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CLINTON HEALTH ACCESS INITIATIVE

Dried Blood Spot Sampling for HCV Viral Load

First Market Potential Report

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About Unitaid

Unitaid brings the power of new medical discoveries to the people who most need them and helps set the stage for large-scale introduction of new health products by collaborating with governments and partners such as PEPFAR, the Global Fund and WHO. Unitaid invests in new ways to prevent, diagnose and treat diseases including HIV/AIDS, hepatitis C, tuberculosis and malaria more quickly, affordably and effectively.

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries. Since 2003, we have been instrumental in the delivery of 21 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention.

About CHAI

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and reducing the burden of disease in low- and middle-income countries, while strengthening the capabilities of governments and the private sector in those countries to create and sustain high-quality healthsystems.Formoreinformation, please visit:http://www.clintonhealthaccess.org.

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To understand the HCV VL DBS market, this report seeks to answer three fundamental questions:

1. What is the total estimated *need* for DBS sampling to support HCV VL testing (2018-2021)?
2. What is the total estimated *demand* for DBS sampling for HCV VL testing (2018-2021)?
3. What are the key drivers that shape the demand for DBS sampling for HCV VL testing?

Acronyms

CHAI	Clinton Health Access Initiative
DBS	Dried blood spot
DXMI	FIND/CHAI Diagnostics Market Intelligence Report 2017
FIND	Foundation for Innovative New Diagnostics
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HR	Human resources
LMICs	Low- and middle-income countries
MOH	Ministry of Health
NAT	Nucleic acid test
NGO	Non-governmental organization
PEPFAR	The United States President's Emergency Plan for AIDS Relief
SSA	Sub-Saharan Africa
SVR (SVR12)	Sustained virologic response (12 weeks (or more) after completion of antiviral treatment)
VL	Viral load
WHO	World Health Organization

Summary

Hepatitis C virus (HCV) is one of the world's most common infectious diseases, with approximately 71M people worldwide chronically infected with the disease.[1] Only 20% of HCV-infected people have been diagnosed with the disease and only 7% of people diagnosed have received treatment.[2] In light of this suboptimal public-health response to the HCV epidemic, the 2016 World Health Assembly committed to the elimination of HCV by 2030, with an interim target of diagnosing 30% of HCV-infected individuals and initiating 3M patients on treatment by 2020.

In 2017, FIND and CHAI, with support from Unitaid, published a Diagnostics Market Intelligence (DXMI) Report on HCV to forecast the diagnostic gaps for low- and middle-income countries (LMICs) to achieve HCV targets.[3] The DXMI Report highlighted the significant disparity between the total market need versus the projected demand for HCV diagnostics in high-burden countries. Specifically, the DXMI Report estimated a total HCV viral load (VL) testing need for confirmatory and treatment response (SVR12) testing of ~31M tests from 2017-2021, with a forecasted demand of only ~17M tests over the same time period.

In this follow-up report, CHAI and FIND have now focused on estimating the potential market size of dried blood spot (DBS) sampling for HCV VL testing. As the HIV VL experience empirically demonstrates, DBS sampling can potentially increase the demand for diagnostic tests by expanding testing access to more remote populations and by simplifying sample collection, storage, and transportation.

The analysis presented in this report leveraged a mix of publicly available data, surveys, and interviews with country stakeholders to answer the above questions. Ultimately, the analysis estimated a total need for DBS samples for HCV VL testing of ~9M tests out of a total HCV VL testing need of ~28M tests from 2018-2021.

On the demand side, DBS sampling is expected to account for ~2M HCV VL tests, whereas plasma demand will account for ~13M HCV VL tests in the same timeframe. DBS demand in this forecast is driven by key factors such as the percentage of a country's rural population, the state of existing sample transport networks, HCV funding availability, and experience with and plans for use of DBS in other disease areas, e.g. HIV.

Overall, DBS sampling is anticipated to increase total HCV VL testing demand and expand access to populations who may not have otherwise been tested. It is also worth noting that demand for DBS sampling is forecasted to increase significantly in Years 3-4 (i.e. 2020-21) of the forecast, implying that DBS sampling might play an increasingly large role in HCV VL testing in the years following 2021.

Growth in the HCV DBS market after 2021 may occur as countries focus their attention on achieving the 2030 WHO target of 90% of HCV-infected individuals being diagnosed, as HCV country programs mature, and as countries begin to expand HCV VL testing beyond the more accessible urban and peri-urban populations to harder-to-reach rural populations.

Given that it will take time to i) educate key decision-makers on DBS sampling, ii) change country guidelines, iii) obtain regulatory approval for HCV VL DBS protocols, and iv) deploy DBS sampling effectively on the ground, diagnostic suppliers, funders, and other key partners should consider investing time and resources in HCV DBS activities in the coming years. By doing so, we can collectively become better prepared to support countries as their demand ramps up for DBS sampling to support HCV VL testing.

1. Polaris Observatory HCV Collaborators. Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. *Lancet Gastroenterology Hepatology* 2017; 2: 161–76.
2. Global Hepatitis Report 2017: Geneva, World Health Organization; 2017
3. The HCV Diagnostics Market Intelligence Report 2017 can be found at https://www.finddx.org/wp-content/uploads/2018/04/HCV-Diagnostics-Market-Intelligence-Report_18APR2018.pdf

INTRODUCTION

Hepatitis C virus is one of the world's most common infectious diseases, with approximately 71M people worldwide chronically infected with the disease, ~80% of whom live in LMICs.[1] Only 20% of HCV-infected people have been diagnosed with the disease and only 7% have received treatment, despite the disease's high prevalence, morbidity, and mortality.[2]

In 2017, FIND and CHAI, with funding from Unitaid, collaborated to develop a Diagnostics Market Intelligence (DXMI) Report on HCV.[3] This report specifically focused on the diagnostics gap for LMICs to achieve the 2020 and 2030 hepatitis elimination targets committed to at the 2016 World Health Assembly (i.e. countries should aim to diagnose at least 30% of all HCV-infected individuals by 2020 and at least 90% of all HCV-infected individuals by 2030).

The 2017 DXMI Report highlighted the significant disparity that exists between the total market need for HCV diagnostics in order to achieve these WHO targets versus the projected demand for HCV diagnostics based on current country characteristics and trends. The 2017 DXMI Report was based on a five-year market forecast developed for 2017-2021. In particular, this analysis found a significant shortfall between need and demand for HCV VL tests, which are used for confirmatory and SVR12 testing. The forecast estimated a need for ~31M HCV VL tests for 2017-2021, while demand over this timeframe was estimated to be ~17M tests (see **Figure 1** below).

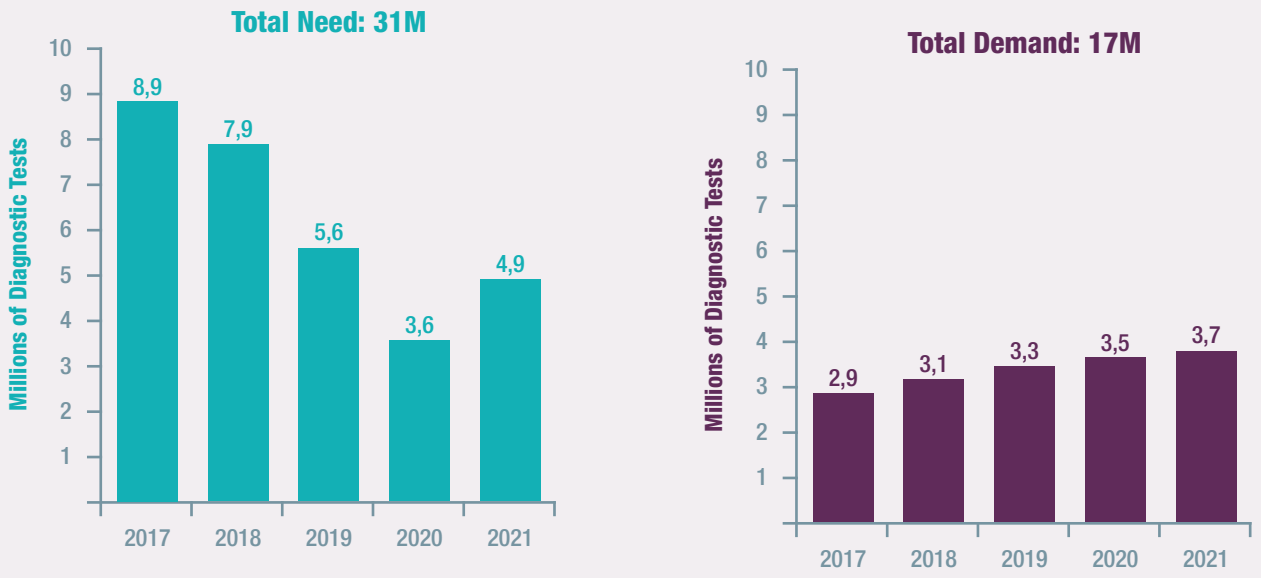


Figure 1. Estimated need and demand for HCV VL tests from the 2017 DXMI Report

Note that the WHO target of 30% of HCV-infected individuals being diagnosed by 2020 was used to determine HCV VL need between 2017-2020. The need estimate for 2021, on the other hand, was based on making progress toward the WHO target of 90% HCV-infected individuals being diagnosed by 2030 (hence the uptick in need in 2021, as shown in **Figure 1** above).

The demand estimate of 17M HCV VL tests was based on historical procurement of HCV VL tests which have been run exclusively on plasma samples. Consequently, to build on the 2017 DXMI Report, FIND and CHAI are now seeking to understand the role that dried blood spot (DBS) sampling could play to further support the scale-up of HCV VL testing.

