.

Table 8: mechanisms directed towards influencing the price of DAA's: summary of assets and risks

Assets	Risks
✓ Win-win situation for all stakeholders.	⚠ Complex multiple contracts.
✓ Proven its working for other medicines.	⚠ Tensions between countries/stakeholders in case of differential pricing.
✓ Focus on collaboration between stakeholders (especially industry-payers).	⚠ Restrictions concerning DAA pricing.

6. SOCIAL IMPACT INVESTMENTS: MAKING PRIVATE CAPITAL SOCIAL

The financial community has developed, in recent years, tools for socially responsible investing that make it possible to invest into companies, social profit and not-for-profit organisations, with the goal of generating measurable, beneficial social or environmental impacts linked to potential financial returns. Since the venture capital market exploded in the 1980s, it has changed the face of entrepreneurship and the global economy. New products and services flooded the market, while competition drove up affordability and quality.

Social impact investment differs from traditional types of investment in that it offers greater flexibility in repayment terms, lower interest rates, and the acceptance of greater risk than commercial lenders would normally consider (67).

Social impact investment can be advantageous to healthcare in low-, middle- and even high-income countries in many ways. For instance the vaccine bonds issued by the International

Finance Facility for Immunization (Ifflm) to support the Global Alliance for Vaccine and Immunization (GAVI, see box) (68-70) are a key innovative financing mechanism in the area of social investments. Social impact investment may be a means to strengthen the position of health-care businesses in low-income countries. Often, small- and medium-sized enterprises that face difficulties in scaling-up are hindered due to a lack of access to sufficient capital, lack of the right type of capital, insufficient information about investment opportunities and lack of understanding about how to engage with civil society actors, small-scale vendors and other companies.

Exploring the wide field of social investments using the large experience of the world of finance for HCV DAA treatments may be a promising undertaking with the potential to open new roads for new investment strategies. Such practices have been implemented in areas as diverse as childhood education, clean technology and financial services for the poor. Their impact is documented and financial returns can be expected if these investments produce the planned outcomes. Nonetheless, social impact investment does imply important challenges. First, the mechanism needs 'patient capital' that is flexible enough to accommodate for unforeseen circumstances. Second, the funding model operates in a 'hybrid' space, balancing between social and financial returns, which may create difficulties in meeting the investors' expectations (71).

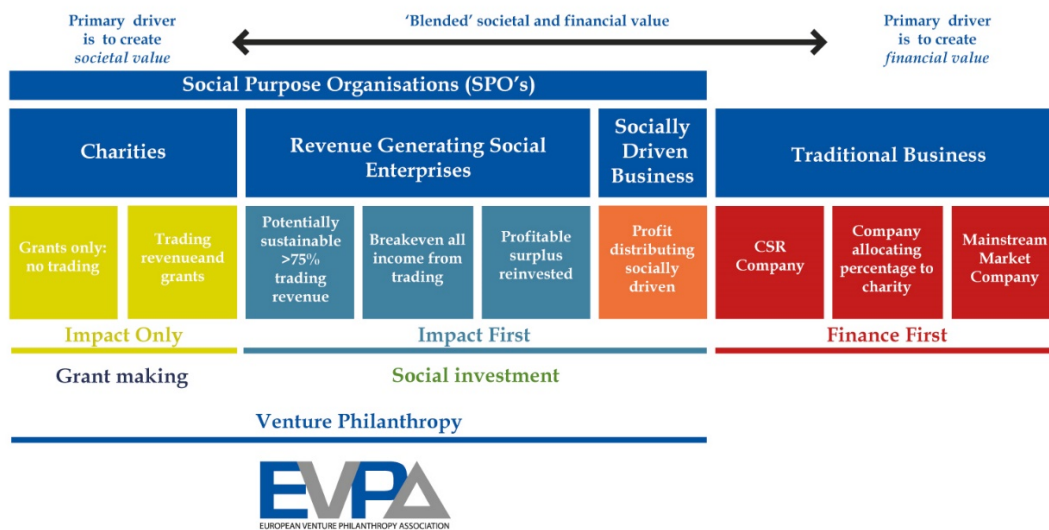
Social impact investing may take various forms, such as soft, forgivable (also known as recoverable grant) or subordinate loans, recoverable grants, hybrid philanthropy, social impact bonds, social franchising, corporate social responsibility or cooperative investment. Figure 1 provides an overview of funding mechanisms in relation to their focus on return (financial versus societal). Though loans and grants are self-explanatory, the other forms and how they may be implemented in health care in general and for treatment of HCV in particular may need more exploration.

GAVI AND IFFIM

As a frontloading mechanism for long term Overseas Development Aid (ODA) commitments, Ifflm mobilizes resources from 8 donor countries that are drawn on in the form of bond issues ('vaccine bonds') on the international capital markets, backed by guarantees from participating governments to maintain future aid flows that can be used to buy back the bonds on maturity. This way, pledges from donors are exchanged for immediately accessible cash resources for the GAVI Alliance.

By the end of 2013, the mechanism had attracted \$4.5 billion from investors.

Figure 1: overview of funding mechanisms in relation to their focus on return (financial versus societal)



Source: European Venture Philanthropy Association

Venture philanthropy

Venture philanthropy aims at strengthening organisations with a social purpose by giving them both financial and non-financial support (e.g. capacity-building) in order to increase their societal (social, environmental, medical or cultural) impact. It includes both the use of social investment and grants. The approach is characterized by high engagement, tailored financing, multi-year support, non-financial support, involvement of networks, organisational capacity-building and performance measurement(71). The advantage of venture philanthropy lies in both the combination of loans and grants, and the non-financial support. It reinforces the management of the borrower/receiver of the grant, which ensures better return on investment.

Social impact bonds

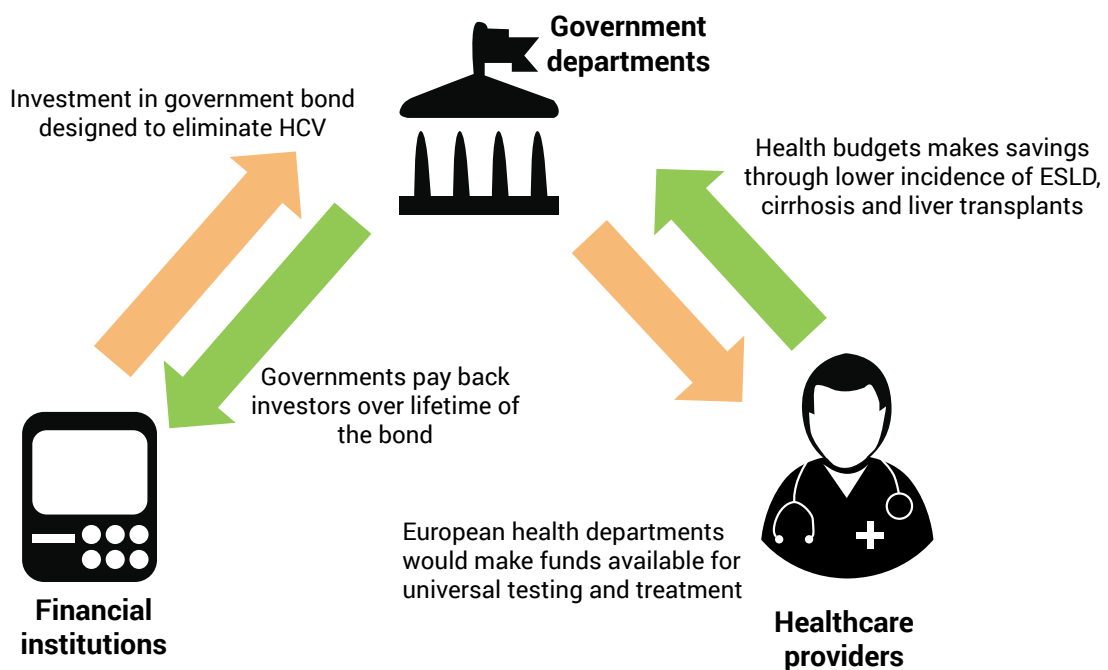
A social impact bond (SIB, also called social bond) is a financial mechanism in which investors pay for a set of interventions to improve a social outcome with the expectation that the outcomes saves future public costs (67). Social impact bonds are a PPP (between a public authority, investors, a service provider and an intermediary organisation). The private investors, who bought the bond, will be paid a return if the associated social project succeeds in obtaining the social outcome within a given period of time (67). New Zealand is one of the first countries piloting and actively exploring social bonds. Social bonds are currently underway in Australia, Belgium, Holland, South Africa, South America, the United Kingdom and the United States, and are being actively explored in Canada, Ireland and Israel (72).

Social impact bonds (figure 2) have the potential to tap large capital markets so as to

launch new social services. Private investors can earn attractive investment returns for assuming the risks associated with the service. Social enterprises can benefit from the business experience of investors, and the interests of all partners may be better aligned from a strict results-oriented approach. As an example the New York State, Social Finance and Bank of America Merrill Lynch teamed up to launch a “social impact bond” designed to cut New York City’s recidivism problem.

Figure 2: social impact bonds to finance preventative health in a sustainable way (73)

Outlining a possible solution - developing a bond to finance preventative health




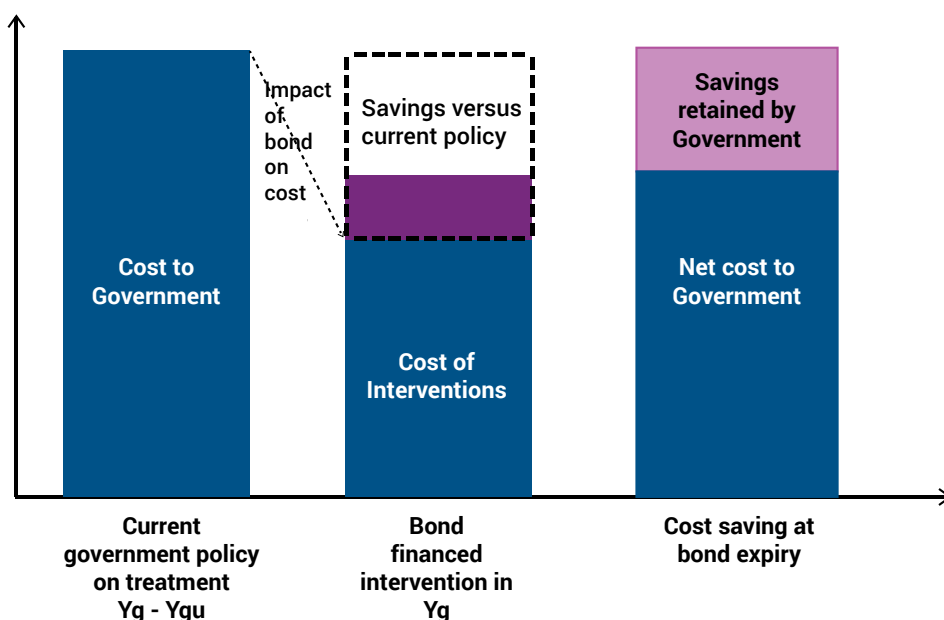
Private sector financing has been used in health but it has focused largely on improving infrastructure and Private Finance Initiatives (PFI) often have a poor public image. Health has remained notable by its absence in ‘social investment bonds’ to-date, not least because of a number of key challenges like the need for a burden analysis and the ability to monitor changes in outcome and the current lack of detailed epidemiology. A SIB-type fund aimed at financing hepatitis C treatment, as proposed by Rob Walton at the VHPB Roundtable on innovative finance in June 2015 (73), may provide a sustainable solution for healthcare, in the sense that it balances the long-term impact of treatment (which averts the need for expensive interventions 20–30 years from now) with the economic pressures currently being felt by governments throughout Europe. Furthermore, it fulfil the government’s obligation to abide by the correspondence principle – the cost of treating hepatitis C should be contained within a generational cycle.

The proposed social impact funding initiative must avoid passing costs onto future generations of taxpayers by paying for itself (through the money saved by the reduced need

for intervention in the manifestations of late-stage disease) within the lifetime of most patients (25–30 years) (73). Depending on the savings achieved, there should be sufficient to offer a return on investment to funders; but in return for the potential gains, funders will have to absorb the risk that savings may vary according to achieved outcomes. The risk-pooling mechanism may allow governments more security in taking action to expand hepatitis C treatment; setting an appropriate balance of risk versus return will affect the types of funding which could be tapped by this mechanism.

Figure 3: social impact bonds, future savings in health expenditure as a return on investment (73)

The value for money case for long term bond investment 
Bond investments work when the cost of achieving the target outcome are less than the resulting public sector saving



Social franchising for health

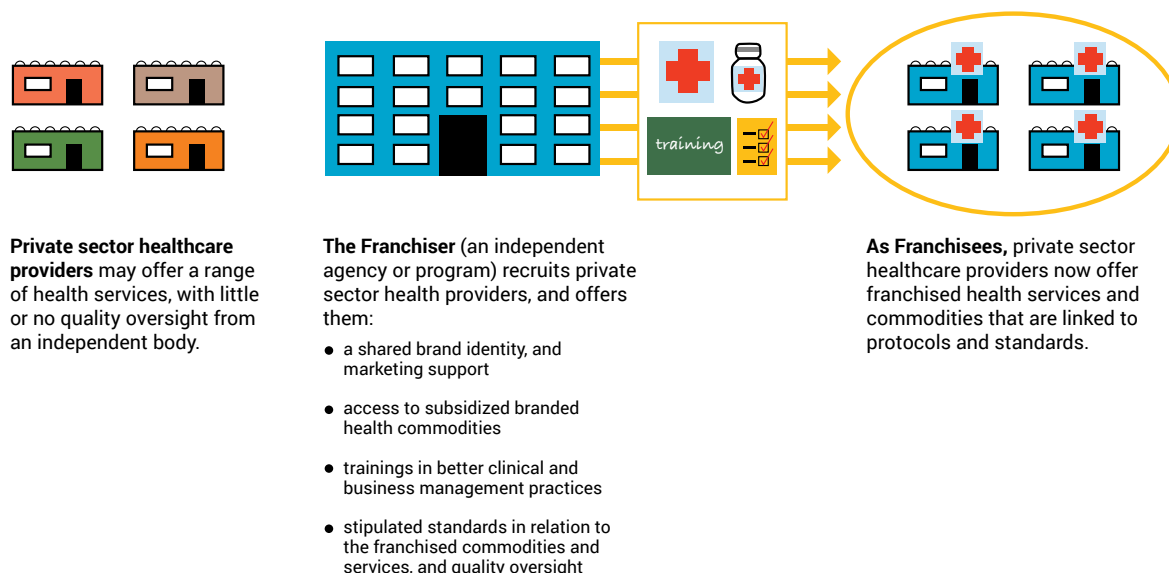
The private healthcare sector in LMICs consists of a wide range of providers, such as traditional healers, non-profit organisations, private clinics, pharmacies and outreach services. Although their role is crucial, the quality of services they offer can be highly variable. More and more, public health initiatives support the development of networks among private sector healthcare providers into building networks. **Social franchising** of health services is one example that applies commercial principles to achieve public health goals by organizing private sector health care providers in networks that use commercial franchising principles.

A social franchise network links private sector healthcare providers under a common

franchise brand to offer socially beneficial health services. A not-for-profit ‘franchisor’ manages the brand and supervises the administration of the programme. The private healthcare providers (or franchisees) in the network are not employed by the social franchise programme; the franchised clinical services are linked to standards and protocols and fees are paid for services or medical commodities. The agency (i.e. franchisor) offers the use of the brand, and access to subsidized commodities, to private healthcare providers who agree to become suppliers of the franchised services or products. Quality control is achieved through business and clinical protocols stipulated by the franchise agency, periodic trainings of health care providers, performance monitoring visits and reporting on utilization data. Often the networks include membership fees. Franchisees retain ownership over their outlets, and can charge fees for their services. A social franchise can be complete or fractional. In case of fractional franchising, participating healthcare providers continue to offer other non-franchised health services (74).

Figure 3: schematic overview of the Social Franchise Model

The Clinical Social Franchise Model



Source: Sf4Health

Social franchising networks are characterized by demand-side payment; fees for health care services are covered in various ways: in some cases clients pay out-of-pocket, sometimes vouchers are issued or services are subsidized or paid by health insurance. Some programmes generate income by purchasing commodities at well below market value, and selling them to franchisees at a slightly marked-up price (but often still lower than normal retail price, thereby passing on cost savings to the franchisee). In this way, franchisees are stimulated to transfer the cost savings to clients. Social franchising networks in LMICs still receive substantial support from international donors, but national public health systems are increasing their contributions. Some social franchising programmes have become commercially self-reliant.

Introducing Corporate Responsibility (CSR) in local companies

CSR is based upon activities or donations by companies beyond their legal obligations to address social or environmental concerns. It has become an important strategy for employment branding. As consumers are increasingly informed and more critical of the impact of products they buy and of the circumstances in which they are made, companies integrate social, ethical and environmental issues in their business process. Multinationals without a CSR strategy are nowadays hard to find. Several companies have created a foundation with part of their profits.

A growing number of distributors and stores promise potential clients that they will donate (a percentage or a fixed amount) to a specific charity goal per product bought. This way, distributors use CSR as a direct marketing and image-building strategy. After a major natural disaster or crisis, emergency relief agencies often collect money by encouraging clients of mobile phone companies to send an SMS at a specific tariff (e.g. 0.50 euros) to a specific number. The revenues go to the relief operation. A typical example of donations as a promise to the customer is Product (Red) Initiative, where part of the revenues of the sales are committed to the Global Fund to finance programmes to fight AIDS, tuberculosis and malaria. Fair Trade certification is also based on the same principle(38).

Another way in which companies mobilize resources through CSR is collection of old products for recycling (e.g. old cell phones, batteries, paper, pairs of shoes, textiles) when customers buy a new model. The recycling premium the company receives can be donated to the charity goal. Stores often use this technique in exchange for a discount on the new product.

By analogy with multinational companies, local enterprises in LMICs can be stimulated to adhere to CSR. Local companies that invest in the treatment of hepatitis B or C not only introduce the concept of CSR among a broader public, but they also inform about a major public health issue. The engagements of the company are made public through information brochures, posters and company websites.

Last but not least, transfer of knowledge from entrepreneurs in high-income countries to counterparts in LMICs is an upcoming trend in the area of sustainable development. Initiatives like 'doctors without borders' or 'veterinarians without borders' are well known. The Belgian NGO Ondernemers voor ondernemers vzw (entrepreneurs for entrepreneurs) sends professionals from high-income countries on short-term specific support missions to companies in LMICs, at the request of the local company (www.ondernemersvoorondernemersvzw.be).

A closer look: Health partnerships with pharmaceutical manufacturers and financial institutions

A lot of the activities we are currently seeing in HCV go beyond traditional CSR programmes and are part of broader commercial initiatives. The development of health partnerships in LMICs is now a component of research based pharmaceutical companies' core business

models. These initiatives suggest that pharmaceutical companies recognize they have an important role to play to achieve greater access to healthcare.

Egypt: Gilead has agreed to provide Sovaldi® and Harvoni® to the Egyptian Ministry of Health at a significantly reduced price. The Ministry of Health provides Sovaldi through government programmes such as the National Liver Program and Health Insurance Organisation. Gilead also partners with the Ministry to invest in local HCV medical education and prevention efforts, as well as screening and patient awareness initiatives(75). Several other pharmaceutical companies have followed up such as BMS, Abbvie and Janssen.

MSD has collaborated with the Ministry of Health, and advocacy and industry partners to develop targeted HCV programmes including communications campaigns, screening programs and treatment subsidies. In 2013, Merck launched the first Middle East School of Hepatology (MESH), which provided medical professionals from across the region with education targeting hepatic disease in the Middle East(75, 84)

In 2007 Roche introduced the re-packaging of Pegasys in order to sell at a lower price in Egypt. Roche also offered products for diagnosis and treatment monitoring(75). AbbVie has been committed to working at the country level to strengthen support for HCV awareness and elimination by collaborating with the National Ministry of Health since 2013 to support the implementation of their National Hepatitis Strategy. By partnering with local experts and the government, AbbVie has crafted a clinical development program and medical education plans for use by clinicians, helped spearhead disease awareness activities and has provided HCV/fibrosis diagnostic support to assist healthcare providers in the screening of HCV patients. Through collaboration with the Egyptian National Committee of Hepatitis C, AbbVie has facilitated improved access for patients and helped Egypt move closer to its goal of HCV elimination.

Georgia: Gilead established an agreement with the Ministry of Labour, Health and Social Affairs, a project which is being carried out in partnership with the U.S. Centers for Disease Control and Prevention. The aim is to achieve universal screening, treatment, prevention and surveillance for HCV.

India: MSD India initiated Project Sambhav (Making It Possible), a programme aimed to educate patients and their families about HCV and help manage the cost of treatment. MSD India provides subsidies for financing for treatment to eligible patients and counselling to help educate about treatment, adherence and transmission prevention(84).

Vietnam: MSD's CSR foundation awarded a multi-year grant to Population Services International (PSI), a leading global health organisation, to conduct educational outreach targeting at-risk populations and healthcare providers. Additionally, service providers from high-prevalence areas were trained to promote an understanding of HCV and facilitate referrals for diagnosis and prevention counselling(84).

Section 3 of this report demonstrates that for organisations that agreed that innovative

funding mechanisms have a role in healthcare, PPPs and direct grant funding were seen as the two most suitable innovative finance mechanism for supporting public health. While CSR projects tend to involve direct funding, it may be possible to expand the reach of these projects by introducing organisations' commercial arms through PPPs. Graph 6 (Q5) demonstrates that few surveyed financial sector organisations said that social investment was outside the scope of their activity; more than half of those surveyed claimed an involvement in social or philanthropic investment to a greater or lesser extent.

Part of the research underlying this report has included an examination of the rapidly-developing CSR departments of regional banks in LMICs. For example: the pan-African Ecobank (mostly operating in West Africa) has developed a role in microfinance, claiming that "the market is largely un-tapped, has tremendous potential and presents a business growth opportunity for the group. It also provides a significant platform to empower African entrepreneurs to upscale their operations, expand income generation and pull themselves out of poverty." The bank and its partner, Accion International (a global microfinance group), are working to establish microfinance banks across Africa with a plan to establish operations in 20 countries. To complement its direct retail operations, Ecobank also acts as banker to microfinance institutions in the countries in which it operates, supporting over 250 of these with wholesale loans and other products (75).

This kind of CSR operation may extend to healthcare provision, although this has usually been restricted to short-term, emergency relief. As an example, ICICI Bank in India has used its CSR arm (ICICI Foundation for Inclusive Growth) to partner with the Government of Rajasthan in implementing a pilot project to improve the nutritional status of under-six-year-olds (76). This kind of pilot project is small-scale, but involves the development of local contacts and co-operation between public authorities and private funders, which could prove to be very useful as CSR, once the province of institutions in high-income countries, continues to develop.

It should be added that the CSR departments of international banks continue to have a role to play. As one major European bank said when responding to telephone survey questions, "We have corporate social responsibility departments around the world, representing different regions." Regional and local financial institutions could be encouraged to follow suit.

With this in mind, the recommendation section of this report will also suggest building on the experience of CSR projects as a way of connecting major funding institutions with local implementers, suggesting that the developing interest in CSR on the part of LMICs' banks and investment funds could be channelled into responsible investment to advance public health and in particular in hepatitis C treatment sponsorship.

Rural health cooperatives

According to the International Labour Office (ILO), cooperatives play a major self-help role in rural areas, especially where private companies are reluctant to act and public authorities do not provide basic services. Next to creating productive employment opportunities, they offer healthcare, education, potable water, improved sanitation, roads, and market

access. Worldwide, approximately one billion people are members of cooperatives, and over 100 million work in them (77). Health cooperatives deliver their members in rural areas medical care that is not available through public or private health programmes. Member-owned, not-for-profit health cooperatives may constitute an alternative to private or public insurers. Various examples demonstrate the role of cooperatives in rural areas and in health services. For example, the *Faîtière des Caisses d'Épargne et de Crédit Agricole Mutuel du Bénin (FECECAM)* is a savings and credit cooperative federation (in Benin) providing financial services including affordable micro-health and life insurance to more than 500,000 individual members, 90% of whom live in rural areas (78, 79). China launched, in 2003, the *New Rural Cooperative Medical System (NRCMS)*, a system of mutual assistance for health protection through risk pooling. The structure is managed, organized and subsidized by the central, provincial, and county governments. It incorporates two major principles: voluntary participation by the rural population and emphasis on protection against catastrophic illnesses (80).

Applicability to hepatitis C treatment

Consideration of social impact investing as a mechanism is a complex question due to the variety of pilot schemes used. Common to all such schemes is the aim of attracting funds (with or without a market rate of return) to socially beneficial projects, all of which (so far) have been relatively small-scale pilots. Risk is shifted to the funders through the use of outcomes measures and there is an element of 'payment by outcome' shared by these schemes.

The main appeal of social investment projects is that they allow healthcare providers access to funds without the corresponding risks; if outcomes metrics are not met, the funder does not receive the same level of repayment. However, these projects require a careful alignment of timeframes to match up the time required to improve social outcomes to investors' preferences for the 'period to investment maturity'. They also need a well-defined target group, an outcomes metric which is a good proxy for the desired social outcome, and they require a multidisciplinary approach to handle what are often complex management structures. Nevertheless, they may represent the best hope of aligning the timescales of interest to the public sector (time to disease eradication) with those required by private sources of funding (typical investment maturities).

Funders of the small-scale 'social impact bonds' piloted so far have been social investors rather than institutional investors expecting a market rate of return. SIBs, therefore, have not yet been adapted to meet the needs of mainstream markets; there is a shortage of specialist intermediaries, and markets are not developed enough for the investments to be liquid. There is much development work to be done before social impact investing can be scaled up to provide the reach of non-outcomes-based global funds. However, a pool of experience does exist as the funding mechanism – quasi-equity debt – has a considerable history in countries such as the UK, having long been used for enterprises that are legally structured as non-profits and cannot obtain equity capital. Although technically a form of debt, returns are indexed to the organisation's financial performance; the security holder does not have a direct claim on the ownership of the enterprise, but the conditions of the

loan are designed to give management incentives to operate efficiently. It should be noted that SIBs, as quasi-equity debt, can potentially be adapted to Islamic finance.

Social franchising for health has demonstrated applicability to hepatitis C screening and counselling. As an example: Population Services International China (part of the US-based PSI group), in collaboration with the Kunming AIDS Bureau and four Community Health Service centres, developed a Clinical Health Network to increase access to a range of HIV and tuberculosis preventive, screening and referral services, serving 240 clients in 2012 with the help of a US\$50,000 contribution from USAID. The local contribution was US\$30,000, with a performance-based reimbursement system to ensure providers adhered to quality standards (81). This kind of programme has attracted public health partnerships, for example: PSI in Vietnam uses social franchising (with Merck Foundation funding) to help at-risk populations in Vietnam gain access to prevention and treatment services for HCV. This is another possible model for the development of local implementation partnerships (82).

Gilead, Bristol-Myers Squibb, Roche, Merck and AbbVie have shown interest in partnerships with governments, healthcare systems, providers, public health entities and generic manufacturers, especially in countries where governments have an active and well-planned HCV policy. A small number of regional financial institutions have implemented local CSR projects that relate to healthcare, but none currently exist in the area of hepatitis C.

The applicability of expanding health insurance through small-scale health plans (rural health cooperatives are an example of potential implementers) has been considered earlier in this report.

Knowledge about various forms of social impact investment is fairly widespread among organisations otherwise interested in the field of innovative finance; knowledge of venture philanthropy was reported by seven out of 27 organisations surveyed. Knowledge of social impact bonds as a funding mechanism was reported by four organisations (and knowledge of quasi-equity debt in general by five), and knowledge of social franchising schemes by two (graph 10). Graph 13 shows that social impact bonds are one of the few innovative finance mechanisms whose recognition was noted by the small pool of governmental organisations surveyed.

On the basis of recent developments in outcomes-based financing and given that considerable efforts have already been made to pilot 'social impact bond' funding arrangements, the recommendation section of this report will suggest that this experience be used to inform the future development of PPPs as a suitable way to expand their reach from their historical use on simple infrastructure projects and toward a more flexible means of outcomes-based funding.

The rapid advance of CSR in the LMICs, could be used as a springboard in introducing CSR among local/regional companies in LMICs. Major funding institutions could be connected with local implementers in treating HCV as a CSR action.

Table 9: social impact investments: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ Minor government involvement. ✓ Directed towards difficult to reach populations. ✓ Involvement of private capital that would otherwise not be directed to social projects. ✓ Less restrictions to release funds than government funds or funds from international donor organisations. ✓ Governments in LMICs that encourage local social impact investment, e.g. in combination with a more effective tax policy, may reduce capital-flight. 	<ul style="list-style-type: none"> ⚠ People may consider the importance of social impact (sustainability) as a hype. ⚠ Difficult to monitor compliance with WHO guidelines or national hepatitis B and C programme.

7. SMALL CONTRIBUTIONS FROM MULTIPLE DONORS

Aid agencies (including associations for specific diseases) collect a significant proportion of funds through campaigns directed at the general public. However, since the latest financial crisis in 2008, people are more reluctant to donate. Requesting small contributions from the general public through the consumer process has different advantages. A relative insignificant donation collected from each donor (e.g. less than a euro), may result in an impressive total amount. The action does not require a lot of effort from the donors and as the amount is so low, not giving may sometimes be more difficult than giving. Furthermore, the collection is at the same time a sensitization campaign that also creates solidarity and social cohesion among donors. Collecting small contributions from multiple donors, either as an investment or donation, is growing in a wide array of sectors.

Crowdfunding

Crowdfunding is the practice of funding by raising monetary contributions from a large number of people, typically via the internet. Contrary to most investment services, which are addressed to institutional or professional investors, crowdfunding focuses on the individual investor. Usually used to gather funding for a new product to be developed and brought to market, various crowdfunding platforms have been created to allow ordinary web users to support specific philanthropic projects without the need for large donations. Not all crowdfunding initiatives promise a financial return on investment; sometimes a reward is exchanged for the investment or the contribution is considered a donation. Crowdfunding not only offers fundraising to reach an (inter)national public, but also has added value

of raising awareness. This tool may be appropriate for small, neglected communities. Various crowdfunding initiatives for a broad array of purposes can be found on the internet. Social media have largely facilitated it as a popular means of fundraising for people and organisations launching innovative projects. A selection of examples:

- ✓ The ice-bucket challenge for research into amyotrophic lateral sclerosis (ALS). People are challenged to either receive a bucket of ice over their head or give a donation.
- ✓ KIVA (www.kiva.org), a non-profit organisation combines **crowdfunding, micro-credit and storytelling**¹³. The organisation uses the internet to find sponsors and lends amounts as little as 25\$ (for health care, medicine, education, business opportunities) through a network of local microfinance institutions. Personal stories of the lenders can be read on the website.
- ✓ **'Adopt a patient'** is an initiative of Medcan, a Belgian NGO that supports the use of cannabis as a medicine. The NGO uses crowdfunding as an instrument to financially aid patients and breaking the proscription against the use of cannabis as a medicine. The mechanism exists in many countries and provides support to patients in various ways

Figure 3: crowdfunding



Source: Crofun (83)

Migrants' remittances

Migrants' remittances are contributions sent by migrants to their relatives in the country of origin allocated for current consumption. At macroeconomic level, migrants' remittances account for significant amounts of money that supplement ODA and form a major source of foreign exchange. Many studies have illustrated the impact of migrant remittances on the economies of developing countries. Official recorded remittance flows to developing

¹³ Introducing personal histories, experiences or anecdotes in the marketing strategy of a company or organisation.

countries reached US\$325.5 billion in 2010, although it is likely that billions more were transferred through non-official channels (World Bank 2010). In certain cases, remittance transfers account for more than 20% of the GDP of receiving countries (40% in Eritrea, 20% in Lebanon, 31% in Tajikistan) (84).

Transfers of migrants' remittances are important fuelling factors for development, in that they provide receiving families with the money needed to buy food, health care and send children to school. Migrant remittances are also often used for local investments. Especially in situations of crisis or natural disasters, transfers from migrants increase, creating an extremely positive countercyclical impact (84).

Furthermore, migrants are considered a vulnerable group, migrants in the EU come from high endemic regions for HBV and HCV. Prevalence rates of HBV and HCV obtained from migrants are higher than obtained from general population surveys. However, so far the issue has received little attention (26). The encouragement of migrants' remittances destined to VH treatment might be an interesting tool to increase awareness among them.