DBS sampling differs from plasma / whole blood sampling in a few key ways:

Attribute	Whole Blood / Plasma Sampling	DBS Sampling
HR skills needed	Qualified phlebotomist	Minimal training
Sample stability at room temperature (see Appendix A for more details)	6 hours (whole blood), 24 hours (plasma)	Multiple weeks
Estimated costs[4]	Lower sample collection cost but higher all-inclusive cost versus DBS	Higher sample collection costs but lower all-inclusive cost versus whole blood / plasma

Given the above attributes, it is hypothesized that DBS sampling could potentially increase the demand for HCV VL tests in the following ways:

1. **By simplifying sample collection:** Healthcare workers require minimal training to collect and prepare DBS samples, unlike for plasma samples. Additionally, the DBS sample collection process has fewer infrastructure requirements as compared to plasma samplings which, for example, requires access to a centrifuge. Due to this relatively simplified sample collection process, DBS sampling can be performed at lower levels of the health system, thereby increasing the potential pool of patients that can access testing services.

2. **By simplifying sample transport and storage:** DBS samples are stable in ambient temperatures for a longer period of time relative to whole blood or plasma samples and can also be stored at ambient temperatures. These features make DBS sampling particularly useful in remote areas where cold chain infrastructure is limited and/or sample transport to testing sites cannot be completed within the 6-hour window required for whole blood samples or the 24-hour window required for plasma samples. Thus, the relative stability of DBS samples can help to increase demand for HCV VL testing in more remote areas.

3. **By reducing costs:** Finally, although limited, there is some empirical evidence that the all-inclusive cost of DBS samples is lower than the all-inclusive cost of plasma or whole blood samples. This cost differential seems to primarily be driven by the lower storage costs for DBS samples versus whole blood/plasma samples as well as the lower sample transportation costs for DBS samples, e.g. because DBS samples do not require any cold chain infrastructure or specialized containers for transport. Potential cost savings associated with DBS sampling could, in turn, support expanded access to testing services.

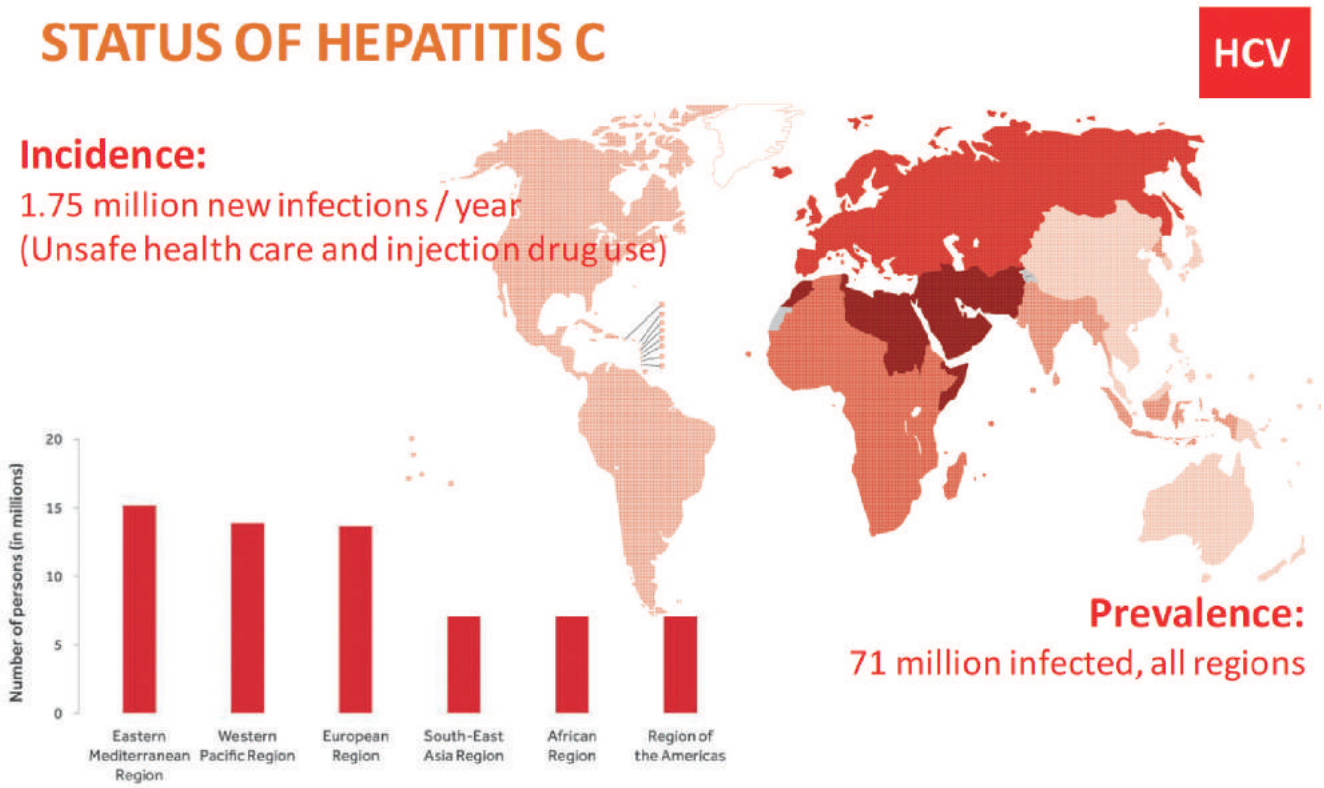
4. Neogi U. et al. 2012. Dried blood spot HIV-1 RNA quantification: A useful tool for viral load monitoring among HIV-infected individuals in India. *Indian J Med Res.* 136(6): 956-962.

Ultimately, DBS sampling has the potential to scale-up access to HCV VL tests, particularly for more remote populations. The impact of DBS sampling on access to diagnostic tests has been observed in HIV where the scale-up of DBS sampling resulted in increased access for patients to both HIV early infant diagnosis (EID) and VL testing.

In order to explore the potential for DBS sampling to increase demand for HCV VL testing, this market report seeks to answer three fundamental questions:

1. What is the total estimated *need* for DBS sampling to support HCV VL testing (2018-2021)?
2. What is the total estimated *demand* for DBS sampling for HCV VL testing (2018-2021)?
3. What are the key demand drivers that shape uptake of DBS sampling for HCV VL testing?

Map showing the risk of contracting HCV (incidence) and how widespread it is (prevalence).



METHODOLOGY

Countries in scope

Similar to the 2017 DXMI Report, this forecast evaluates the HCV VL testing market in LMICs that represent ~80% of the global HCV burden. The forecast also includes several high-prevalence countries that contribute a disproportionate amount to global diagnostics demand despite their small size because of their active and well-funded HCV programs (e.g. Georgia). Appendix B contains the list of the 28 in-scope countries for this analysis.

DBS sampling need

The dried blood sampling need is defined as the theoretical number of HCV VL tests required to achieve WHO HCV elimination targets between 2018-2021 that could potentially be addressed by DBS sampling. WHO has set the target of 30% of HCV-infected individuals being diagnosed by 2020 and 90% of HCV-infected individuals being diagnosed by 2030. The 2017 DXMI Report forecasted the total need for HCV VL testing by estimating how many VL tests would be required if these WHO targets were to be achieved. This need forecast used Polaris Observatory country data on HCV infections and the number of patients diagnosed with, and treated for, HCV. The number of HCV viral load tests was estimated by factoring in chronicity rates, prevalence, testing algorithms, and false negative rates.

The analysis in this report used a four-step process to estimate what portion of total HCV VL need could potentially be addressed by DBS sampling:

1 Adjust the total HCV VL need forecast from the 2017 DXMI Report to the 2018-2021 timeframe

The 2017 DXMI analysis found a total need for HCV VL tests of ~30.9M between 2017-2021. For the current analysis, the total HCV VL need had to be adjusted to reflect a 2018-2021 timeframe. Specifically, it was assumed that the remaining HCV VL need between 2018-2021 was equivalent to the total estimated HCV VL need between 2017-2021 (~30.9M tests) minus the estimated 2017 HCV VL demand from the 2017 DXMI Report (~2.9M tests). This adjustment resulted in a total remaining need of ~27.9M tests for the period 2018-2021.

2 Estimate rural population percentage per country as a proxy for HCV DBS need

We used United Nations data[5] on the rural population percentage for in-scope countries to roughly estimate the need for DBS sampling for HCV VL tests. The rationale for this approach is that patients who benefit from DBS samples are most likely to be those who live far away from testing sites. This approach yielded an estimated DBS need of 46% of the total need for HCV VL tests or 12.8M tests between 2018-2021.

5. United Nations Population Division: World Urbanization Prospects 2018. Available at: https://population.un.org/wup/Download/

3 Refine Step 2 estimates by identifying an appropriate adjustment factor (based on an empirical CHAI analysis of DBS need for HIV VL)

While the percentage of the rural population is a useful approximation for DBS need, it is likely that this approach overestimates the true need for DBS for two reasons. First, urban areas for the in-scope countries tended to be defined somewhat narrowly in the UN dataset, thus artificially inflating the rural population percentage. For examples, in-scope countries sometimes used narrow definitions such as "city proper" or "metropolitan area" to identify urban areas as opposed to using the broader "urban agglomeration" definition that more accurately captures both urban and peri-urban populations.[6] Second, the rural population percentage likely over inflates DBS need since it does not account for mitigating factors like sample transport systems or decentralized laboratory networks, which could reduce the need for DBS sampling even among more remote populations.