Dedicated local, national or international taxes on specific commodities

The idea of collecting small contributions among multiple donors finds a means of implementation in dedicated taxes on specific commodities. This way a funding pot (e.g. rolling funds) is created with resources from specific new taxes (e.g. small amounts on each oil barrel, air ticket levy, tax on airline CO2 emissions or other commonly used commodities). Dedicated taxes can be considered as painless contributions that promote solidarity and responsibility. The

example of UNITAID(41) (see box) illustrates the advantages of collecting small amounts among multiple individual donors. They are different from taxes on sugar, tobacco and alcohol, in the sense that the latter encourage lesser consumption of the product rather than income generation for a specific charity goal.

UNITAID

An innovative voluntary solidarity movement

1. Micro tax levied for global health.
2. Inclusion of funds collected in low and middle income countries.
3. Leveraging market mechanisms.
4. Low per cent overhead costs.
5. Requires a simple effort from the individual donor.

Applicability to hepatitis C treatment

Crowdfunding: this is an increasingly popular way of raising money, usually for small projects. The example given above, Kiva, makes small-scale loans (typically US\$2–5,000) to entrepreneurs on behalf of online investors. This model, then, does not exclude market-based investments, nor does it exclude long-term projects with multiple beneficiaries. However, given the large number of such projects and the eye-catching nature of those which successfully spread their appeal via social media, any such project would need a strong and impactful means of gaining attention, while each successful appeal such as the 'ice bucket challenge' exhausts one more mode of presentation. The applicability of this model to HCV, as with the use of all 'micro' models for 'macro' problems, is doubtful. In particular, the nature of crowdfunding makes long-term budgeting hard to plan.

Migrant remittances, by their very nature, are unsuited to the funding of any 'public good'. They are aimed at family, relatives and perhaps friends, not public health projects for people unknown to the donor. Migrants from LMICs to high-income countries are rarely individuals of high net worth, at least initially, and therefore may be less likely to have surplus income available to devote to charitable purposes. In particular, great care is usually taken to avoid the taxation of remittances, and even if a government announced that it planned to use remittances to fund some useful social goal, it is uncertain whether this would be believed and how much it would reduce tax avoidance.

The taxation of 'sinful' activities in order to promote virtuous goals is widespread, but the hypothecation of tax revenues for specific ends is surprisingly rare. It may be that governments prefer to keep control over how they use their income. Whether dedicated taxes are considered to be painless depends on how immediately they affect consumer prices: for instance, a tax on CO2 emissions applied to airline profits might be resented less than a levy marked as part of an air fare. The main problem is that most 'sin taxes' have long been implemented and it may be difficult to find new ones which do not meet with resistance from either industry or consumers. An alternative would be for governments to devote a percentage of national income to a specific purpose, e.g. the UK government's international aid budget; but this would make funding depend on economic performance, and it would be hard to fit with a hepatitis C treatment model that required most of the funding up-front. It might be less complicated to persuade donor nations to simply fund hepatitis C treatment from their aid budgets, without the connection to any specific revenue stream.

Part 3 of this report (see graph 11) shows that knowledge about crowdfunding schemes is limited among organisations otherwise interested in the field of innovative finance, being reported by five out of 27 organisations surveyed; perhaps surprisingly, most of these were finance organisations. Knowledge of the use of taxation on specific commodities as a funding mechanism is even more limited, being reported by three organisations (none of them in the for-profit sector). It should be noted that there is no necessity for the bodies involved in crowdfunding campaigns to be the same bodies involved in local implementation projects. Larger institutions, possibly commercial ones with an interest in CSR, could potentially recruit for funds and disburse to implementers.

Table 10: small contributions from multiple donors: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> ✓ Long-term financial engagements. ✓ No additional costs for budget administration. ✓ Pooling of resources. ✓ Could be used as an awareness-raising tool. 	<ul style="list-style-type: none"> ⚠ Fragmentation of funding. ⚠ Difficult to estimate total (possible) budget. ⚠ Difficult to organize transparency and accountability to the individual investor (except for migrant remittances that go directly to a patient related to the donor).

8. PERFORMANCE-BASED FINANCING OR CONTRACTING

In performance-based financing of healthcare, health providers are, at least in some measure, funded on the basis on their performance, as opposed to the line-item approach, where financing is based on the provision of inputs (e.g. drugs, services, personnel). Many low-income countries have a health system where all functions (resource collection, pooling of funds, purchasing, regulation, provision, employment, drug supply, ownership of infrastructure and equipment, monitoring and evaluation) are centralized. Performance-based financing initiates a radical shift, by giving substantial decision rights over resources (i.e. autonomy) to organisational units. When health facilities are remunerated according to their outputs, consumers can vote ‘with their feet’. This makes it a powerful tool to improve health care services¹⁴, especially in combination with other patient empowering mechanisms as health insurance or micro-finance.

The Taskforce on Innovative International Financing for Health Systems (38), proposes specific formats for results-based financing, such as results-based credits and buy-downs related to the achievement of predetermined performance targets in order to reduce the cost of a loan if, for instance, a loan for a certain health MDG could be turned into a grant. Result-based credits and buy-downs contribute to strengthening the effectiveness of funding as it gives recipients of funds a motivation to achieve specific results. Result-based buy-downs have been implemented for polio eradication (86).

Applicability to hepatitis C treatment

The search for ‘value for money’ in public service provision has resulted in outcomes-based contracts being used routinely for the private provision of public services in developed countries, and the spread of this model to lower-income countries offers a way for lenders or donors to ensure appropriate use of funds. Some aspects of performance-based contracting have been considered earlier with regard to social impact investing and the use of PPPs. Benefits include the possibility of risk transfer from funders to investors

¹⁴ Performance-based financing, a catalyst towards comprehensive health care reform.

or implementers, making the latter more responsible for outcomes. The use of ongoing evaluation, outcome metrics and independent assessors may improve transparency. It may even save money, as it encourages governments to replace or reform existing programmes which cannot demonstrate improvement in social outcome, or at least encourage implementers to collect data to demonstrate programme effectiveness.

There are several ways incentives could be undermined if the outcome metric is poorly defined. First, the outcome metric may not be an ideal proxy for the actual desired social outcome. Secondly, if a target group is poorly defined in the ‘control group’ (e.g. ‘business as usual’ without the planned intervention) the metric may provide a distorted view of the outcome. Thirdly, payment-by-results might encourage an overly-narrow focus on the single outcome used to determine payment.

The risk-return balance must be carefully considered in such projects. Investors and providers have an incentive to develop too-easily-achieved outcomes. Governments and agencies may also do so, for instance if they strongly desire the success of a popular, promising, or theoretically appealing intervention. If the rewards are too generous, payers and eventually taxpayers may lose interest; on the other hand, If investors fail to make a profit, this will discourage future programmes.

Part 3 of this report (graph 11) shows that knowledge about performance-based schemes/ PPPs is widespread among organisations otherwise interested in the field of innovative finance, being reported by nine out of 27 organisations surveyed.

Table 11: performance based financing: summary of assets and risks

Assets	Risks
<ul style="list-style-type: none"> • Powerful tool to improves quality of health care. • Empowerment of the patient. • Needs management capacity building for units that hitherto were not involved in management tasks. 	<ul style="list-style-type: none"> • Coverage of expensive medicines remain problematic. • Private hospitals may compete public hospitals out of the market.

9. PUBLIC-PRIVATE PARTNERSHIPS

In 2010, the World Health Assembly passed a resolution calling on countries to ‘constructively engage the private sector in providing essential healthcare services’ (87). In countries where the public sector lacks the resources to provide universal healthcare coverage, it might seem obvious that public authorities may seek access to private capital or contract with the private sector to build infrastructure or provide services. However, the development of PPPs has so far been pioneered by high-income countries as a means of bringing competition into the public sector. In the UK, for example, PPPs are a tried and tested means by which major industries provide public infrastructure, receiving traditional

sources of finance from well-established financial markets, and with government contracts making the risks involved low enough to attract such finance.

In a typical PPP project, a Special Purpose Vehicle (SPV) manages and finances the design, construction and operation of a new facility. The financing of the initial capital investment is provided by the owners of the SPV together with lending institutions. Repayment is made through a periodic charge paid by the public authority over the lifetime of the facility. The charge may, to some extent, depend on outcomes: e.g. if there is a delay in construction, if the facility is not fully operational, or if services fail to meet agreed standards (88).

In theory, this not only transfers risk to the private sector but also encourages timely delivery, since the SPV is not paid until the asset has been delivered. This is a major attraction in view of the delays and cost overruns often involved in public sector infrastructure projects. Nevertheless, if the public sector is inexperienced in private contracting money may be wasted rather than saved. Examination of UK PPP projects has shown that in some cases government could have spent less by borrowing directly from the capital markets rather than through an SPV intermediary, and although it is often assumed that the costs of construction, maintenance and services will be cheaper where PPP is used, this is not always the case. Risk transfer needs to be carefully designed to avoid this (89).

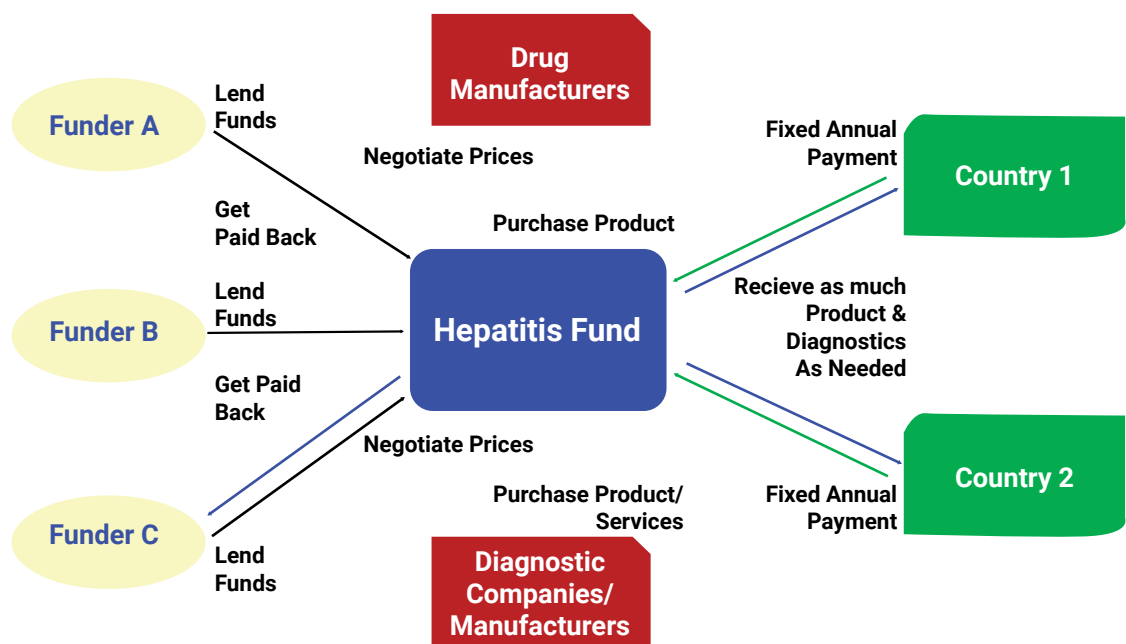
Because PPP contracts have typically been used to fund infrastructure projects, they often depend on a simple model of payment-by-results in which the 'outcome' measured is the delivery of (for instance) a hospital. Although there have been moves towards outcomes-based contracts (e.g. lower maintenance payments if a hospital is under-used), the vast majority of the borrowing finances an asset which is normally delivered after a few years of a contract several decades in duration. Cost and time overruns are therefore obvious. SPVs are usually set up and owned by one of the larger construction groups; finance is then obtained from the banking sector which is already well-placed to provide large-scale investment to the construction sector (88).

Newer models of finance, like the SIB for hepatitis C treatment (figure 6) (73) may need to be used for non-infrastructure PPPs in order to allow more sophisticated outcomes measurement and more flexible assignment of risk. Most development in this area has been in the area variously referred to as 'payment by performance', 'payment for success', 'social impact bonds' or 'human capital performance bonds'.

A proposal comparable to the SIB fund model presented by Rob Walton and Angelos Hatzakis was made by Homie Razavi at the EU HCV Summit in Brussels on 17 February 2016(90). Figure 6 illustrates the potential workings of a Hepatitis Fund in Europe, which would address the central issue facing HCV elimination: how to pay for it now and recover investment later(91).

Figure 6: A potential Hepatitis Fund in the EU

Hepatitis Fund: The fund will negotiate & purchase products/services & provide it to countries in return for a fixed annual payment



The funders are not donating money. They are loaning funds that will be paid back in the following 10-15 years.

What these funds have in common is that investors and the intermediary are paid by performance if the programme delivers the desired social outcomes in the long term; the use of ongoing evaluation, outcome metrics and an independent assessor improve transparency. As well as matching up timeframes between investors (who need a suitable period to investment maturity) and governments (who can estimate the time needed to eliminate HCV), this approach may also help bring together different government agencies, e.g. the body which pays for hepatitis C treatment and the bodies which will save money in the future through improvements in public health and economic activity.

Applicability to hepatitis C treatment

A 'Hepatitis Fund' with the characteristics listed above could either be global or country-specific. In either case it would involve an SPV managing funds from donors, market-based investors or a mixture of both, and making loans either to countries or to local implementers (depending on the countries' capacity or willingness to provide central management). Levels of repayment would depend on outcomes achieved, in such a way that, if outcomes are as expected, the fund would be attractive to large-scale investor institutions. The SPV itself, if non-profit, could act as an outcomes assessor, fix rates of return and negotiate contracts with other parties. A key lesson learnt from competitive tenders for SIBs is the resource-intensive nature of contracting and performance management(92). Preparing for this process would involve building relationships with possible partners and experts in legal,

finance, statistics and social policy who could assist with a proposal.

Part 3 of this report demonstrates that, for the surveyed organisations which agreed that innovative funding mechanisms have a role in healthcare, PPPs were seen as the most suitable innovative finance mechanism for supporting public health (12 organisations), followed by grant funding (9 organisations). Venture capital/private equity, subordinated loans and health insurance (6 organisations each) were seen as the next most suitable methods (see Q11). In particular, the financial services organisations surveyed were overwhelmingly in favour of a role for private provision within healthcare (see graph 17), believing that private provision or funding is important either as a means of funding/supporting universal healthcare, or necessary (or even more efficient) as a means of securing universal coverage. This interest on the part of regional financial groups could be channelled towards PPP projects.

Charitable, CSR or philanthropic groups envisioned less of a major role for the private sector, but the majority still agreed that private provision of funding or support had a part to play in the provision of free, universal healthcare. A majority of organisations (21 of 26) were 'in favour' or 'very much in favour' of using innovative finance mechanisms to achieve universal hepatitis C treatment. Graph 19 gives an overview of the opinions of respondents on this item by type of organisation, and it can be seen that non-profit organisations were almost as enthusiastic as the financial sector.

On the basis of the proven track record of PPP in large-scale project funding, and the promise of recent developments in outcomes-based financing, the recommendation section of this report will suggest a future emphasis on the development of non-infrastructure PPPs as a suitable way to bridge the funding gaps in hepatitis C treatment.

10. CONCLUSION

The implementation of the WHO targets to control VH on a global level by the year 2030 demands an estimated yearly budget starting at US\$2 billion in 2016 and rising to US\$8 billion in 2020, peaking at US\$11 billion in 2025, and thereafter descending to US\$9 billion in 2030. It goes without saying that to mobilize these resources the global community will have to undertake serious and urgent steps. Experience in other sectors, however, show that this mission is not impossible. Since the financial crisis of 2008 (and even before), various innovative ways of funding have been tested and deployed in the public and private sectors and in international development. These initiatives, sometimes small, sometimes larger in scale, could serve as an inspiration to all stakeholders involved in suppressing the HBV/HCV epidemics. This report explored a range of these mechanisms and their feasibility for deployment in the area of prevention and treatment of hepatitis B and C in LMICs.

Some mechanisms have a proven track record, such as creating a specific funding body (UNICEF, GAVI, etcetera). A specific funding body mobilizes both financial and human capital towards one concern and is therefore well placed to move the topic higher on the international agenda. Furthermore, the creation of a specific body can facilitate local or regional initiatives.