Given the above considerations, we wanted to understand how well the rural population percentage empirically maps against DBS need. To do so, we leveraged a 2014 empirical analysis conducted by CHAI that estimated the percentage of HIV patients in Malawi, Zimbabwe, Uganda, and Kenya who attended facilities located more than 24 hours away from a testing site and therefore needed DBS sampling in order to access HIV VL testing. This 2014 analysis found an overall DBS need of ~52% across the four countries. In 2014, the rural population percentage across Malawi, Zimbabwe, Uganda, and Kenya was ~76%. Thus, it appears that true DBS need is actually 68% (i.e. 52%/76%) of the rural population percentage.

4 Apply the adjustment factor to determine HCV VL DBS need

We applied this 68% adjustment factor to the figures in Step 2 to arrive at an overall DBS need of 8.7M tests across the in-scope countries. **Figure 2** below summarizes the steps that were used to obtain this number.

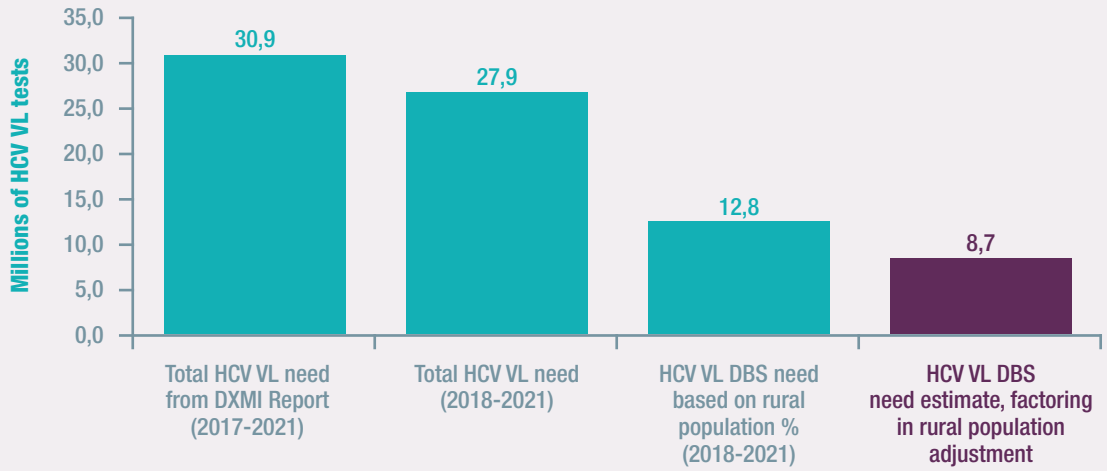


Figure 2. Overview of the HCV VL DBS need methodology

6. https://population.un.org/wup/General/FAQs.aspx. For reference, the definition of key terms are as follows: 1) City proper: Urban settlement defined according to legal/political boundaries and an administratively recognized urban status that is usually characterized by some form of local government; 2) Metropolitan area: Urban settlement defined by both the contiguous territory inhabited at urban levels of residential density and additional surrounding areas of lower settlement density that are also under the direct influence of the city (e.g. through frequent transport, etc.); 3) Urban agglomeration: The population contained within the contours of a contiguous territory inhabited at urban density levels without regard for administrative boundaries. It usually incorporates the population in a city or town plus that in the suburban areas lying outside of, but being adjacent to, the city boundaries.

DBS sampling demand

Dried blood sampling demand is defined as the likely number of HCV VL tests addressed by DBS sampling that countries are expected to procure between 2018-2021, based on key demand drivers.

A four-step approach was used to estimate the actual DBS demand for HCV VL testing in the 28 in-scope countries:

1 Develop a DBS demand index factor model

Since the use of DBS sampling for HCV VL testing is currently nonexistent, we were unable to use any empirical procurement data to estimate DBS demand. In light of this, we developed instead an index factor model to assess demand, which aims to identify and evaluate the impact of different qualitative factors on the adoption of DBS for HCV VL testing in a country.

We identified a total of 12 key index factors across three categories:

i. HCV country context, composed of six factors:
- Level of HCV viremic prevalence
- Use of Direct-acting Antiviral therapies (DAAs) for treatment
- Existence of a national HCV strategic plan
- Active HCV screening programs
- Active HCV demand generation programs
- HCV testing laboratory capacity

ii. Funding, composed of two factors:
- General financing availability
- Level of HCV funding

iii. DBS-specific factors, composed of four factors:
- Rural population size
- Quality of existing sample transport systems
- Current DBS demand for HIV VL
- Future DBS demand for HIV VL

Appendix C of this report provides a detailed overview of these index factors, the rationale for including them in the forecast, and the maximum score (i.e. weight) that they were assigned.

The DBS-specific category was weighted most heavily in the model since these factors are expected to directly impact demand for DBS sampling for HCV VL testing. Within the DBS-specific factors category, size of the rural population and sample transport gaps were the topmost issues since countries with a large rural population or significant concerns with existing sample transport systems will likely have a greater demand for DBS sampling. Current and future use of DBS sampling for HIV VL testing are also important factors that will shape demand for DBS sampling but given that HIV is generally less of a widespread epidemic in many of the in-scope countries, we did not want to weight these variables too heavily.

Funding was the second biggest category, since the size of the HCV budget or availability of other financing sources will directly impact the ability of countries to deploy DBS sampling.

Finally, factors related to the HCV country context were included in the analysis, since they cannot be ignored when assessing DBS demand for HCV VL testing. Country policies around HCV screening and treatment, as well as the strength of HCV program activities, will most likely affect the demand for DBS sampling.

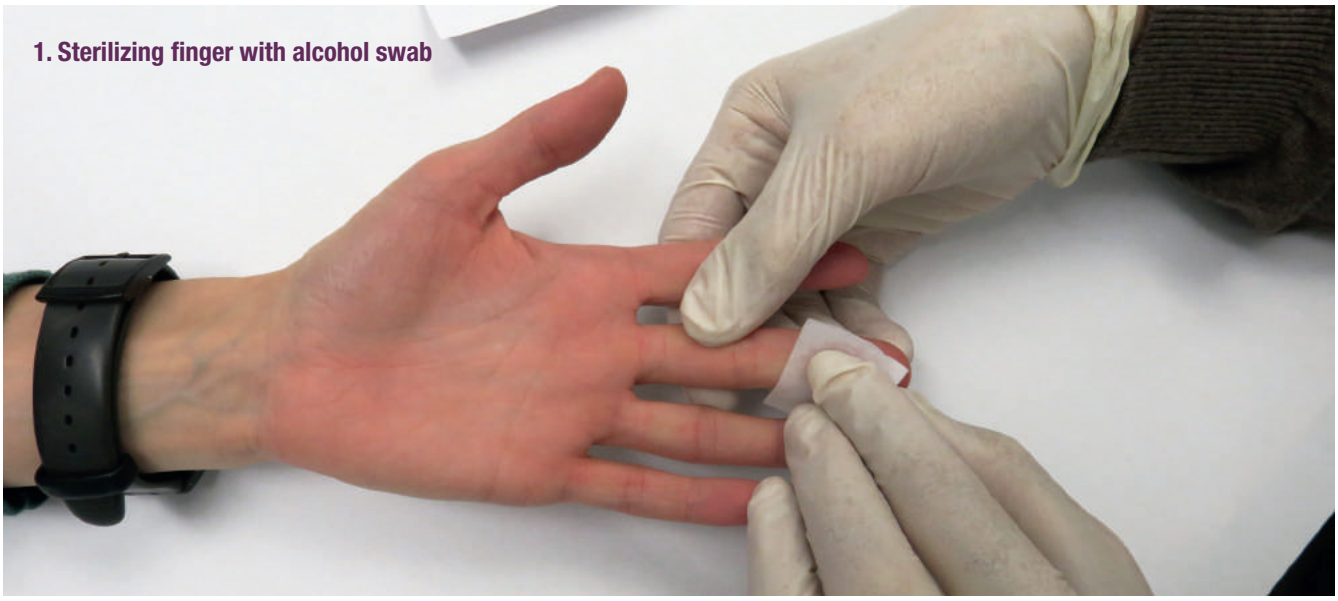
2 Assess countries against the index factor model

After identifying key index factors and their weights, the 28 in-scope countries were then assessed against these factors in order to arrive at a total demand score.

Index factor ratings for each country were based on empirical and/or quantitative data points wherever possible. This data was also supplemented by qualitative assessments or proxy measures where empirical data was limited. See Appendix D for details on the index factor scoring methodology and Appendix E for a summary of the index factor assessment by country.

Demonstration of finger prick blood sample collection for DBS sampling.

1. Sterilizing finger with alcohol swab



2. Using draw needle to prick finger tip

3. Drawing small amount of blood using Pasteur pipette

Photo credit: © FIND /Francois Lamoury

3 Map countries against different DBS sampling demand scenarios based on their index factor scores

Countries with similar total scores on the index factor assessment were assumed to have similar levels of demand for DBS sampling for HCV VL testing. After grouping similar countries together based on their index factor scores, we used data on the demand for DBS versus plasma sampling for HIV VL testing as benchmarks for the demand for DBS versus plasma sampling for HCV VL testing. **Table 1** below shows the four scenarios that were defined for HCV DBS demand, the countries that fall within each scenario, and estimated demand rates.