Health insurance and certain mechanisms to influence the price of medicine, a common good in high-income countries, are underused in LMICs, where out-of-pocket payment can be high and often prevents people from seeking treatment. Adapted versions (micro-health insurance, health savings accounts and mechanisms that involve price negotiation) focus on the particular merit of these instruments, like strengthening financial protection of patients and empowering individuals. A particular instrument, the regional tables for negotiating prices brings together, sometimes opposing, stakeholders to reflect on the common goal to increase patients' access to health.

With the growing pressure on donors to conserve resources and raise development effectiveness, governments have been looking for new financing models such as performance-based financing. This initiates a radical shift in healthcare management in those countries, by giving substantial decision rights over resources to organisational units. Performance-based financing could go together with social impact investments (e.g. venture philanthropy, social impact bonds, social franchising, health cooperatives) in order to alleviate the strain on government and this may attract private sector capital that would otherwise not be used for social purposes.

Another source of funding in the private market could come from companies that want to start or extend their corporate social responsibility (CSR) activities in the form of grant-giving or perhaps in PPPs. In LMICs the potential of involving local companies in CSR activities is far from exhausted. In countries with high HBV/HCV endemicity, local companies could be convinced of the benefit of prevention and treatment for their employees and hence for productivity.

Finally, collecting relatively small contributions from multiple donors by means of

crowdfunding, dedicated taxes on specific commodities and migrant remittances, may combine the advantage of pooling resources with awareness raising on the topic for which the resources are mobilized.

Innovative financing has major possibilities in the health sector in LMICs. Part 3 of this report will explore funders' experiences and knowledge of innovative funding mechanisms and what is needed to present HBV/HCV as a convincing case for them to deploy innovative funding.

PART 3: STAKEHOLDER LISTING AND PERCEPTION ANALYSIS

Given the urgency of treating the worldwide hepatitis C epidemic, and the costs which national health systems would suffer in the long run if it were to be ignored, it is vitally important for new methods of funding to be devised in order that the benefits of early and systematic care can be gained for people living with the virus, governments, health service systems and tax-payers.

It is especially unfortunate that the prevalence of HCV infection appears to be especially high in a high proportion of LMICs. However, the impact of globalised financial investment on LMICs still working their way towards universal healthcare coverage provides opportunities as well as challenges. It is likely that these countries may not only have more need of innovative models for healthcare provision, but also have more scope to implement them than countries in Western Europe where preferences in healthcare provision may have already become entrenched.

Whilst finance institutions work in a broad range of healthcare settings, much more could be done to develop sector wide understanding of the challenges society face in tackling hepatitis C and the clear economic benefits of doing so. Opportunities exist for some in the hepatitis C community to engage more closely with the financial community as it exists in LMICs. Such opportunities should be seized with both hands if the rising tide of hepatitis is to be rolled back within a generation.

This part of the report identifies and analyses the opinions of existing and potential funders of innovative mechanisms of healthcare provision in a selection of LMICs¹⁵ with a particular focus on the treatment of hepatitis C. They are largely multi-national or supra-national bodies which have an interest in the financing of healthcare whether for-profit institutions or 'social investors'.

¹⁵ Armenia, Bangladesh, Benin, Brazil, Egypt, Ghana, India, Indonesia, Moldova, Mongolia, Morocco, Nigeria, Uzbekistan and Vietnam.

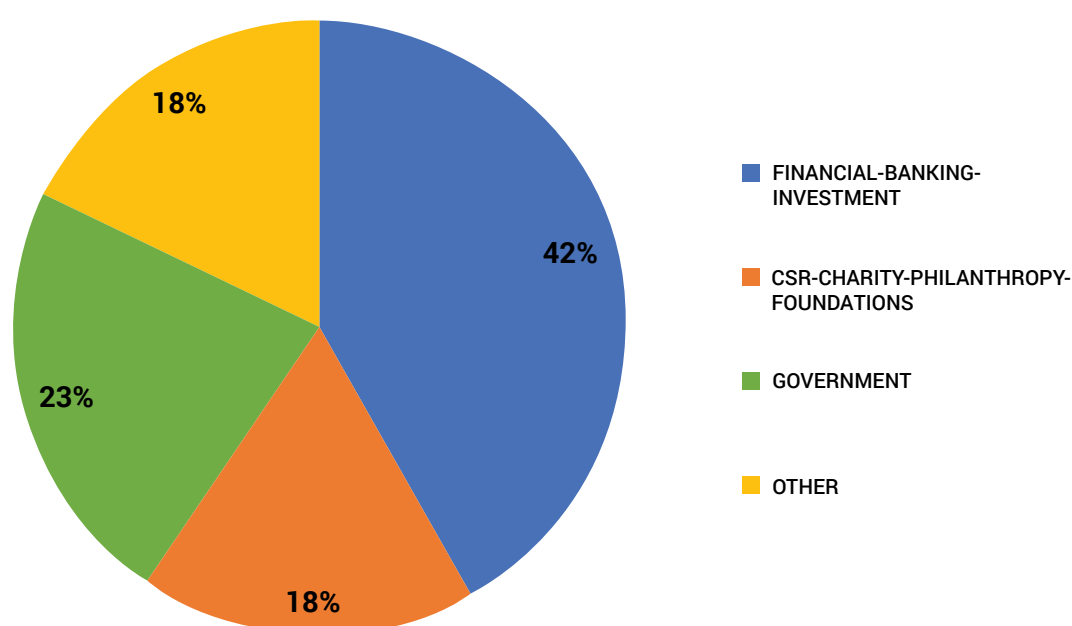
1. STAKEHOLDER MAPPING AND LANDSCAPE

A desk research¹⁶ resulted in a list of 265 organisations¹⁷ that are active in (one or more of) the selected countries. Stakeholders were grouped in four categories based on their primary activity: 1) CSR/Charity/Philanthropy/Foundations; 2) Financing/Banking/investment; 3) Government; and 4) Other. Table 12 and graph 2 show the division of organisations according to their primary activity. 111 (42%) are involved in financial activities. The second largest response was from government organisations (60, 23%), followed by CSR/charity/philanthropy organisations (48, 18%). This proportion is also reflected in the number of organisations completing both telephone and online surveys.

Table 12 : division of organisations according to primary activity

	CSR-CHARITY-PHILANTHROPY-FOUNDATIONS	FINANCING-BANKING-INVESTMENT	GOVERNMENT	OTHER	TOTAL
Number of mapped organisations	48	111	60	46	265
Number of phone interviews	8	14	3	8	33
Number of online surveys	8	12	4	3	27

Graph 2: division of organisations according to primary activity (% , N=265)

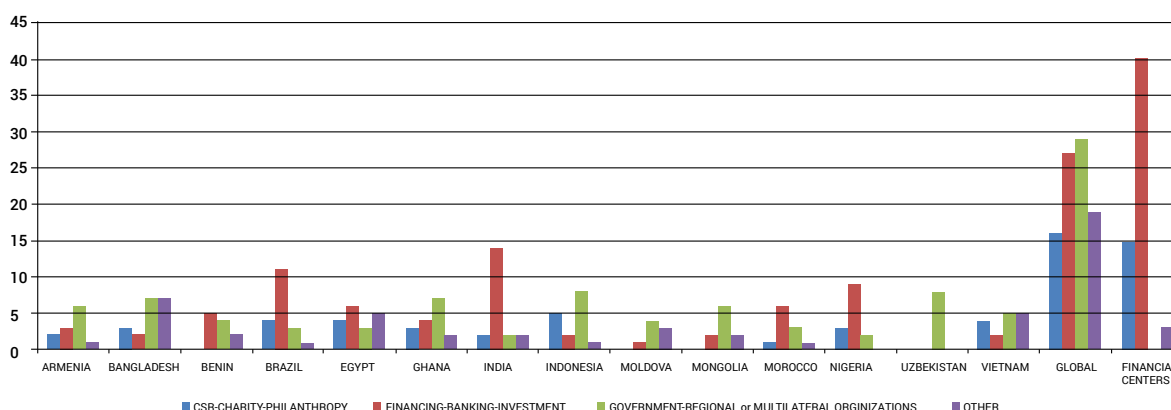


¹⁶ Appendix 4 describes the methodology used.

¹⁷ Appendix 1

Graph 3 shows the spread of organisations across the range of countries. This was based on the results of the Boolean searches (see appendix 4) and therefore indicates that the use of the array of search terms led to the identification of these organisations as actors within the countries listed; in other words, it is not necessarily an exhaustive list of the countries in which these organisations work.

Graph 3: spread of organisations across the range of countries (N=265)



It is clear that each of the identified countries has multiple types of organisation investing or working on projects in these areas. Financial organisations have a higher presence in Brazil, India and Nigeria than other types of organisation. Government organisations and non-profits have a higher presence in Bangladesh than others do, and the only type of organisation working in Uzbekistan are government organisations.

Networks identified

The desk research process revealed a number of links and affiliations between organisations. Not all organisations state affiliations or links on their websites, but among those that do, there is crossover and there are common themes arising. By means of example, table 13 lists 9 organisations with more than five affiliations mentioned on the website.

Some organisations such as the African Development Bank (AfDB), the Australian Agency for International Development (AUSAID), the World Bank, Rotary International and the Global Fund list links with health funds and programmes such as the Joint United Nations Programme on HIV/AIDS, GFATM or to partnerships in diseases, vaccines and immunisation. Indirect links to health, for example organisations involved in infrastructure, those that focus on water and sanitation, are also found.

The desk research did not find affiliations between stakeholders and specific hepatitis-related organisations, e.g. none stated a link to the WHA, an international umbrella of non-governmental organisation (NGO) with over 220 organisation members covering all regions of the world. This does not indicate lack of involvement, just that the links were not declared on the websites of the organisations that were reviewed.

Table 13: Organisational links indicated on the stakeholder's website

Organisation name	Organisational links shown on organisation's website
African Development Bank (AfDB)	<p>International organisations:</p> <ul style="list-style-type: none"> • United Nations Organization (UN) • United Nations Educational, Scientific and Cultural Organization (UNESCO) • United Nations Population Fund (UNFPA) • World Health Organization (WHO) • Joint United Nations Programme on HIV/AIDS • United Nations Development Programme (UNDP) • United Nations Children's Fund (UNICEF) • International Labour Organization (ILO) • Food and Agriculture Organization (FAO) • World Food Programme (WFP) • International Fund for Agricultural Development (IFAD) <p>Multilateral Development Banks:</p> <ul style="list-style-type: none"> • World Bank (WB) • International Monetary Fund (IMF) • International Finance Corporation (IFC) • Inter-American Development Bank (IaDB) • Asian Development Bank (ADB) • European Bank for Reconstruction and Development (EBRD) • Islamic Development Bank (IsDB) • Regional bodies: <ul style="list-style-type: none"> • Southern Africa Development Community (SADC) • Common Market for Eastern and Southern Africa (COMESA) • Economic Community of West African States (ECOWAS) • Economic Community of Central African States (ECCAS) • Arab Mahgreb Union (AMU) • Intergovernmental Authority for Development (IGAD) <p>European Commission:</p> <p>The African Development Bank (AfDB) and the European Commission (EC) are partners in the EUAfrica Infrastructure Trust Fund, the Infrastructure Consortium for Africa and the African Water Facility.</p> <p>Microsoft:</p> <p>The African Development Bank (AfDB) Group and Microsoft signed a Memorandum of Understanding (MoU) in 2008 to work together to increase access to Information and Communication Technology (ICT) for all Africans.</p>

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- | | |
|---|---|
| Australian Agency for International Development (AU-SAID) | <ul style="list-style-type: none"> • United Nations Development Programme (UNDP) • United Nations Children’s Fund (UNICEF) • Gavi, the Vaccine Alliance • Global Fund to fight AIDS, Tuberculosis (TB) and Malaria • Global Partnership for Education • Global Environment Facility • Green Climate Fund • Global Partnership on Output-Based Aid |
|---|---|

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|--|--|
| Black Sea Economic Cooperation Organization (BSEC) | <ul style="list-style-type: none"> • United Nations (UN) • United Nations Economic Commission for Europe • United Nations Development Programme (UNDP) • United Nations Environment Program (UNEP) • United Nations Industrial Development Organization (UNIDO) • United Nations Food and Agriculture Organization (UN/FAO) • World Bank • World Trade Organization • Energy Charter Secretariat • Eurasian Economic Community (EAEC) • Intergovernmental Commission • Traceca |
|--|--|

- | | |
|-------------|---|
| Global Fund | <ul style="list-style-type: none"> • Product (RED) • Bill & Melinda Gates Foundation • Chevron • BHP Billiton Sustainable Communities • Takeda Pharmaceutical Company Limited • Goodbye Malaria • Comic Relief • Vale • United Methodist Church and • Lutheran Malaria Initiative • United Nations Foundation • Gift from Africa • United Against Malaria • Standard Bank |
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Pharma Access

Donors:

- The Dutch Ministry of Foreign Affairs
- Dutch Aids Fonds
- PEPFAR: US President's Emergency Plan for AIDS Relief
- STOP AIDS NOW!
- NWO (Netherlands Organisation for Scientific Research/ WOTRO Science for Global Development)
- United States Agency for International Development (USAID)
- World Bank
- International Labor Organization (ILO)
- Kwara State Government

Partners:

- PSI
- The Clinton Health Access Initiative (CHAI)
- Therapeutics Research, Education and AIDS Training in Asia (TREAT Asia)
- Marie Stopes International
- KMET
- World Bank
- The Brooking Institution, Washington DC
- Amsterdam Institute for International Development (AIID)
- Amsterdam Diner Foundation
- Hygeia
- AAR
- Medilink
- Council for Health Service
- Accreditation of Southern Africa
- Joint Commission International
- North Star Alliance

Program for Appropriate Technology in Health (PATH)

- BHP Billiton Sustainable Communities
- Exxon Mobil
- Medtronic Philanthropy
- Merck for Mothers
- Microsoft
- Sanofi
- Tableau
- Urbano Agroindustrial

<p>Rotary International</p>	<ul style="list-style-type: none"> • Bill & Melinda Gates Foundation • Centers for Disease Control and Prevention (CDC) • Global FoodBanking Network • ShelterBox • UNESCO-IHE • UNICEF • United Nations • World Health Organization
<p>World Bank</p>	<ul style="list-style-type: none"> • Onchocerciasis Control Program (OCP) • Global Alliance for Vaccines and Immunization (GAVI) • Consultative Group for International Agricultural Research (CGIAR) • The Carbon Fund • Global Environmental Facility (GEF) • Roll Back Malaria • Consultative Group to Assist the Poor (CGAP) • Joint United Nations Programme on HIV/AIDS • Financial Sector Reform and Strengthening Initiative (FIRST) • Education for All • Global Water Partnership (GWP) • Infodev • Global Development Learning Network (GDLN) • Haiti Reconstruction Fund (HRF) • Harmonization for Health in Africa (HHA) • Stolen Asset Recovery Initiative (StAR) • Water and Sanitation Program (WSP) • Global Partnership on Output-Based Aid (GPOBA)
<p>World Health Organization (WHO)</p>	<ul style="list-style-type: none"> • Roll Back Malaria • Partnership for Maternal, Newborn and Child Health • Alliance for Health Policy and System Research • Global Health Workforce Alliance • UNITAID • European Observatory on Health Systems and Policies • UNAIDS • United Nations International Computing Centre • Special Programme on Research and Training in Tropical Diseases • Special Programme of Research, Development and Research Training in Human Reproduction • African Programme for Onchocerciasis Control • Global Polio Eradication Initiative

2. FUNDERS' INSIGHTS, RESULTS OF TELEPHONE SURVEYS

A total of 33 surveys were completed by telephone. 14 of these (42%) were answered by financial organisations, 8 by CSR/charity/philanthropy organisations, 3 by government organisations and 8 by organisations classified as 'other'.

Scope of the organisation

Q2. Does your organisation play any role in funding or providing healthcare or public health programmes? Whether private or public.

18 individuals (58% of respondents) surveyed confirmed that their organisation did play a role in funding or providing healthcare or public health programmes, 4 said that they played an indirect role, and 11 said that they did not play a role in funding or providing healthcare or public health programmes.

Q3. Does your organisation have a social investment or philanthropic arm?

19 survey respondents (58%) confirmed that either their organisation had a social investment or philanthropic arm, or that social investment or philanthropy was the principal function of their organisation, rather than an 'arm' or department. Two additional respondents indicated that their organisations were 'intermediaries', managing social investments on behalf of clients, rather than having a dedicated internal department. 12 organisations did not have a social investment or philanthropic arm.

12 organisations were involved in both health funding and social investment.

Understanding the budgets that are available

Q4. Are you able to disclose your organization's approximate annual budget?

There were a range of responses to the budgetary questions, with several respondents unable to provide the appropriate information. 7 respondents disclosed their organisation's approximate annual budget, or the total sum of investments managed by their organisation (table 14). Other respondents were either not able to disclose their organisation's budget, did not have the relevant information, or did not feel the question was applicable to their organisation. Several of these were investment funds who did not have their own budget as such, but managed the funds of clients.

Table 14 : Organisation's budget

Organisation type	Annual budget (currency cited)	Annual budget (EUR)*
Financing-banking-investment	1 million US\$	915,470 EUR
Financing-banking-investment	20 million US\$	18,309,400 EUR
Financing-banking-investment	2015 budget: 190K US\$ 2016 budget: 450K US\$	2015 budget: 173,939 EUR 2016 budget: 411,961 EUR
CSR-charity-philanthropy-foundations	1 million US\$	915,470 EUR
CSR-charity-philanthropy-foundations	85 million Nigerian naira (NGN)	390,784 EUR
CSR-charity-philanthropy-foundations	1.5 million Brazilian Real (BRL)	349,350 EUR
CSR-charity-philanthropy-foundations	5 million EUR	5 million EUR

[1 US\$ = 0.909604 EUR; 1 EUR = 1.09938 US\$; 1 NGN = 0.00457510 EUR; 1 EUR = 218.574 NGN. Date of conversion: 15th December 2015.]

Q5. Of this budget, approximately how much is directed towards social investment purposes? How much towards healthcare? Is there an overlap?

Responses to this question varied according to the nature of the organisation. Some respondents did not have the necessary information to answer this question, while others directed us to their website.

- A significant proportion of the annual budget for most of the charities or non-profits questioned is directed towards social investment purposes or healthcare or both
- Some respondents from investment funds felt the question was not applicable to their own organisations, so their answers were based instead on their clients' budgets and the funds they managed

Table 15 : Organisation's budget

Organisation type	Proportion of budget directed to social investment	Proportion of budget directed to healthcare	Overlap in budget?
Financing-banking-investment	Not cited	6%	Not cited
CSR-charity-philanthropy-foundations	40%	0%	Not cited
Financing-banking-investment	100%	0%	Not cited
Financing-banking-investment	100%	Not cited	Not cited
Financing-banking-investment	100%	0%	Not cited
Other	Not cited	100%	Yes (no specifics)
Financing-banking-investment	100%	2015: 10% 2016: 20-25%	According to healthcare budget
Other	100%	30%	According to healthcare budget
CSR-charity-philanthropy-foundations	Not cited	>50%	No
Financing-banking-investment	100%	Not cited	Not cited
CSR-charity-philanthropy-foundations	Not cited	100%	Not cited

Investment criteria and priorities

Q6. What are your organization's main priorities when deciding how and where to invest?

Organisations cited a range of priorities when deciding how and where to invest, which have been categorised into the themes below (table 16). Some organisations indicated

the funds or clients they work with, rather than their own organisation’s budget. Other organisations emphasised that their priorities were decided or influenced by other actors, e.g. governments or the UN.

Table 16 : Investment priorities

Priority	No of organisations	Details
Social impact	8	<ul style="list-style-type: none"> • Direct investments towards companies or projects that provide some kind of social return to low income groups or underserved populations eg employment or livelihood generation, public health programmes, legal support • Sustainability of impact eg improve quality of life • Scale of impact, for example numbers of jobs created • The ‘bottom of the pyramid’ (BOP) market, and using IRIS metrics to measure social impact within this market. One crowd funding platform has a mandate of impacting approximately 1 million people over the next two years, based on these metrics

Financial viability and sustainability	6	<ul style="list-style-type: none"> • Whether a project or organisation is credit-worthy and/or profitable, and whether the recipient will have the ability to pay back loans • Transparency of the companies or programmes being invested in, as well as a sense of how well customers or recipients of programmes might be treated e.g. specifically regarding microfinance, ensuring that less educated borrowers are not being taken advantage of • The financial sustainability of a project, including whether the benefits generated by the outcome of a programme are greater than the cost of actually delivering the programme • Assessing sustainability through developing strong relationships with investee organisations or programmes, conducting due diligence with regard to the particular social issue, working collaboratively with different parties, using KPIs, and maintaining a strategic overview on the investment
Geography	3	<p>The organisations surveyed specifically mentioned their own focus areas:</p> <ul style="list-style-type: none"> • Sub Saharan Africa (low income countries) • Nigeria and Malawi • India (health)
National Priorities	4	<ul style="list-style-type: none"> • Priorities based on donor government or recipient government priorities • Distribution of funds to UN organisations which then decided their own focus
Health	3	<p>The organisations surveyed specifically mentioned their own focus areas:</p> <ul style="list-style-type: none"> • Sole focus on hepatitis, in particular on running impactful vaccination, prevention and care programmes at the grassroots level • Investments with an impact on the health-care system in India • Research and development for diseases that affect lower and middle income countries

Specific interest areas	3	<p>Non-health focus:</p> <ul style="list-style-type: none"> Education, entrepreneurship, investing in small and medium sized businesses, early childhood development, early childhood learning opportunities, secure families, community engagement and racial equality
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Q7. What types of information would your organization require before deciding to participate/invest in a social investment project in the field of healthcare? What criteria do you use in order to select projects?

The criteria required by most organisations before participating or investing in a social investment project in the field of healthcare can largely be categorised into financial criteria (table 17) and social impact criteria (table 18):

Table 17 : Financial criteria for investment

Criteria	No of organisations	Details
Business plans	4	<p>Business plans, models or portfolios that demonstrate a number of criteria</p> <p>The capacity of an organisation to be able to do the work and deliver the project</p> <p>Financial viability, the potential to scale, the potential for foreign investments</p>
Financial viability	4	<p>Financial profile of the company, the strength of its ownership and management team, how the company or organisation is positioned within its sector, and the level of financing required</p>
Financial sustainability	3	<p>Applies particularly when organisations are looking to invest overseas.</p> <p>Sustainable financial model</p> <p>Currency risk, political risk, risk of bribery and corruption</p> <p>Reputational risk for the investor</p>

Financial return	1	Loans: near market rate or market rate returns Equity investment: would expect to take ownership in the organisations they were investing in, and expect a return upon exiting the organisation
Market studies	1	In order to assess the value of a programme or project, some investors would want to carry out market studies and field studies, through focus groups, client discussions in the field, and survey based research
Due diligence and feasibility studies	3	Examples included: Investigating an organisation’s environmental impact, accounting, tax liabilities, labour relations A detailed year-long due diligence project before embarking on any new investment, which begins with making sure that the social mission of the programme is aligned to pure financial information and information about future plans Due diligence of several months which includes evaluating the data or evidence on the subject area, and considering this in the context of the needs of the demographic involved

Table 18 : Social criteria for Investment

Criteria	Number of organisations	Details
Tangible local outcomes	5	The reach and scale of a programme, for example how many people it would be supporting In terms of healthcare, impact metrics cited included the number of patients being seen and the number of examinations conducted

Value of solution	2	<p>Want to know that the solution being offered by a project was significantly better or disruptive in comparison to incumbent offers in that field</p> <p>The social issue itself would need to be more pressing than other problems that they could invest in solving instead. If their target population was particularly affected by a specific issue, investors might be more likely to consider addressing it</p>
Community context	2	<p>A non-profit working in hepatitis would expect to see information that demonstrates an understanding of the community that the programme would operate in, in particular the local prevalence rate</p> <p>One organisation would consider the visibility of a project within a local area</p>
Bottom of the pyramid (BOP)	1	<p>Some organisations said that they would only consider a project that had an intentional impact on 'bottom of the pyramid' (BOP) communities</p>

“ We want to advocate for people living with hepatitis to get free treatment, subsidised. We want government, we want NGOs, we want international bodies to be able to fund it and save the lives of people living with hepatitis.”

– CHARITY ORGANISATION WORKING GLOBALLY

3. FUNDERS' INSIGHTS, ONLINE SURVEY RESULTS

27 online surveys were completed by representatives of a range of different organisation types. 10 organisations completed both the online survey and the telephone survey.

12 finance organisations, 8 CSR/charity/philanthropy organisations, 4 government organisations and 3 organisations classified as 'other' completed the survey.

Scope of organisations surveyed

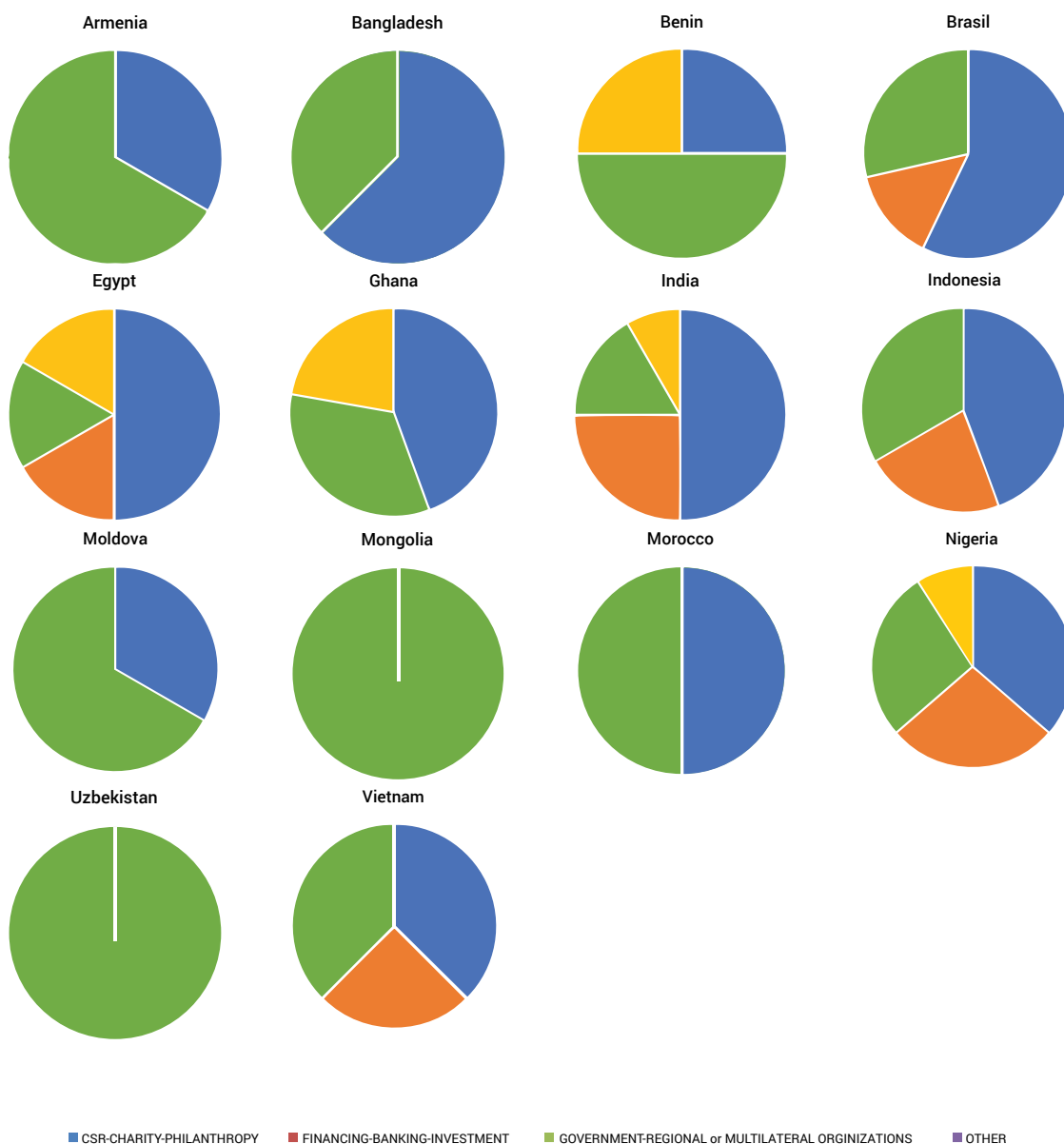
Q2. In which of these LMICs does your organization work?

Charts are shown on the next page (graph 4), indicating types of organisations in the survey that work in each country. In Mongolia and Uzbekistan only government stakeholders were reported as being present. Graph 2 (stakeholder mapping) shows a similar image for Uzbekistan though not for Mongolia, where also financing and other organisations are operating.

Graph 3 shows that for Armenia, Bangladesh, Morocco and Moldova only government agencies and financing organisations participated in the survey. CSR and other organisations, however, do work in the first three countries. In Moldova, next to the organisation types that participated in the survey, also other organisations are found.

For the other countries (Benin, Brazil, Egypt, Ghana, India, Indonesia, Nigeria and Vietnam), at least three types of organisation, responded to the survey.

Graph 4: spread of organisations across the range of countries (N=27)



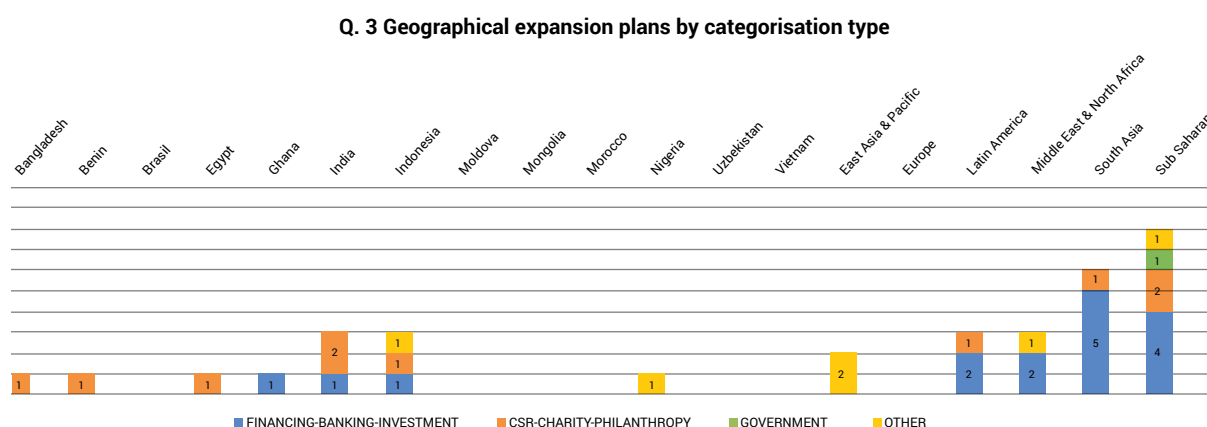
Q3. Do you have plans to expand into any other countries/regions within the next 5 years?

27 online surveys were completed by a range of different organisation types. Graph 5 shows the spread of organisation types across the range of countries.

The following specific countries were mentioned with regard to desired expansion in the next 5 years; Bangladesh, Benin, Egypt, Ghana, India, Indonesia and Nigeria. 8 organisations plan to expand into Sub Saharan Africa in the next 5 years, 6 into South Asia, 3 into Latin America, 3 into Middle East & North Africa. 10 organisations stated 'none of the above', 3 other.

No particular pattern can be observed from this data, other than to note that expansion is planned into regions of lower- and middle-income.

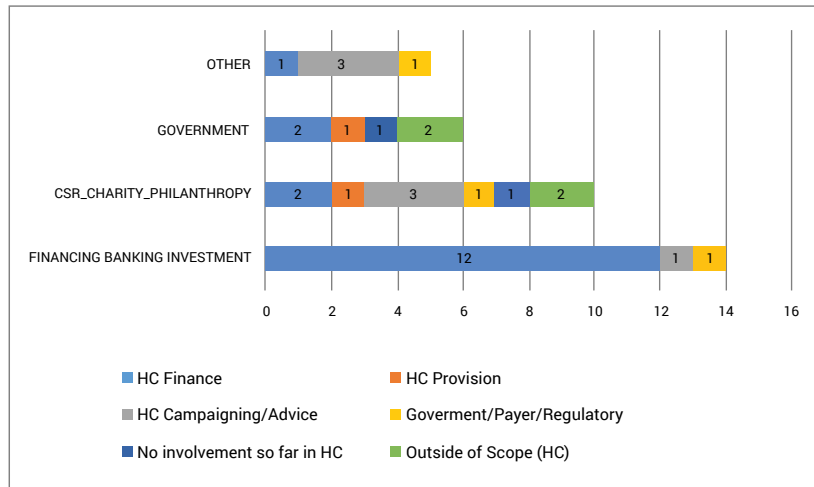
Graph 5: spread of organisation type across the range of countries (N=27)



Q4. What involvement does your organization have in healthcare?