Scenario	1. Low demand (immature and/or financially-constrained HCV programs)	2. Medium demand	3. High demand	4. Low demand (elimination-track HCV programs)
Description	• Incipient HCV programs often with limited funding availability • Minimal current or expected interest in DBS for HIV, sometimes driven by strong existing sample transport systems	• Fairly active HCV programs with some funding availability • Notable rural populations	• Fairly active HCV programs • Significant funding availability • Notable rural populations, sample transport coverage gaps and/or current or future use of DBS for HIV VL testing	• Advanced HCV programs with high levels of funding • Strong sample transport systems and/or minimal current or future DBS use for HIV VL testing
Countries	China, Syria, South Africa, Philippines, Colombia, Ghana, Malaysia (7)	Pakistan, Russia, Uzbekistan, Turkey, Algeria, Kazakhstan, Argentina, Morocco (8)	India, Nigeria, Brazil, Indonesia, Ethiopia, Romania, Mexico, Thailand, Cambodia, Cameroon (10)	Egypt, Georgia, Mongolia (3)
Index factor score	<21 pts	21 - <33 pts	33 - <45 pts	≥ 45 pts
DBS demand as % of total HCV VL demand	Year 1: 0% Year 2: 0% Year 3: 0% Year 4: 4%	Year 1: 0% Year 2: 7% Year 3: 13% Year 4: 20%	Year 1: 0% Year 2: 17% Year 3: 33% Year 4: 50%	Year 1: 0% Year 2: 0% Year 3: 0% Year 4: 4%
	Minimal DBS uptake expected in coming years; assume DBS demand for HCV VL testing will remain at similar levels as that of a country with low demand for DBS for HIV VL testing (e.g. South Africa)	Assume DBS demand will eventually achieve similar levels as in countries with medium demand for HIV VL DBS but with slower ramp up. Kenya has medium HIV VL DBS demand of ~30-40%.	Assume DBS demand will eventually achieve similar levels as in countries with high demand for HIV VL DBS but with slower ramp up. Malawi has high HIV VL DBS demand of 80-90%.	Interviews with Egyptian stakeholders revealed limited to no DBS envisioned for HCV, so we used similar assumptions as for Scenario 1

Table 1. Demand scenario categorization and country mapping for DBS sampling

Scenario 1: Low demand (immature and/or financially-constrained HCV programs)

Scenario 1 countries are forecasted to have low demand for DBS sampling for HCV VL testing since they have incipient HCV programs,often with limited funding available. These countries also have some combination of robust sample transport systems and/or minimal use of DBS sampling for HIV VL testing, either currently or planned in the future. South Africa, for example, has exclusively focused on plasma sampling for HIV VL testing and is likely to leverage its existing plasma sample transport system for HCV VL testing rather than create a separate DBS sampling infrastructure.

Scenario 2: Medium demand

Scenario 2 countries are expected to have medium demand for DBS sampling since they have fairly active HCV programs, a need for DBS given a sizable rural population, and the ability to rollout DBS since there is some funding available for HCV. The forecast leverages HIV VL DBS demand from Kenya as the benchmark for medium DBS uptake for HCV VL, since Kenya has a DBS demand of approximately ~30-40% of all HIV VL tests processed.

Scenario 3: High demand

Scenario 3 countries are expected to have the highest demand for DBS sampling for HCV VL testing since these countries have significant funding available for HCV management, large rural populations, significant sample transport gaps, and/or notable experience with or interest in DBS for HIV VL testing. The forecast uses HIV VL DBS demand from Malawi as the benchmark for high DBS uptake for HCV VL testing since Malawi has one of the highest percentage of HIV VL tests being run on DBS samples (~80-90%).

Scenario 4: Low demand (elimination-track HCV programs)

Finally, the Scenario 4 countries of Egypt, Georgia, and Mongolia are considered to be on the HCV elimination track. These are high-prevalence HCV countries with significant HCV funding and advanced HCV programs. We expect limited demand for DBS sampling in these countries since they can continue down the elimination path by bolstering their current plasma sampling activities. For example, interviews conducted with Egyptian stakeholders confirmed that there is limited DBS use expected for HCV VL testing in country.

Note: in Scenario 2 and 3, we have assumed that the growth of DBS sampling demand for HCV VL testing will be slower than the growth of DBS sampling for HIV VL testing. There are two primary reasons for this assumption:

- **Level of global attention on HCV DBS sampling:** When HIV DBS sampling was first introduced, there was significant attention devoted to scaling up this sample type and significant funding was made available for this. There does not currently seem to be a similar level of attention on scaling up DBS sampling for HCV VL testing.
- **Urban population percentages:** The HCV countries in scope for this analysis generally have a higher urban population than the sub-Saharan African countries that have scaled up DBS sampling for HIV. Consequently, there is relatively less urgency, on average, to scale up DBS sampling in these high-burden HCV countries than there was in high-burden HIV countries.

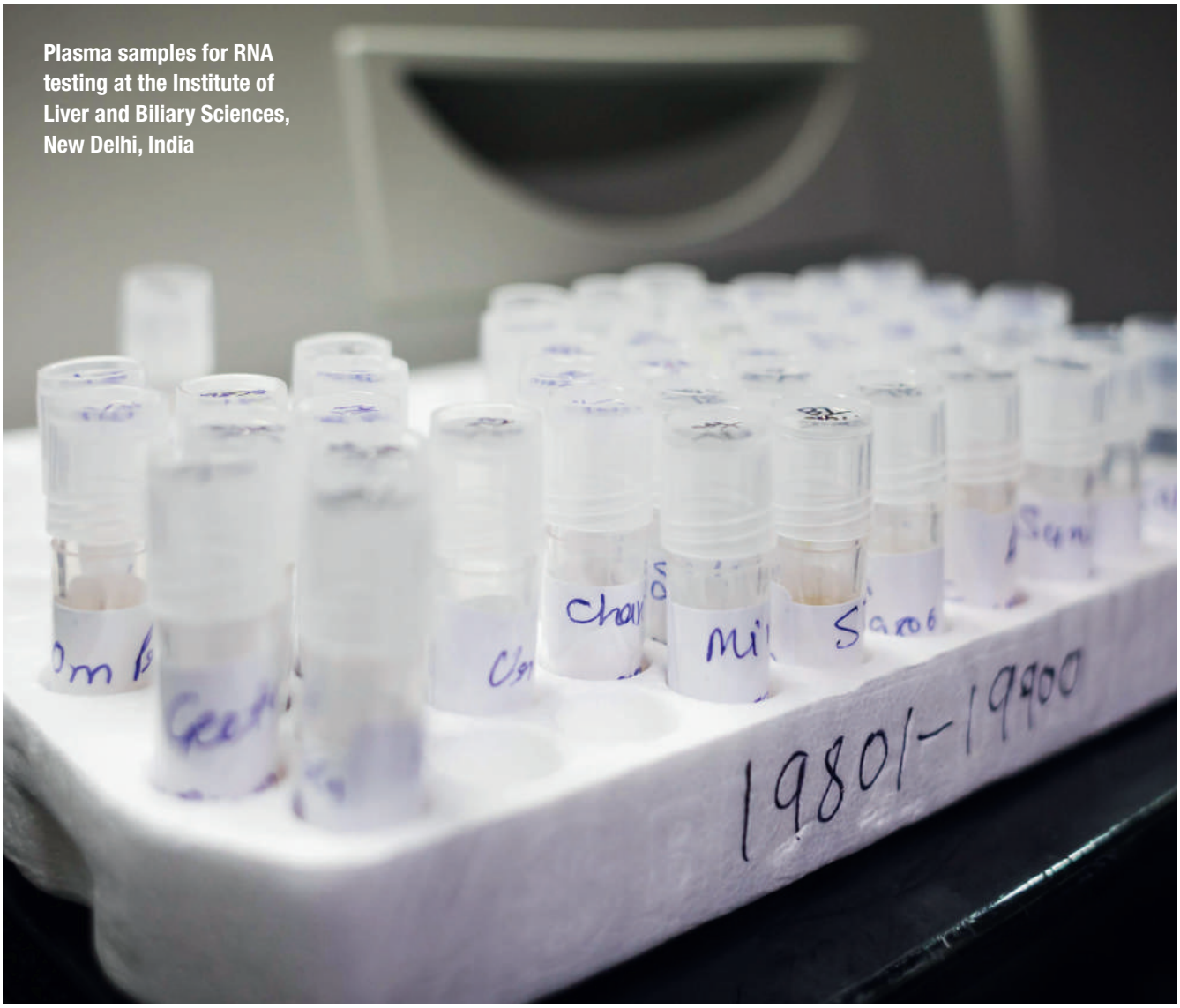
4 Apply DBS sampling demand rates to calculate total HCV VL DBS demand, taking into account some cannibalization of plasma sampling

Dried blood spot sampling demand for HCV VL testing was calculated using the demand rates for each scenario. Specifically, we converted these demand rates into "plasma demand multipliers" that we could multiply against the plasma demand estimates from the 2017 DXMI Report in order to calculate the estimated HCV VL DBS demand by country.

Note that we also applied a cannibalization rate to the plasma demand estimates from the 2017 DXMI Report since we anticipate that a portion of DBS demand will represent a substitution away from plasma sampling. In other words, the DBS demand in this model is not 100% additive to the plasma demand from the 2017 DXMI Report.

In order to estimate cannibalization rates, we leveraged empirical data from the HIV VL testing experience. Specifically, based on an assessment of the difference in growth rates for plasma versus DBS samples for HIV VL testing in Kenya, the analysis assumes that the increased usage of DBS in "medium demand" HCV countries will decrease the 2017 DXMI plasma demand estimates for these countries by ~4%. Similarly, leveraging empirical data on plasma versus DBS growth rates for HIV VL testing in Malawi, the analysis assumes that increased usage of DBS in "high demand" countries will decrease the 2017 DXMI plasma demand estimates for these countries by ~16%.

Finally, as a last step, we calculated total demand (i.e. plasma demand plus DBS demand) for HCV VL tests across 2018-2021 in order to understand the net effect that DBS introduction has on total HCV VL testing demand after taking into account cannibalization.