Of the 27 organisations which responded to the survey, 17 are involved in healthcare financing, 2 are involved in provision of healthcare, 7 are involved in campaigning/advice and 3 are involved in a government/payer/regulatory capacity. 5 organisations are involved in more than one aspect of healthcare.

Graph 6: Involvement in healthcare by organisation type (N=27)

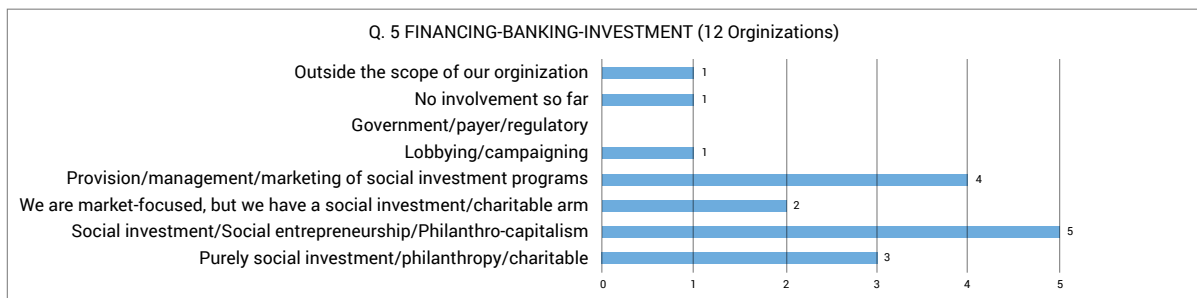


Overall this indicates that the surveyed organisations do have an interest in healthcare and have existing financing or projects in progress in the sector. This suggests that they would be likely to consider investment or involvement in further projects in the area of health.

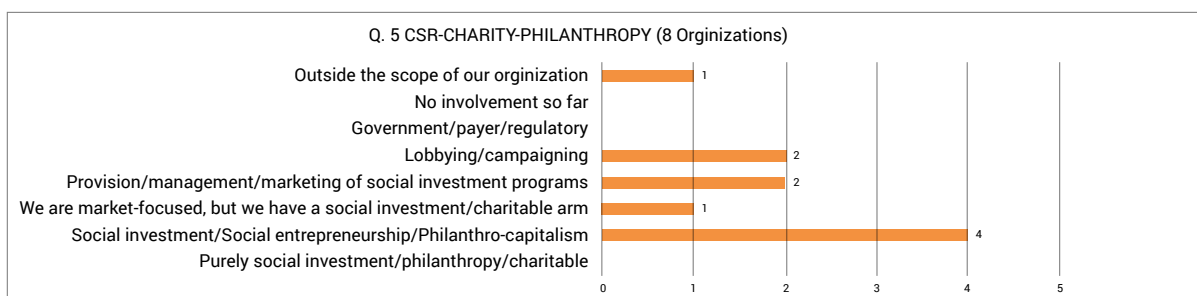
Q5. What involvement does your organisation have in social investment?

Data shows a general involvement in social investment. Graphs 7-10 give an overview of the involvement in social investment by organisation type.

Graph 7: Involvement of finance organisations in social investment (N=12)



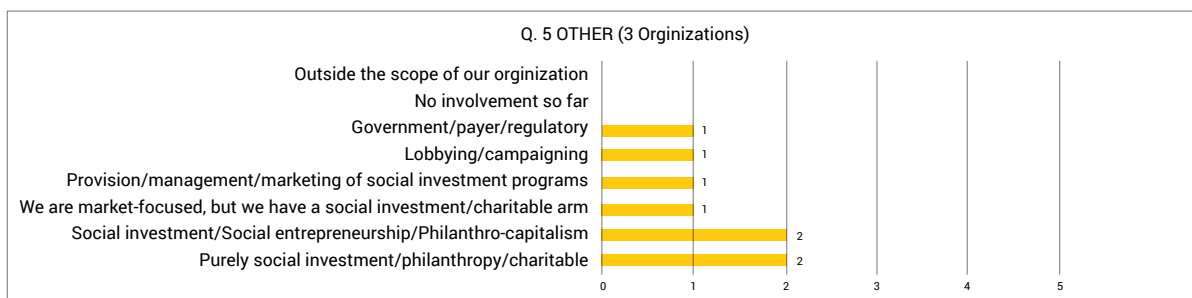
Graph 8: Involvement of CSR/charity/philanthropy organisations in social investment (N=8)



Graph 9: Involvement of government organisations in social investment (N=4)



Graph 10: Involvement of 'other' organisations in social investment (N=3)



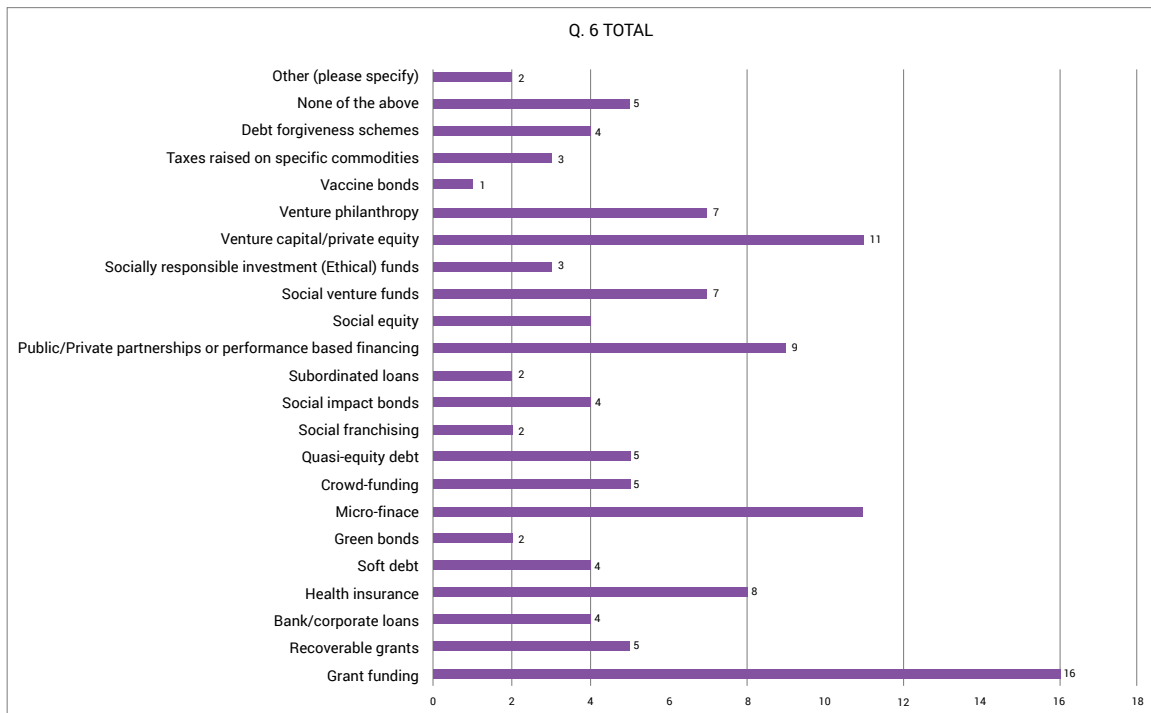
Of the 27 organisations that responded to the survey, 11 (40%) are involved in social investment, 7 are involved in provision or marketing or social investment and for 6 organisations, social investment/philanthropy/charitable activities are their primary focus. 6 organisations are involved in more than one of the aspects of social investment mentioned. CSR/charity/philanthropy and financial organisations are generally involved in multiple types of social investment.

Knowledge of innovative funding mechanisms in healthcare

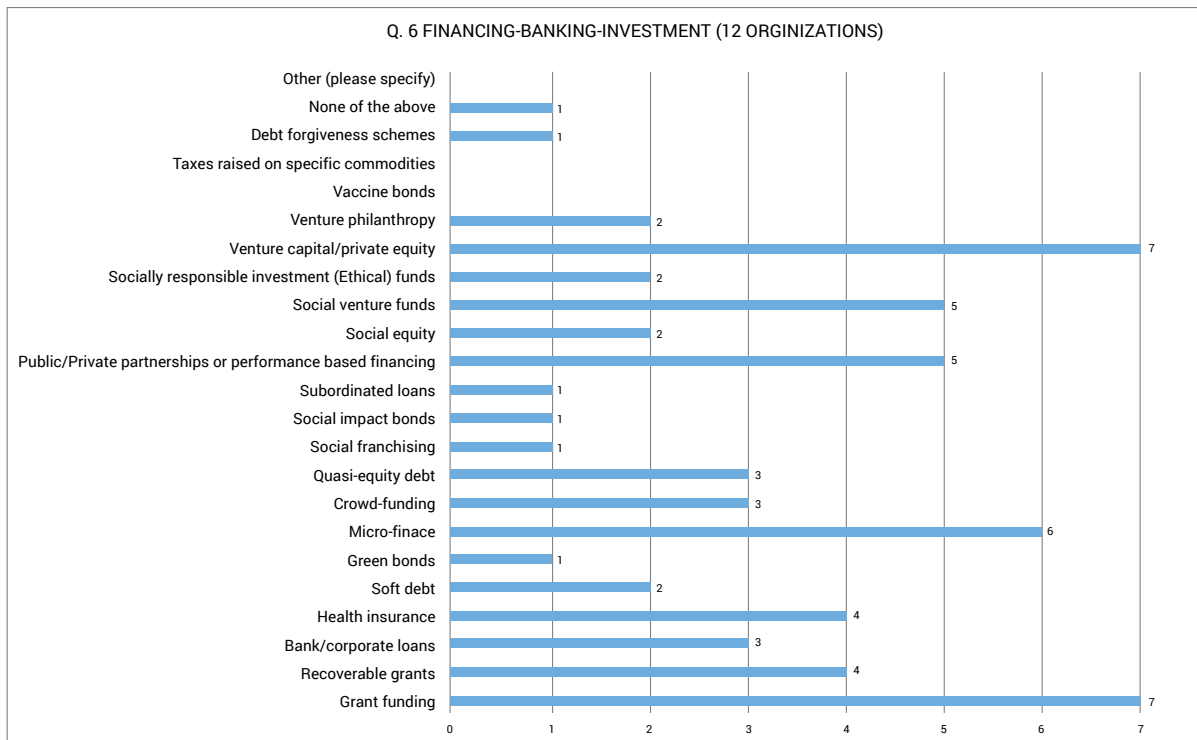
Q6. Do you know of innovative funding mechanisms that are in place/planned for healthcare projects in the countries where your organization works?

The funding mechanism most frequently known by the organisations surveyed is grant funding (16 organisations; 59%), 11 organisations are aware of micro-finance and venture capital. Public-private finance partnerships or performance-based funding are known to 9 organisations. Contrary to respondents from government agencies, who are familiar with only a small number of innovative funding mechanisms, knowledge about diverse mechanisms seems to be higher among respondents from financing CSR and other organisations (graphs 11 - 15).

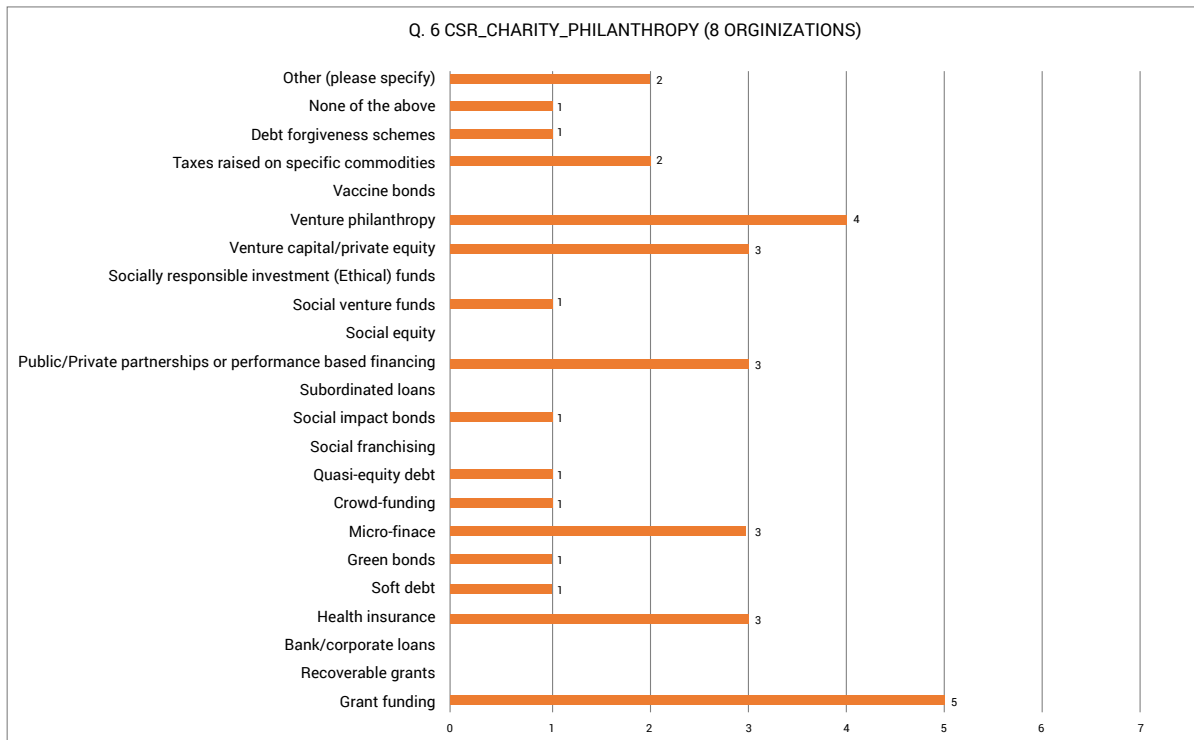
Graph 11: Knowledge of innovative funding among organisations surveyed (N=27)



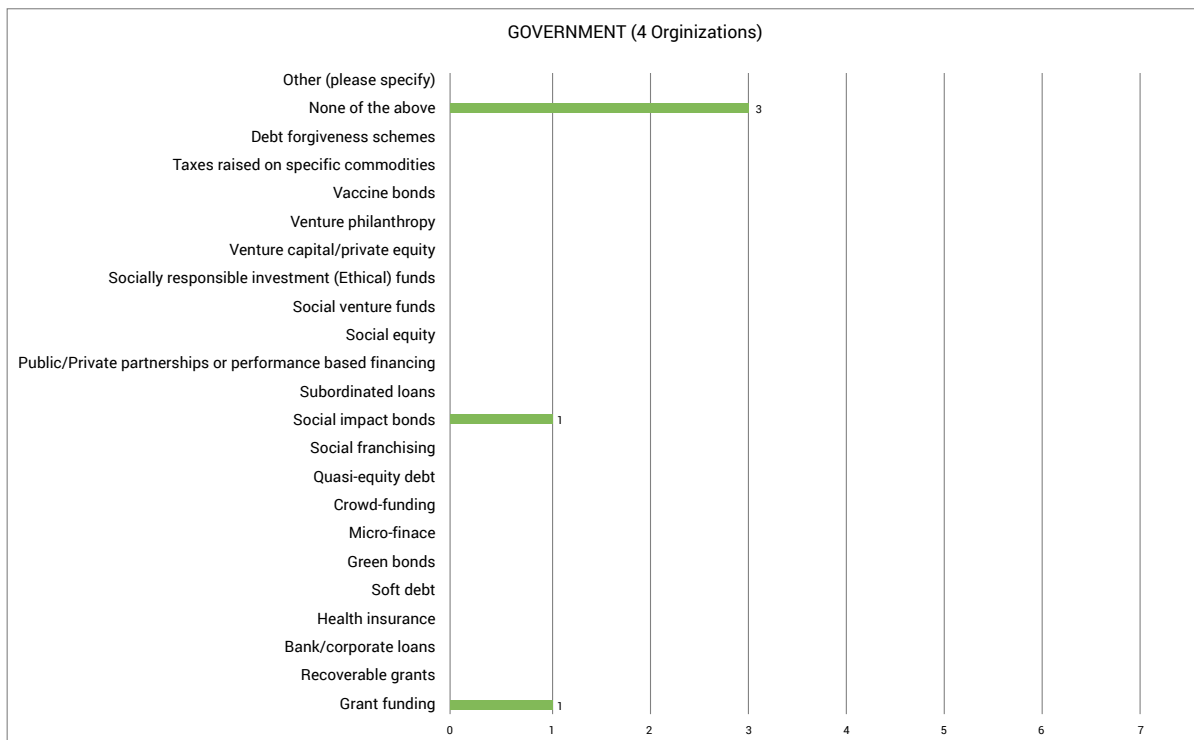
Graph 12: Knowledge of innovative funding among finance organisations surveyed (N=12)