Plasma samples for RNA testing at the Institute of Liver and Biliary Sciences, New Delhi, India

Photo credit: © FIND / Ben Phillips

Methodological limitations

Appendix F provides an overview of the different data inputs that informed this model. While the analysis aimed to use quantitative, country-specific data where possible, it is important to note a few key methodological limitations:

The DBS need adjustment factor is based on an empirical analysis of distinct countries that uses simplifying assumptions: While it is useful to adjust DBS need estimates based on the rural population percentage with empirical data on DBS need from the 2014 CHAI analysis in sub-Saharan Africa (SSA), it is important to note that there is no overlap between the countries in the 2014 CHAI analysis (Malawi, Uganda, Kenya, and Zimbabwe) and the 28 countries evaluated in this HCV analysis. As a result, we cannot know for certain whether the 68% adjustment applied to the rural population estimate for the four SSA countries necessarily holds true for the in-scope HCV countries.

Additionally, the 2014 DBS need analysis uses a simplified assumption, namely, that facilities located within 20 kilometres of a testing site should be able to transport samples to the laboratory within 24 hours and therefore could rely upon plasma sampling. However, in reality, this "plasma radius" likely varies by country, based on factors such as the state of the sample transport infrastructure or the setup of the laboratory network. As a result, the 68% rural population adjustment factor that we applied does not fully capture country differences.

Reliance on qualitative or proxy data for index factor ratings where quantitative, country-specific data is limited: In cases where there was limited data on index factors for each country, we relied on qualitative or proxy measures as an approximation. This approach is most significant for the sample transport index factor, which is heavily weighted in the analysis. For 17 out of the 28 countries where we were unable to find specific data on the sample transport system in country, we used instead proxy data from the World Bank's Logistics Performance Index[7] that assigns a rating to each country on the strength of their trade and transport infrastructure. It is possible that this World Bank assessment of infrastructure may not accurately reflect the state of the sample transport system within the health sector.

Comprehensiveness of DBS demand drivers factored into the model: The analysis aimed to capture the primary factors that shape DBS demand. However, the model does not capture all factors that could shape DBS demand for HCV VL testing. For example, the level of centralization of the lab network may influence country interest in DBS demand or the regulatory environment in country may influence when DBS sampling could actually be rolled out. However, both for the sake of simplicity and in light of data limitations for the in-scope countries, we have chosen to focus our analysis on the 12 index factors described earlier in this report.

The above limitations are important to keep in mind as we now turn to the results of the HCV DBS market analysis.

7. The World Bank Logistics Performance Index – International Scorecard, https://lpi.worldbank.org/international/scorecard

Photo credit: © FIND / Francois Lamoury

HCV DBS FORECAST

Need

The total HCV VL testing need between 2018-2021 is estimated to be ~27.9M tests in order to meet WHO targets. Of these 27.9M tests, the estimated need for DBS samples between 2018-2021 is projected to be 8.7M (or ~31% of the total HC VL need). See **Figure 3** below for a breakdown of total HCV VL need by year and sample type.

As seen in **Figure 3**, the estimated need for plasma samples (69%) is greater than the need for DBS samples (31%) between 2018-2021. The preference for plasma samples is driven by the urban-rural ratios for the 28 HCV in-scope countries. The majority of the populations across these countries live in urban areas and, as such, we expect there to be a lesser need for DBS sampling, since people on average most likely live closer to HCV VL testing sites and/or have access to better sample transport infrastructure. It is worth noting that the urban-rural ratio is particularly high for China, which accounts for ~40% (11M) of the total HCV VL need between 2018-2021. China's urban population percentage between 2018-2021 is ~60%.

Finally, **Figure 4** below breaks down total DBS need for HCV VL testing by country. As seen in the graph, the countries with the largest HCV VL DBS need in terms of volume of tests are China, India, Pakistan, Nigeria, and Egypt. China in particular accounts for the largest portion of DBS need (~35%). While HCV prevalence in China is quite low (~0.7%), the magnitude of the population in China translates this relatively low prevalence into a large volume of HCV-infected people and thus a significant volume of HCV VL tests. The curve in **Figure 4** represents the cumulative percent of total DBS need moving from left to right.

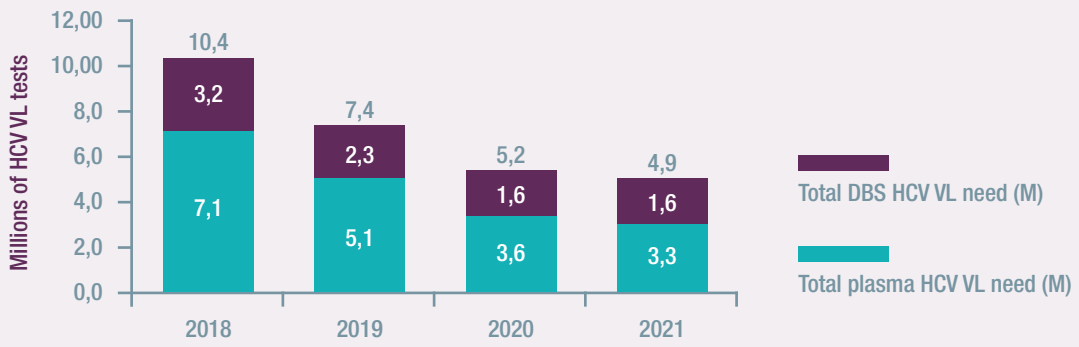


Figure 3. Estimated HCV VL need by sample type (millions of tests)

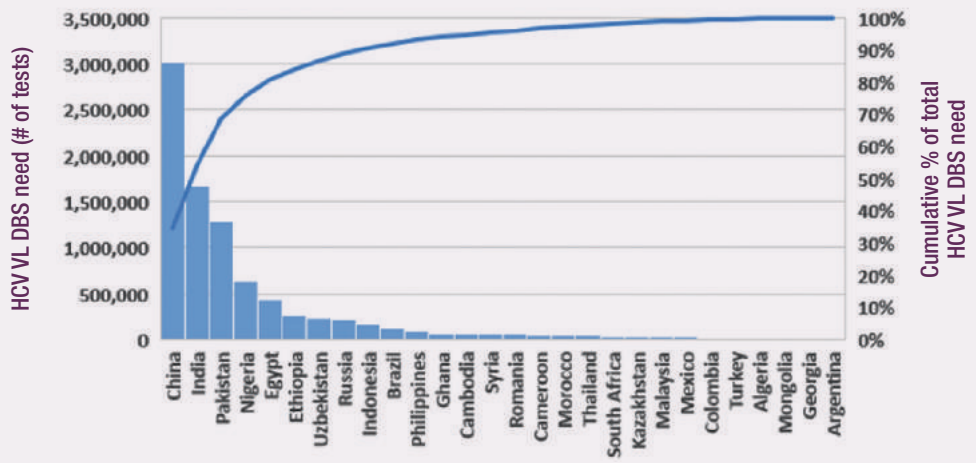


Figure 4. Breakdown of HCV VL DBS sampling need by country

Demand

While the estimated need for DBS is 8.7M tests between 2018-2021, the estimated demand is ~1.7M tests in this same timeframe. **Figure 5** below breaks down the total demand for HCV VL tests each year between the forecasted number of plasma versus DBS samples.

Adoption of DBS sampling is a gradual process as it will take time for funding, regulatory contexts, policies, and political will to coalesce around scaling up DBS for HCV VL testing. Additionally, in the near-term, it is likely that health systems will prioritize addressing the "low hanging fruit" of HCV VL testing, i.e. ensuring that populations living within 24 hours of the urban-based testing laboratories are getting their HCV VL tests. Once the testing need for these urban populations is being better met, say in Years 3 and 4 of the model, then it is more likely that countries will shift focus to increasing access for more rural populations, thus deploying DBS sampling more actively. This pattern of first scaling up access to VL testing for urban and peri-urban populations that can be served with plasma samples before subsequently shifting focus to remote populations that can be served with DBS samples was seen empirically in the scale-up of HIV VL testing in sub-Saharan Africa.

Figure 6 below shows the net effect of DBS demand on the overall demand for HCV VL tests across both DBS and plasma sample types. The purple columns reflect the estimated demand for plasma samples from the 2017 DXMI Report. The blue columns reflect the total estimated demand across both plasma and DBS samples, taking into account the appropriate cannibalization of plasma demand once DBS sampling comes on board. Across the 4 years, there is estimated to be an incremental increase in HCV VL demand of ~1.3M tests once DBS is introduced.

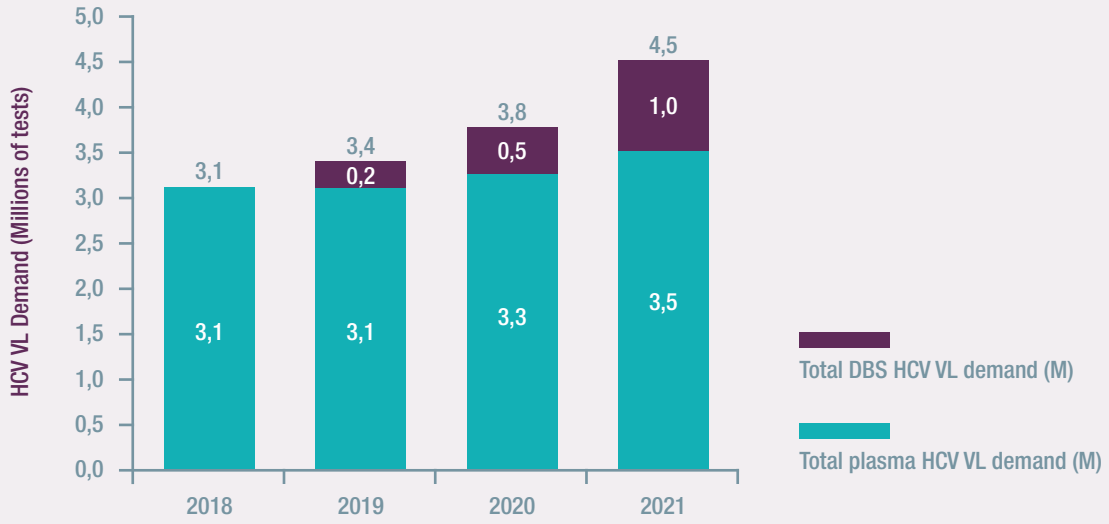


Figure 5. HCV VL demand by sample type (millions of tests)

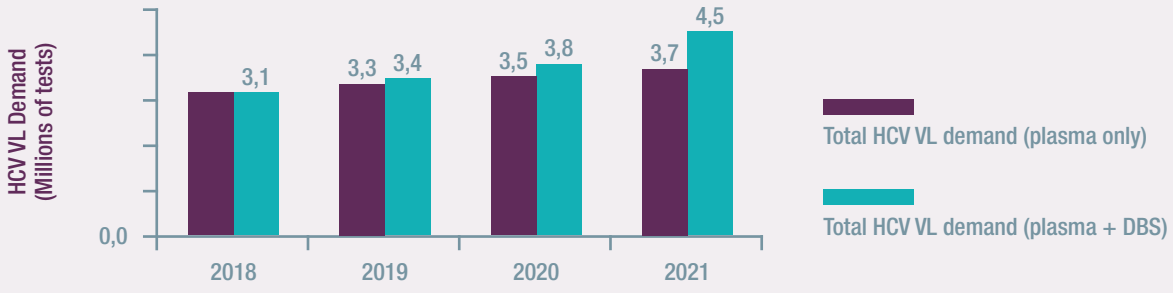


Figure 6. Total estimated HCV VL demand (2018-2021) with and without DBS sampling

As expected, the bulk of HCV VL DBS demand is coming from the "high DBS demand" countries and primarily in Years 3 and 4 (i.e. 2020-21). See also **Figure 7** below.

In terms of countries, India is expected to account for the largest percentage of HCV VL DBS demand (~39%), with Pakistan coming in second place (15%). India and Pakistan both account for high volumes of HCV-infected people and have contexts that are conducive to HCV DBS adoption. See **Figure 8** for breakdown on country-specific DBS demand.

Finally, it is worth noting that the demand forecast is quite sensitive to the demand rate assumptions. For example, doubling the demand rates for each of the four scenarios will increase total demand for DBS for HCV VL testing from 1.7M to 3.4M tests. Therefore, going forward, efforts should be made to continue to refine demand rate assumptions especially for high-volume HCV countries (e.g. China) and countries expected to generate significant DBS demand for HCV VL testing (e.g. India).

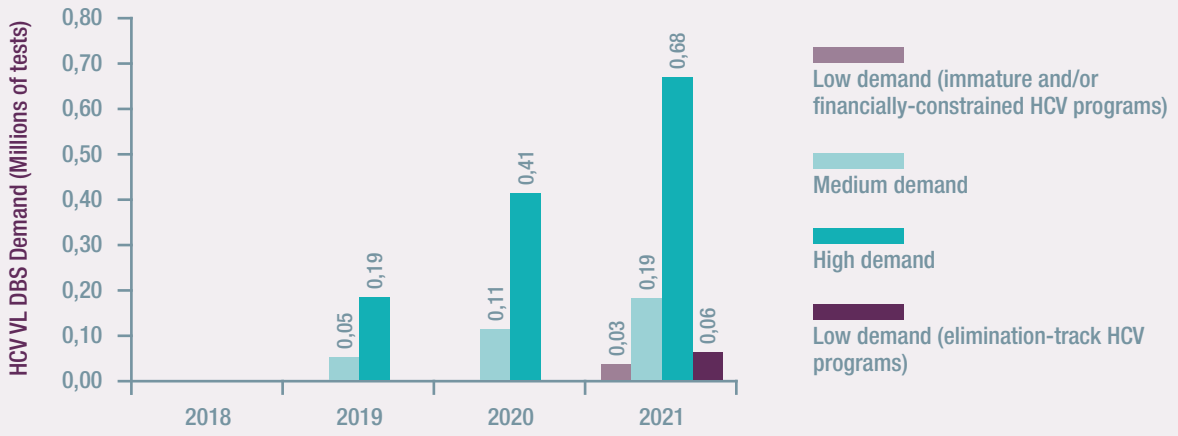


Figure 7. DBS demand for HCV VL by scenario (millions of tests)

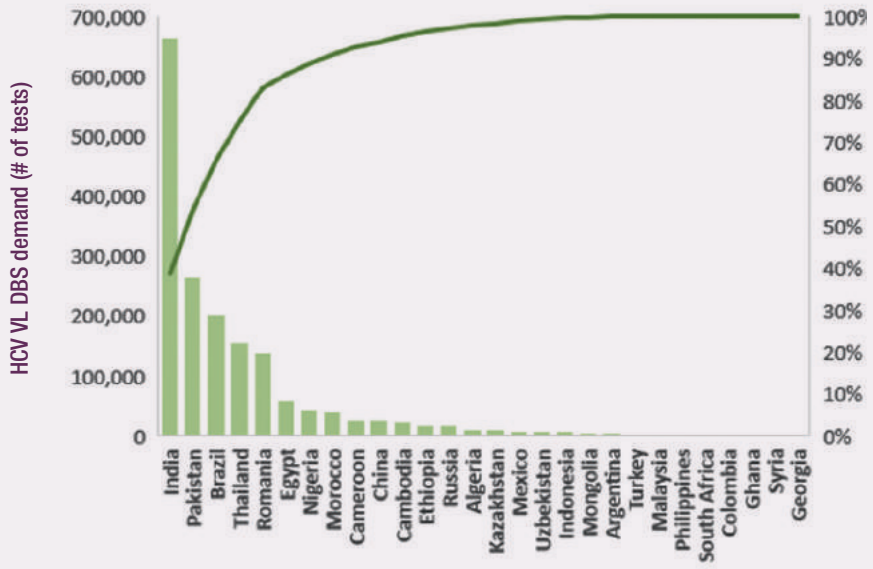


Figure 8. Breakdown of HCV VL DBS demand by country

KEY DRIVERS OF DBS DEMAND

Sample transport infrastructure

Gaps in a country's existing sample transportation infrastructure will directly impact its demand for DBS sampling for HCV VL testing. Generally speaking, countries would want to deploy DBS sampling to increase access to HCV VL testing in situations where there is low and/or ineffective coverage of existing sample transportation networks or where sample pickup from facilities or hubs does not happen in a timely manner.

For example, Cameroon has significant gaps in its sample transportation infrastructure. While motorcycle drivers are used to transport samples in select areas in the country, sample transport coverage overall is quite low. As such, an easier-to-implement DBS sampling approach may be compelling.

On the other hand, Pakistan has a plasma sample transport infrastructure that is quite strong. In Pakistan, plasma samples are collected at sample collection sites and transported to city labs by road, after which samples are flown to central testing labs. Results are then returned electronically to sample collection sites. While stakeholder interviews indicated that this plasma sample transportation system is generally working quite well, there are still a few rural pockets that are not well-covered. In these areas, DBS sampling could have an attractive value proposition.

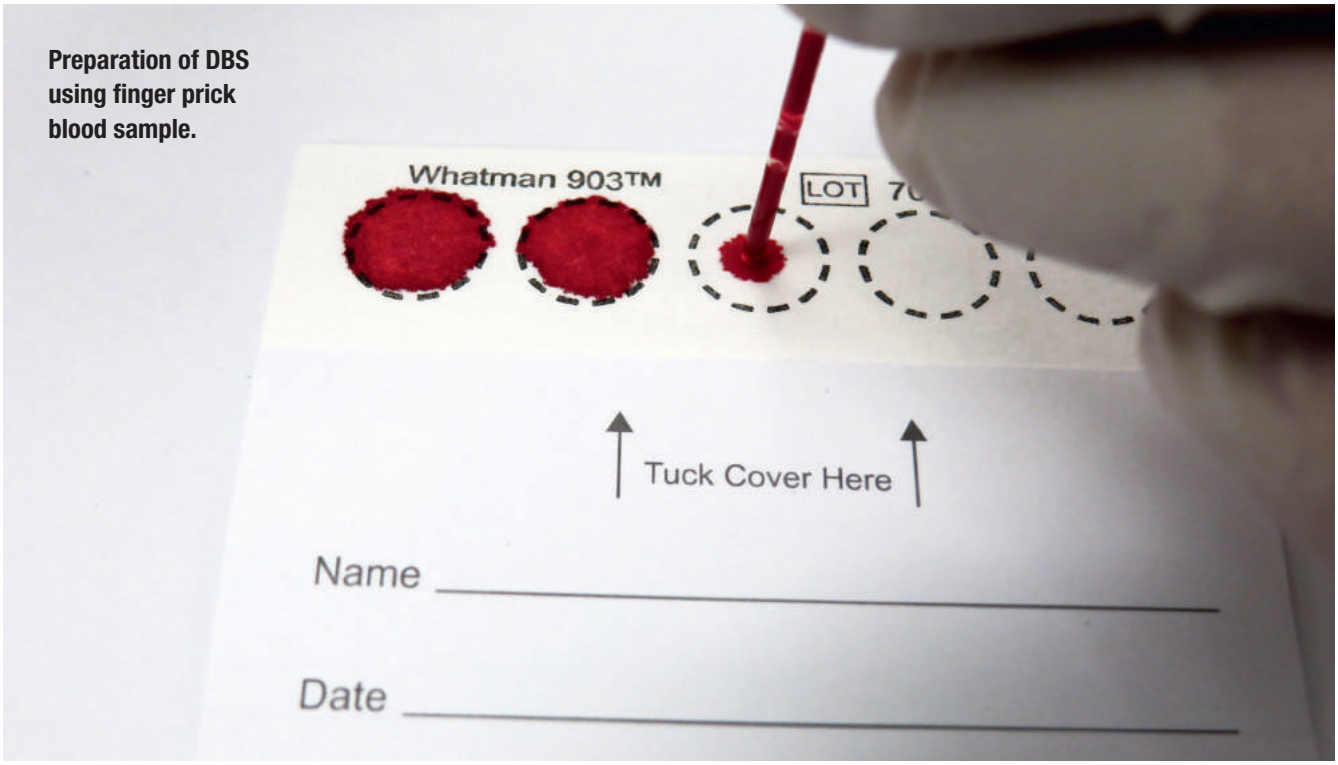
Finally, it is also worth noting that DBS demand for HCV VL testing will also be higher in countries where there are robust postal or courier networks, which are naturally conducive to transporting DBS samples. DBS samples can be transported via couriers or postal mail, since the DBS cards are safe to handle and no cold chain is required during the transportation process. Interviews with Indian stakeholders, for example, revealed a strong and reliable courier and postal network in place across the country which could be leveraged to transport DBS samples. The existence of this widespread courier system makes it more likely that India would consider deploying DBS sampling to expand access to both HIV and HCV VL testing.