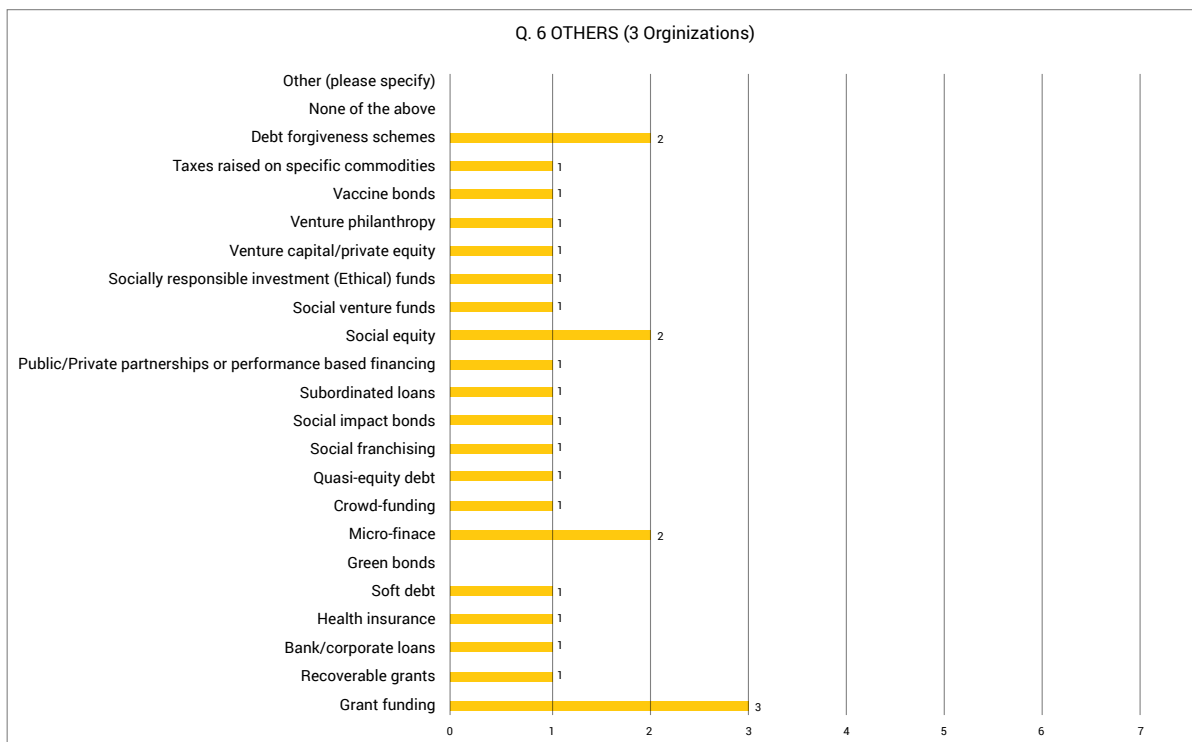
Graph 13: Knowledge of innovative funding among CSR/charity/philanthropy organisations surveyed (N=8)



Graph 14: Knowledge of innovative funding among government organisations surveyed (N=4)



Graph 15: Knowledge of innovative funding among 'other' organisations surveyed (N=3)



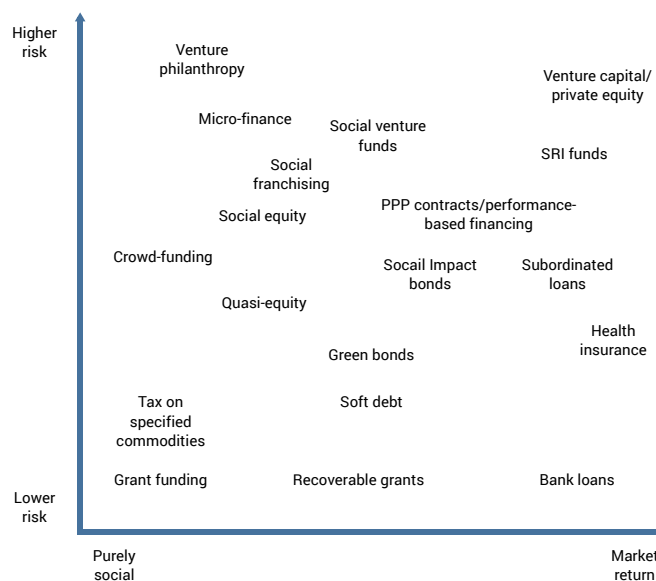
These results demonstrate an awareness of some methods of innovative funding, but show that in order to suggest specific types of funding and encourage conversations about them, more information needs to be provided.

Attitude to risk and returns

Finance mechanisms can be distributed according to risk (high versus low) and return (purely financial versus purely social). Graph 16 is based on information from The landscape of social investment in the UK(93). It uses an array of innovative and less innovative finance methods to encourage respondents to think about the similarities and differences amongst them, and to illustrate the axes of low versus high risk and market versus social returns using concrete examples.

Questions 7 and 8 aim to show where an organisation falls on the spectrum for each.

Graph 16: Innovative finance methods grouped by risk and return types
Source: Oxford university



Q7. Where on the spectrum of low risk to high risk would you place your organization's involvement?

[Scale 1–5 where 1 = low risk, 5 = high risk, plus 6 = not sure/not relevant]

Q8. Where on the spectrum of purely social returns to purely market-based returns would you place your organization?

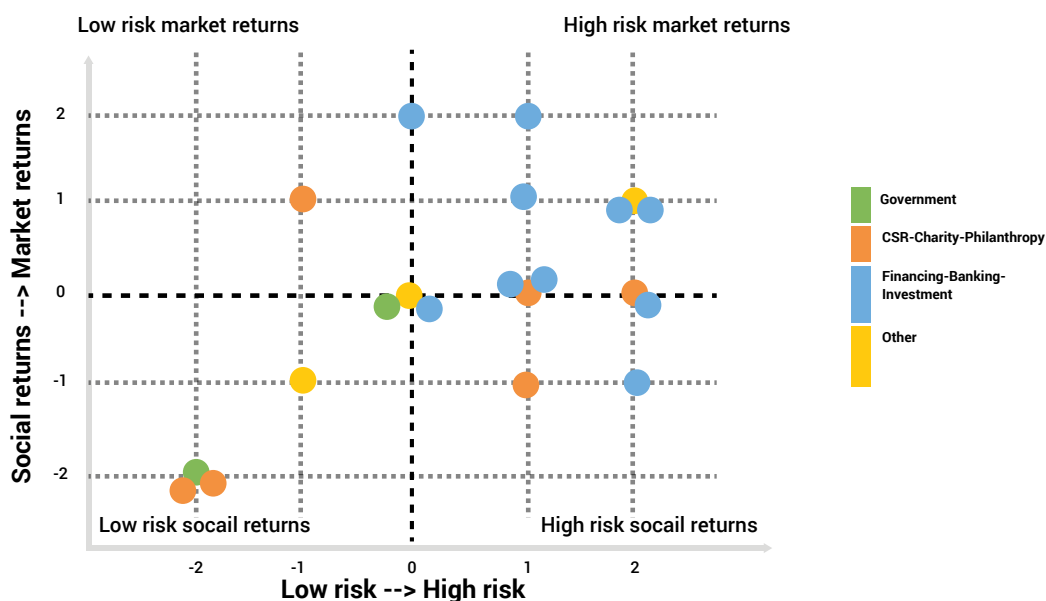
[Scale 1–5 where 1 = purely social returns, 5 = purely market-based returns, plus 6 = not sure/not relevant]

The responses to this question have been displayed on a matrix (graph 16) similar to the one shown on the previous page. Where circles are clustered together, this indicates that they share the same data point.

Finance organisations show a higher level of risk in their involvement in funding organisations and projects (all answered 4 or 5 on a scale of 1 to 5, where 5 is high risk). 6 CSR/charity/philanthropy organisations (75% of non-profits surveyed) answered this question. The responses from these organisations with regard to risk were spread across the spectrum available. There was no clear preference for high or low risk activity.

A clear majority (89%) of financial respondents demonstrated an affinity for higher risk returns. 44% expressed no preference for either market or social return. A third of CSR/charity/philanthropy sector respondents expressed no preference for social or market return. 50% of CSR/charity/philanthropy respondents expressed favourability towards higher risk returns, with 50% demonstrating a lower affinity for risk.

Graph 17: Matrix indicating level of risk and returns preferred by the organisations surveyed (N=27)



The numbers of organisations answering from the other organisation types were low and therefore no conclusions can be drawn from their responses specific to their organisation type.

Overall, it would seem that the finance organisations have a preference for higher risk activities and market returns, and the CSR/charity/philanthropy organisations have no preference on risk but prefer social returns. Based on small numbers of responses this is not sufficient to draw a firm conclusion but concurs with what could logically be thought to be the case.

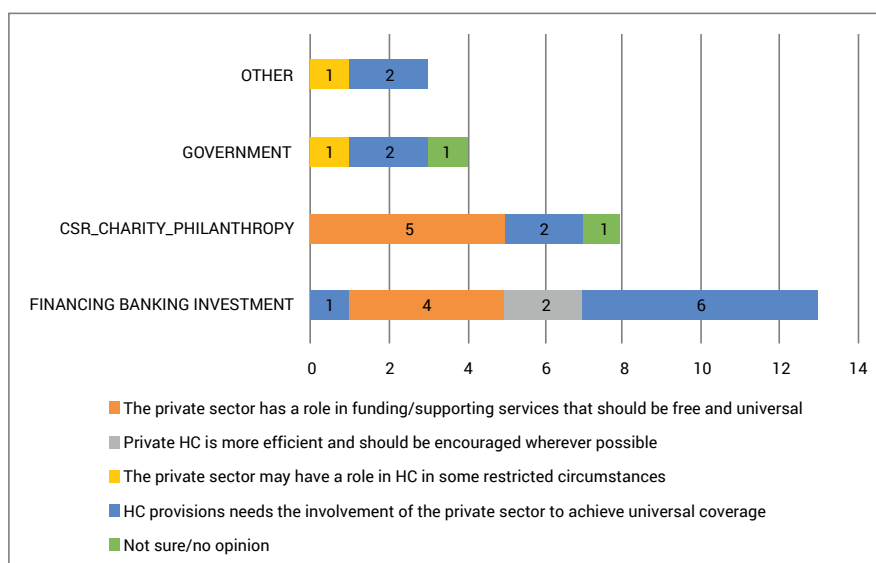
Innovative finance mechanisms and viral hepatitis

Q9. In the countries where your organization works, how much of a role do you think innovative finance mechanisms should have in healthcare?

23 organisations were positive towards the involvement of the private sector in health. A clear majority among all key stakeholder groups felt that the private sector has a critical role to play in the provision of healthcare. It was less clear to what extent the private sector should be involved. Graph 18 gives a view of the role innovative finance could/should play in health care split by type of organisation. 12 organisations felt that healthcare provision needs the involvement of the private sector to achieve universal coverage. 9 organisations (5 CSR/charity/philanthropy organisations and 4 financial) felt that the private sector has a role in funding/supporting services that should be free and universal. 2 organisations (both financial) thought that private healthcare is more efficient and should be encouraged wherever possible. Last we note that 4 organisations were unsure or more reserved in their outlook, 2 of them considered that the private sector may have a role in limited

circumstances. None of the organisations indicated that the private sector should have no involvement in HC, this category is therefore left out in the graph.

Graph 18: View on role of innovative finance in healthcare by organisation type (N=27)



Q10. Between countries where your organization works, is there a difference in the climate of opinion on innovative funding mechanisms? Which is the most open to innovative funding mechanisms? Which is the least open?

The question about the openness of countries towards innovative funding gives an indication of how difficult/easy it may be to launch a novel type of funding. The question was not answered by all organisations (6 chose not to answer or their text answers indicated that they didn't know). In addition, a number of organisations answered 'none of the above' (which could mean that they also work in other countries that they perceive as more open to innovative funding).

Table 19 shows that 4 organisations (from all different types, except government) consider India as most open. 2 countries see Egypt as most open and 2 think Brazil is. One country also saw Ghana as most open. However, seen the high rate of 'none of the above' and the high non-response rate, these answers need to be read with the reservation that this is the opinion of a small number of respondents.

Table 19: Countries considered to be most open to innovative funding mechanisms (N=27)

	CSR-CHARITY- PHILANTHROPY	FINANCING- BANKING- INVESTMENT	GOVERNMENT	OTHER
Armenia				
Bangladesh				
Benin				
Brazil		2		
Egypt	1			1
Ghana				1
India	1	2		1
Indonesia				
Moldova				
Mongolia				
Morocco				
Nigeria	1			
Uzbekistan				
Vietnam				
None of the above	3	5	3	

Table 20 shows which countries are considered least open to innovative funding. The results of the table need to be read with even more reservations than table 19. As such this may be positive in the sense that many countries don't seem to be viewed as undoubtedly negative towards innovative funding.

Table 20: Countries considered to be least open to innovative funding mechanisms (N=27)

	CSR-CHARITY- PHILANTHROPY	FINANCING- BANKING- INVESTMENT	GOVERNMENT	OTHER
Armenia				
Bangladesh				1
Benin				1
Brasil				
Egypt				
Ghana				
India		1		
Indonesia		1		
Moldova				
Mongolia				
Morocco				
Nigeria				
Uzbekistan	1			
Vietnam	1	1		
None of the above	4	4	3	

Conclusions as to the attitudes of sample countries to innovative funding mechanisms in support of public health cannot be drawn. There was a lack of certainty about the interest in innovative funding for different countries. This would suggest that more information, data and communication is required to provide an understanding and interest in innovative finance in general.

Q11. If your organization agrees that innovative funding mechanisms have a role in healthcare, which kinds do you think would support public health best (more than one answer is possible)?

PPPs were seen as the most suitable innovative finance mechanism for supporting public health (12 organisations), followed by grant funding (9 organisations). Venture capital/

private equity, subordinated loans and health insurance (6 organisations each) were seen as the next most suitable methods.

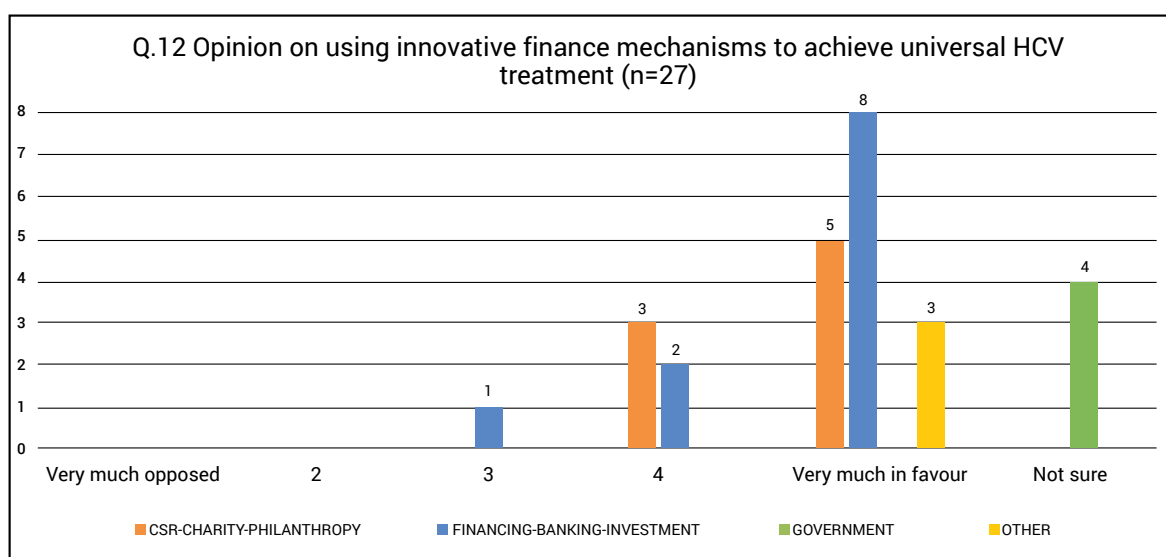
The most suitable types of finance methods were indicated by the highest awareness in graphs 10-14, suggesting that other types of finance methods were not considered for this question because the organisations were not aware of them. The answer to this question suggests that more information would need to be provided about innovative finance methods that are not currently well known.