As we think about demand drivers that impact DBS uptake for HCV VL testing, **it is worth noting a couple of sample transport-related actions that may boost demand for DBS sampling**:

- **Action 1** – **Sample transport mapping**: Countries may have multiple sample transport networks in place across different regions, disease areas, or sample types. Therefore, a key first step in understanding DBS need would be to map existing sample transport systems in terms of quality, coverage, and frequency of sample pickup in order to identify geographic areas that could most benefit from DBS sampling.
- **Action 2** – **Integration of sample transport networks:** Some countries already implement DBS sampling for HIV EID and/or HIV VL testing. Therefore, it is worthwhile to work with country stakeholders to develop a plan for further integrating sample transport networks across disease areas and assay types. This discussion, in turn, could spur explorations of how existing EID DBS sample transport systems, for example, could be easily expanded to support DBS for HCV VL testing.

DBS sample transportation is sometimes carried out by means of motorcycles in remote areas.

Photo credit: © FIND / Joseph Ndung'u



Preparation of DBS using finger prick blood sample.

Photo credit: © FIND /Francois Lamoury

Funding

Funding availability for HCV programs will directly impact a country's ability to scale up DBS sampling and to increase access to HCV VL testing. In terms of financing, countries vary in their funding landscape for diagnostics. Some countries rely on external funding from sources such as PEPFAR or GFATM while other countries have significant state-funded health programs.

For HIV, the existence of concentrated funding across large donors was vital for encouraging suppliers to invest in regulatory approvals for DBS protocols. However, the funding and procurement landscape for the in-scope HCV countries is more varied and this fragmentation may be less conducive to encouraging suppliers to invest in the development and approval of DBS assays for HCV VL testing. Different procurers may also have different requirements in terms of the regulatory approvals needed to deploy DBS in specific countries.

While the complex funding landscape may pose a barrier to DBS scale-up for HCV VL testing, the potential cost savings associated with DBS could be compelling for countries with limited health budgets. **Specifically, there are a couple of key actions that could be taken to boost DBS sampling for HCV VL testing:**

- **Action 1** – **Build the DBS "business case":** As described earlier in the report, there is some empirical data that the all-inclusive cost of DBS sampling is estimated to be lower than the all-inclusive cost of plasma sampling. Since many of the in-scope LMICs have limited funding available for HCV, potential cost efficiencies associated with DBS are especially compelling. To the extent feasible, starting to quantify DBS cost savings and associated health impact, especially for the medium- and high-demand countries, could help to accelerate DBS uptake since doing so can concretely demonstrate how countries can utilize DBS to increase the reach of their HCV VL testing programs at a relatively lower cost than if they just relied on plasma sampling.
- **Action 2** – **Understand funding availability and requirements in medium- and high-demand countries:** Given the fragmented funding landscape for HCV diagnostics, it is important to map the funding situation in medium- and high-demand HCV DBS countries. Doing so will clarify which country contexts are most financially conducive to scaling up DBS sampling for HCV VL testing and will also highlight important regulatory requirements needed in order for HCV VL DBS assays to be rolled out in key countries.

HIV DBS experience

Finally, countries that have experience implementing DBS for HIV VL and EID testing are most likely better suited to deploy DBS sampling for HCV VL testing in a timely manner. The importance of previous DBS experience was shown empirically in the HIV space. Here, scaling up DBS for HIV VL testing was easier in countries that were already using DBS cards for EID testing since healthcare workers had already been trained on this type of sampling and sample transport networks were already in place.

For this reason, we expect countries like India and Cameroon to generate significant demand for HCV DBS in the coming years. In India, the Abbott DBS assay for HIV VL is currently being validated for use and the country is planning to significantly scale up public-sector HIV VL testing using Abbott instruments. Similarly, in Cameroon, DBS for HIV VL is already validated in country and the Ministry of Health, in collaboration with key partners such as FIND,is currently exploring ways to implement DBS sampling for HCV VL testing.

It is worth noting, however, that many other countries in-scope for this HCV market analysis are not currently implementing DBS sampling for HIV VL testing. This may be because the nature of the HIV epidemic looks different in these countries than it does in sub-Saharan African countries. While HIV has a relatively high prevalence in SSA and is spread across rural and urban areas, HIV epidemics in countries such as China, Uzbekistan, Turkey, and Thailand tend to be of lower prevalence. Additionally, they tend to be concentrated in high-risk populations (e.g. drug users, sex workers) that live primarily in urban areas. As such, it seems reasonable that DBS demand for HIV VL is lower in these countries than it is in SSA.

In light of the above, there are a few key actions that could be taken to boost DBS sampling demand for HCV VL testing:

- **Action 1** – **Demonstrate how DBS sampling for HCV VL testing could build off DBS for HIV VL testing:** In countries with HIV DBS experience, it would be worthwhile to develop concrete examples for how implementation of DBS for HCV VL testing could easily build off existing DBS efforts (e.g. by highlighting how there is minimal additional training required for sample collection staff or how existing DBS sample transport networks can also be used for HCV VL testing).
- **Action 2** – **Develop case studies to educate countries less familiar with DBS sampling:** Since many high-burden HCV countries may not have firsthand experience with DBS, time will need to be spent informing key decision makers, funders, and procurers on the value of DBS sampling. The DBS value proposition can be demonstrated through cost-benefit analyses as well as empirical country case studies that show how DBS sampling can help to simplify sample collection, preparation, transportation, and storage while also increasing access to diagnostic tests.

Conclusion

FIND and CHAI, with support from Unitaid, were eager to explore the potential impact of DBS sampling on the HCV VL testing market. As described in this report, the total need for DBS samples for HCV VL testing between 2018-2021 is expected to be ~8.7M tests out of a total HCV VL testing need of ~28M tests. Plasma sampling, therefore, is expected to remain the dominant sample type for HCV VL testing needs through 2021. On the demand side, DBS sampling is expected to account for ~2M HCV VL tests between 2018-2021 whereas plasma demand will account for ~13M HCV VL tests over this same timeframe. Incorporating estimates of how DBS introduction may cannibalize a portion of plasma demand, the net increase in the overall demand for HCV VL tests once DBS is implemented as compared to a plasma-only world is expected to be ~1.3M tests between 2018-2021.

This incremental increase is notable since it implies that an additional ~1.3M people will have access to HCV VL testing due to DBS who would not have had access in a plasma-only world. It is also worth noting that DBS demand is forecasted to increase significantly in Years 3-4 (i.e. 2020-21) implying that DBS might play an increasingly more important role in HCV VL testing in the years leading up to 2030.

Key factors driving demand for HCV:

1 **Existing sample transport networks:** Gaps in existing plasma sample transport networks, such as limited facility coverage or infrequent sample pickups, can strengthen the case for DBS sampling in high-burden HCV countries. Mapping existing sample transport networks can be a useful exercise to identify how distinct sample transport networks can be integrated going forward in a way that could accelerate DBS implementation for HCV VL testing.

2 **Funding:** Unsurprisingly, countries with more funding available for their HCV programs will likely be better-situated to deploy DBS sampling. Even for countries with limited funding available, however, it can be worthwhile to build a DBS business case since the potential cost-efficiencies associated with DBS sampling could still be compelling.

3 **HIV DBS experience:** Finally, we would expect to see greater and faster uptake of DBS sampling for HCV VL testing in countries such as India that are already exploring DBS for HIV VL testing. Given that several high-burden HCV countries do not have firsthand experience using DBS for HIV VL testing, there will likely be some upfront investment required to inform key decision-makers, partners, and funders on the potential public-health and financial impacts of DBS sampling for HCV VL testing.

While DBS demand for HCV VL testing is expected to be ~2M tests between 2018-2021, it is possible that this market could grow significantly in the years beyond 2021 as countries focus their attention on achieving the 2030 WHO target of 90% of HCV-infected individuals being diagnosed, as HCV country programs become more mature, and as countries begin to expand their focus on HCV VL testing beyond the more accessible urban and peri-urban populations to more remote communities. Given that it will take time to change country guidelines, to obtain regulatory approval for HCV VL DBS protocols, and to deploy DBS in practice, diagnostic suppliers should consider investing time and resources into their HCV DBS protocols in the coming years. By doing so, suppliers will be better-positioned to support countries as the demand for DBS sampling for HCV VL continues to grow. In parallel, additional steps can be taken to refine this HCV DBS market forecast particularly in countries expected to have medium-to-high levels of DBS demand or medium-to-high HCV disease burdens.