Respondents from the CSR/charity/philanthropy and financial sectors reported the widest range of innovative finance mechanisms as being best suited to supporting public health.

Q12. You may have heard that a new treatment has been discovered which is a potential cure for Hepatitis C, a disease which is a serious problem in middle- and lower-income countries. The costs of extending treatment to all Hepatitis C patients will be high. What is your organization’s opinion on the use of innovative funding mechanisms to achieve universal treatment?

A majority of organisations (21) are in favour or very much in favour of using innovative finance mechanisms to achieve universal hepatitis C treatment. Graph 19 gives an overview of the opinion of respondent on this item by type of organisation (26 organisations answered the question). Of the sample surveyed, government respondents were the most uncertain of the value of innovative finance mechanisms to achieve universal hepatitis C treatment.

Graph 19: Opinion on innovative finance to achieve universal hepatitis treatment by type of organisation (N=27)



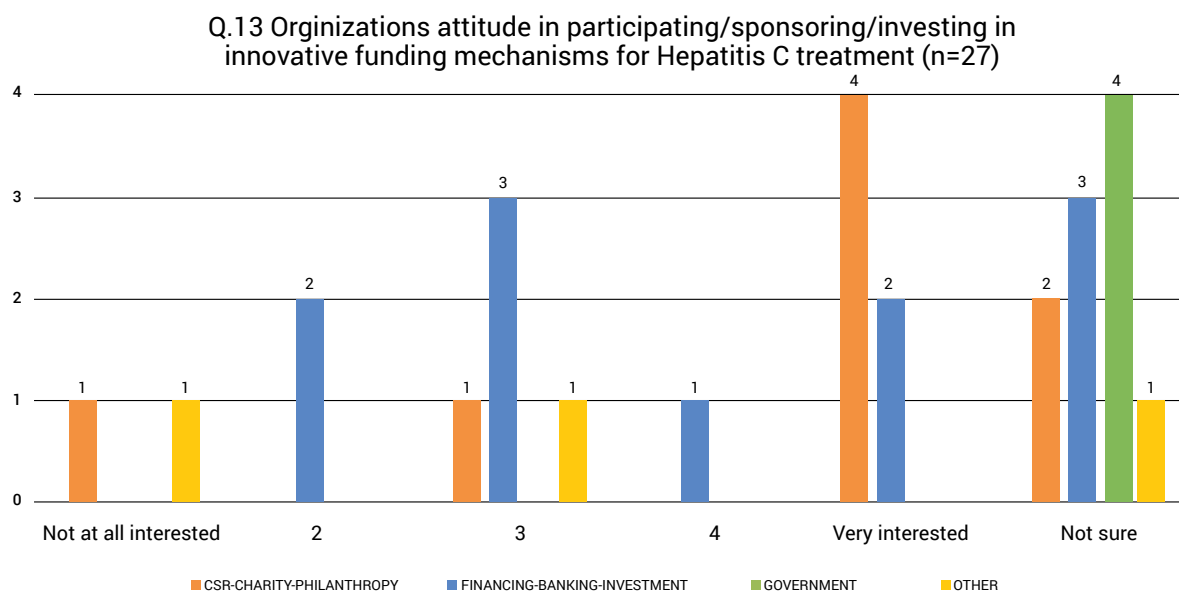
For innovative finance mechanisms to be seriously considered for the provision of universal hepatitis C treatment, especially government stakeholders must be convinced of the case for such action.

Q13. Would your organization be interested in participating in/sponsoring/investing in innovative funding mechanisms for hepatitis C treatment?

Especially CSR and financial organisations are interested in participating in innovative funding for the treatment of hepatitis C. 7 organisations (3 CSR and 4 financial) stated in the survey that they would be interested or very interested in participating in/sponsoring/ investing in innovative funding mechanisms for hepatitis C treatment.

Still a big number of organisations (14, all types of organisations) were either not sure or answered the survey with no opinion either way. This indicates that more information would need to be provided in order to communicate the benefits of participating in innovative funding mechanisms, given the response to the previous question that showed openness to the concept of applying innovative finance mechanisms in this area.

Graph 20: Attitudes towards participation/sponsoring/investing in innovative funding mechanisms for hepatitis C (N=27)



4. CONCLUSION

From the research undertaken, 265 organisations have been identified as relevant stakeholders in the development of innovative funding mechanisms in public health. Our research identified a diverse array of stakeholders who report themselves as being interested in the innovative financing of hepatitis C treatment. Stakeholders are actively involved in a range of health finance issues and initiatives. For the most part this work is of a philanthropic or social investment nature. The strongest indications of involvement are reported by the finance, banking and investment respondents as well as by CSR/charity/philanthropy organisations. Organisations cite a range of priorities when deciding how and where to invest. The most important financial criteria reported are the provision of business plans, financial viability and financial sustainability. Key social impact criteria are tangible local outcomes, value of solution and community context. There is favourability among those interviewed to be more involved in health financing from a market-based perspective.

Overall, the surveyed organisations do have an interest in healthcare and have existing financing or projects in progress in the sector. A clear majority of organisations surveyed are positive towards the idea of private involvement in healthcare, indicating that the interest from these organisations could be harnessed appropriately. It is less clear to what extent the private sector should be involved in healthcare provision.

The results demonstrate an awareness of some methods of innovative funding among some key groups (especially finance and CSR organisations). PPPs are seen to be the most suitable innovative finance mechanism for supporting public health, followed by grant funding. Government stakeholders seem to be least informed.

It is therefore concluded that all stakeholder categories, but most notably government agencies, require more information, data and communication in order to increase understanding and interest in innovative finance. Informing organisations about the potential of innovative funding for health care in general and hepatitis C treatment in particular, will encourage them to invest in the sector.

PART 4: RECOMMENDATIONS

The recent possibilities for a hepatitis C cure brought onto the market, and their inclusion on the Essential Medicines List, may provide a unique opportunity to foster international collaborations and call for a trend-setting approach towards prevention and treatment of hepatitis B and C in LMICs. In this report we have considered the external influences on the treatment of hepatitis C, for example government and NGO policies or strategies. We have also commented on over 20 different funding mechanisms and have reviewed the attitudes of stakeholders to innovative financing models. With this in mind we make the following five recommendations:

1. FIRST A PLAN, THEN A FUNDED CONTROL OF VIRAL HEPATITIS

Providing safe, curative medicines is only one element in a comprehensive public health approach to managing chronic viral hepatitis. Therefore, **funding of medicines for the cure of viral hepatitis should be part of a comprehensive package built on national strategies and action plans**. Countries or regions that have not already done so should be encouraged to develop a national or regional strategy with a plan of action and a business case that will elaborate the details of the implementation process – a process that should be backed and financed by international expertise. The WHO, currently developing a global health sector strategy on viral hepatitis (2016–21), has the appropriate mandate to assist.

Funders agree that the private sector needs to be involved to achieve universal health coverage, though they may not all have a similar idea of the preferred extent of private sector involvement. In any case, funders can only be convinced on the basis of a concrete, feasible and relevant 'business plan' that ensures (social) measurable outcome (see table 16, business priorities). Funders also want to be informed about the benefits of the programme and in what way their benefits would exceed programme costs. Can countries give a stronger signal to funders about their political will and commitment to control VH than by developing a (national) control programme? Using the existence of a national VH control programme as criterion for funding priorities may encourage governments to take steps towards, or seek support for its development.

2. ACCESS IS PART OF A SUPPORT PLAN

Availability of therapy is not equivalent to access to treatment. Once access to hepatitis treatment is established, the challenge lies in preserving the supply chain, individual adherence rates and the monitoring and evaluation process. The new hepatitis C treatment has a relatively short treatment period (12 weeks), but hepatitis B treatment is lifelong. This implies that **funding should invest in all stages of the therapy cycle, including proper screening and patient identification, additional therapy compliance and support plans** (e.g. peer support, directly observed therapy, text reminders, home visits, electronically monitored pill administration or blister packaging). Access is the gate to therapy.

3. A MIXTURE OF FUNDING APPROACHES MAY HAVE MOST EFFECT

There is no sole financing mechanism that is best. **An adequate combination of funding mechanisms, adapted to the context of the country, payers and patients, can accurately target country-specific challenges.** Issues at stake to be considered by country are:

- HBV/HCV prevalence and incidence rate
- the population affected
- the existence of a VH national programme
- the organisation of the healthcare system
- the patients' out-of-pocket share for health care

As a result of the research and analysis undertaken for this report, the following mechanisms are suggested as the most applicable for viral hepatitis. This list takes into account the relevance of the mechanisms to the treatment of hepatitis, an understanding of the views of the stakeholder types surveyed and knowledge of existing or similar projects that could be adapted.

Public-private partnerships with a focus on non-infrastructure interventions – this mechanism is included as a recommendation on the basis of recent developments in outcomes-based financing and given that considerable efforts have already been made to pilot 'social impact bond' funding arrangements. This experience can be used to inform the future development of non-infrastructure PPPs as a suitable way to expand their reach from their historical use in simple construction projects and toward a more flexible means of outcomes-based funding.

The development of a 'Hepatitis Bond' or creating a 'Hepatitis Fund', as discussed in this report, could either be global, regional or country-specific. In either case it would involve a Special Purpose Vehicle (SPV) managing funds from donors, market-based investors or a mixture of both, and make loans either to countries or to local implementers (depending on the countries' capacity or willingness to provide central management).

Levels of repayment would depend on outcomes achieved, in such a way that if outcomes are as expected the fund would be attractive to large-scale investor institutions. The SPV itself, if non-profit, could act as outcomes assessor, fix rates of return and negotiate contracts with other parties.

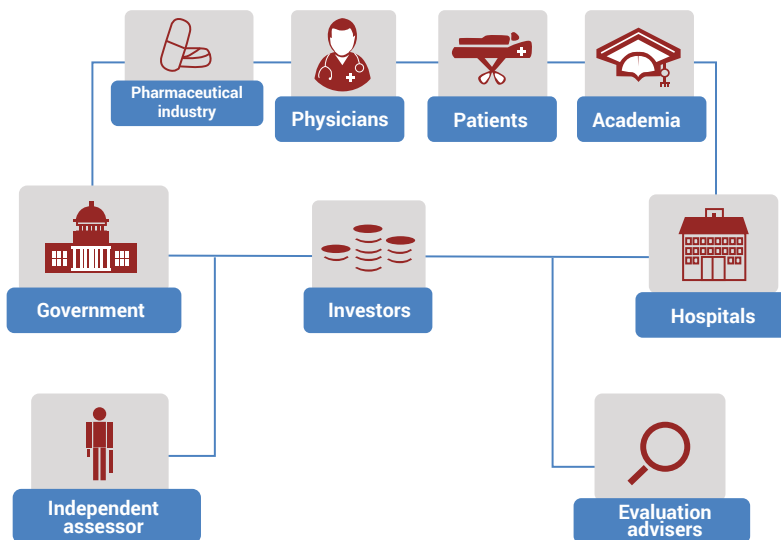
A key lesson learnt from competitive tenders for Social Impact Bonds (SIB) is the resource-intensive nature of contracting and performance management. Preparing for this process would involve building relationships with possible partners and experts in legal, finance, statistics and social policy who could assist with a proposal. Insights from funders surveyed show that regional (development) banks have the potential to play a critical role in the process of creating such a mechanism at a regional level. Figure 7 illustrates the various stakeholders that should be involved in a PPP to issue bond finance to eradicate hepatitis C within 20–30 years (73):

Figure 7: stakeholders in an innovative bond initiative for the prevention and treatment of HCV (73)

Who would be involved in developing the bond finance initiative?



*Bond financing models have the following characteristics and components**



*The schematic above illustrates the common characteristics of a bond/financing model and we would anticipate that these components would form the best structure for a new financial instrument.

Shared value approaches – Building on the experience of CSR projects as a way of connecting major funding institutions with local implementers in LMICs be used as a springboard. Local enterprises in LMICs can be stimulated to adhere to CSR. Local companies that invest in the treatment of hepatitis B or C not only introduce the concept of CSR among a broader public, but they also inform about a major public health issue. The engagements of the company can be made public through information brochures, posters and company websites.

In parallel, health partnerships are increasingly viewed as a core component of business strategies by research based pharmaceutical companies. The integration of hepatitis B and C partnerships as part of companies’ commercial activities provides a solid basis for a more sustainable dynamic to strengthen access to healthcare.

Micro-finance – this mechanism is included as a recommendation on the basis that local or regional lending institutions in LMICs will often have experience of partnership with local micro-finance providers. Micro-finance is a mechanism that is well placed to connect major commercial sources of funding with smaller NGOs and not-for-profit projects.

The network of contacts developed through the operation of micro-finance projects, together with the local knowledge built up in the course of project development, can be recommended as a way of connecting funding institutions with local implementers able to

deliver targeted services to 'hard to reach' groups.

It is important to understand the characteristics of successful finance provision in order to make appropriate decisions on suitable mechanisms for a given situation. These might include sustainability, replicability, management of risk and a clear repayment schedule (examples of such criteria as applied by investors are discussed in tables 16–18).

4. PARTNERSHIP IS THE WAY FORWARD

In line with innovative finance in other areas, the introduction of **new financing mechanisms for the prevention and treatment of hepatitis B and C will have the most success if embedded in PPPs:**

- The main financial criteria reported by funders were the provision of business plans, financial viability and financial sustainability. Key social impact criteria reported were tangible local outcomes, value of solution and community context. This requires capacity-building support to public and private healthcare providers. Funding from venture philanthropy comes precisely with this form of capacity-building support (tables 17 and 18).
- Partnerships will encourage collaboration and will bring conflicting interests together, striving towards the same goal of controlling viral hepatitis B and C and improving the patients' quality of life.
- Partnerships could function as accelerators for the provision of services to develop and implement national, regional or local strategies for surveillance, prevention and control of hepatitis B and C combined with funding strategies for hepatitis B and C prevention and treatments.
- While clinicians and patient advocates are active in raising awareness of viral hepatitis and the need for access to testing and treatment, in order to effectuate change and ensure the financial viability of the recommended treatments it is important to gain support from financial institutions such as regional banks. Existing healthcare projects funded by banks are discussed in the paragraph on rural health cooperatives, earlier in this report.

5. THERE IS A NEED TO DISCUSS INNOVATIVE FINANCING MECHANISMS WITH STAKEHOLDERS

Although organisations are familiar with the concept of innovative financing, they are not necessarily acquainted with the wide array of inventive methods available and their potential. This was demonstrated in the research findings in part 3 of this report (see graphs 10–14).

Besides, global awareness of viral hepatitis as a public health concern is generally low among all stakeholders.

Advocacy on how to use innovative finance to tackle viral hepatitis will increase interest in innovative finance in general and will raise awareness about viral hepatitis. **Consequently, the urgency to mobilise resources for prevention and treatment of hepatitis B and C could**

be seen as a unique market opportunity.

We recommend that in addition to initiating a multi-stakeholder group to investigate further possibilities of innovative funds for viral hepatitis, making contact with key financial stakeholders on an individual basis should be considered a priority.

SUMMARY OF SUGGESTED NEXT STEPS

- ✓ Encourage development of regional strategies by building on existing relationships in key countries
- ✓ Continue to network with clinical experts to ensure that funding discussions are relevant
- ✓ Work with relevant partners to further develop suggested concepts or funding streams
- ✓ Convene a multi-stakeholder group to discuss financing options
- ✓ Engage with key financial stakeholders that have been identified during the research

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