Appendix A: Details on whole blood and plasma sample stability

Temperature	EDTA tube	Plasma Preparation Tube (PPT)	Notes
Whole blood (prior to centrifugation)			
Room temp.	6 hours	6 hours	Plasma must be separated from whole blood within these timeframes
2 - 8°C	24 hours (Abbott: 48 hours)	24 hours	
Plasma (post centrifugation)			
Room temp.	NA	24 hours	Roche: PPT tube must be re-centrifuged 600xg five minutes prior to use
2 – 8°C	NA	5 days	
- 70°C	NA	Months	Applicable only to Abbott
≤ - 70°C	6 months - 5 years		

Appendix B: List of in-scope countries for the HCV DBS market analysis

Countries included in this HCV VL DBS need and demand forecast:

1. Algeria
2. Argentina
3. Brazil
4. Cambodia
5. Cameroon
6. China
7. Colombia
8. Egypt
9. Ethiopia
10. Georgia
11. Ghana
12. India
13. Indonesia
14. Kazakhstan
15. Malaysia
16. Mexico
17. Mongolia
18. Morocco
19. Nigeria
20. Pakistan
21. Philippines
22. Romania
23. Russia
24. South Africa
25. Syria
26. Thailand
27. Turkey
28. Uzbekistan

Additional countries interviewed to inform the analysis:

- Kenya
- Malawi
- Myanmar
- Vietnam

Appendix C: Overview of index factors and their weighting

Category	Index factor	Rationale for inclusion in demand model	Max. score
HCV country context	HCV viremic prevalence	Countries with higher HCV prevalence are likely to have greater demand for HCV diagnostics since HCV has a bigger impact on their national disease burden	3
	Direct-Acting Antiviral therapies (DAAs) in use	Countries using DAAs for HCV treatment are more likely to demand HCV VL tests for confirmatory and SVR12 testing	3
	National HCV Strategic Plan	Countries with an HCV strategic plan are more likely to have political will and resources dedicated to HCV diagnostics procurement	3
	Active screening	Countries in which active HCV screening is occurring will have greater demand for HCV VL testing	3
	Demand generation	Countries that are actively working with patients and healthcare workers to boost demand for HCV diagnostic testing will tend to have greater demand for HCV VL testing	3
	Level of HCV lab capacity	Countries with greater HCV VL lab capacity are more likely to demand an additional sample type to boost instrument utilization	3
	Subtotal		18
Funding	Financing availability	Countries with more financing options available (e.g. from external funders) will be better situated to rollout DBS sampling for HCV VL	16
	HCV funding	Countries with bigger HCV budgets are better situated to add another sample type for HCV VL testing	16
	Subtotal		32
DBS-specific factors	Size of rural population	Countries with a greater rural population percentage are more likely to need DBS sampling	18
	Sample transport system gaps	Countries with gaps in their current sample transport systems are more likely to demand a different sample type which is simpler to implement	18
	Current DBS demand for HIV VL	Countries where DBS sampling is already in use for HIV are more likely to demand DBS for HCV	6
	Future DBS demand for HIV VL	Countries that are planning to scale up DBS use for HIV in coming years are also more likely to demand DBS for HCV VL testing in coming years	8
	Subtotal		50
Maximum score across index factors			100

Appendix D: Overview of index factor scoring assumptions and ratings

Section	Index factor	Definition	Weighting (max score)	Scoring			
HCV country context	Viremic Prevalence	HCV prevalence % based on Polaris data; pulled from DXMI Report	3	<	1%	Low	0
				<	2.50%	Medium	1.5
				> or =	2.50%	High	3
	Country Using DAAs for Treatment	Yes or No; pulled from DXMI Report	3			No	0
						Yes	3
	National Strategic Plan for HCV	Yes or No; pulled from DXMI Report	3			No	0
						Yes	3
	Active Screening Program in Place	Yes or No; pulled from DXMI Report	3			No	0
						Yes	3
	Demand Generation Activities	Took number of HCV implementing partners in country as a proxy; pulled from DXMI Report	3	<	2	Low	0
				<	5	Medium	1.5
				> or =	5	High	3
	Level of Lab Capacity	Qualitative assessment (high, medium, low) based on country instrument data where possible; pulled from DXMI Report	3			Low	0
						Medium	1.5
						High	3
Funding	Level of Financing Availability	Qualitative assessment based on % health budget from external sources, presence of HCV in national budget / national insurance system, cost of diagnosis / treatment relative to per capita spend, etc.; pulled from DXMI Report	16			Low	0
						Medium	8
						High	16
	HCV funding	Size of HCV budget (high, medium, low); pulled from DXMI Report	16			Low	0
						Medium	8
						High	16

Section	Index factor	Definition	Weighting (max score)	Scoring			
DBS-specific factors	Size of rural population	Based on UN rural populations estimate (average over 2018-2021)	18	<	40%	Low	0
				<	70%	Medium	9
				> or =	70%	High	18
	Gaps in coverage of existing plasma sample transport system	Estimated based on country input on the portion of health facilities that have access to sample transport; where country data was lacking, used the World Bank Logistics Performance Index (LPI) rating of country transport infrastructure as a proxy	18	Good coverage with a few gaps or greater than 3 on LPI		Low	0
				Patchy coverage or between 2-3 on LPI		Medium	9
				Minimal coverage or less than 2 on LPI		High	18
	Current DBS % for HIV VL	Portion of a country's total HIV VL tests in 2018 that used DBS samples; where data exists, low coverage was considered <25%, medium between 25-50%, and high > 50%	6			Low	0
						Medium	4
						High	6
	Future DBS % for HIV VL	Portion of a country's total HIV VL tests in 2021 projected to use DBS samples; where data exists, low coverage was considered <25%, medium between 25-50%, and high > 50%	8			Low	0
						Medium	4
						High	8

Appendix E: Detailed index factor categorization by country

Country		Egypt	Georgia	Mongolia	Ethiopia	Brazil	Mexico	Indonesia	Thailand	Romania
Total index factor score		63.5	56.0	45.5	43.5	43.5	39.5	39.0	37.0	35.5
Scenario		Scenario 4	Scenario 4	Scenario 4	Scenario 3	Scenario 3	Scenario 3	Scenario 3	Scenario 3	Scenario 3
HCV country context	Viremic Prevalence	High	High	High	Medium	Medium	Medium	Medium	High	Medium
	Country Using DAAs for Treatment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
	National Strategic Plan for HCV	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No
	Active Screening Program in Place	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes
	Demand Generation Activities	Low	Low	Medium	Low	Medium	Medium	Low	Low	Medium
	Level of Lab Capacity	Medium	High	Low	Low	Medium	Medium	Medium	High	Medium
Funding	Level of Financing Availability	High	High	High	Low	Medium	High	Low	High	Medium
	HCV funding	High	High	High	Low	High	High	Low	Low	Medium
DBS-specific factors	Size of rural population	Medium	Medium	Low	High	Low	Low	Medium	Medium	Medium
	Gaps in coverage of existing plasma sample transport system	Medium	Low	Low	Medium	Medium	Low	High	Low	Low
	Current DBS % for HIV VL	Low	Low	Low	Medium	Low	Low	Low	Low	Low
	Future DBS % for HIV VL	Low	Low	Low	High	Low	Low	Low	Low	Low

Country		Cambodia	India	Nigeria	Cameroon	Morocco	Uzbekistan	Argentina	Pakistan	Kazakhstan
Total index factor score		34.5	34.0	34.0	33.5	28.0	27.5	26.5	26.0	24.5
Scenario		Scenario 3	Scenario 3	Scenario 3	Scenario 3	Scenario 2	Scenario 2	Scenario 2	Scenario 2	Scenario 2
HCV country context	Viremic Prevalence	High	Low	High	High	Low	High	Medium	High	High
	Country Using DAAs for Treatment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
	National Strategic Plan for HCV	No	No	Yes	No	Yes	Yes	Yes	No	No
	Active Screening Program in Place	No	No	No	No	Yes	No	No	No	Yes
	Demand Generation Activities	Low	High	High	Medium	Low	Low	Medium	High	Low
	Level of Lab Capacity	Medium	High	Low	Low	High	Medium	Medium	Low	Medium
Funding	Level of Financing Availability	Low	Low	Low	Low	High	Medium	Medium	Low	Medium
	HCV funding	Low	Medium	Low	Low	Low	Low	Medium	Medium	Low
DBS-specific factors	Size of rural population	High	Medium	Medium	Medium	Low	Medium	Low	Medium	Medium
	Gaps in coverage of existing plasma sample transport system	Medium	Low	Medium	Medium	Low	Low	Low	Low	Low
	Current DBS % for HIV VL	Low	Low	Low	Medium	Low	Low	Low	Low	Low
	Future DBS % for HIV VL	Low	High	Medium	Medium	Low	Low	Low	Low	Low

Country		Russia	Turkey	Algeria	Malaysia	China	Ghana	Philippines	South Africa	Colombia	Syria
Total index factor score		23.0	22.0	20.5	20.0	18.5	18.0	15.0	14.0	10.5	10.5
Scenario		Scenario 2	Scenario 2	Scenario 2	Scenario 1	Scenario 1	Scenario 1	Scenario 1	Scenario 1	Scenario 1	Scenario 1
HCV country context	Viremic Prevalence	High	Low	Medium	High	Low	High	Medium	Medium	High	Medium
	Country Using DAAs for Treatment	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No
	National Strategic Plan for HCV	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No
	Active Screening Program in Place	Yes	No	No	No	Yes	No	No	No	No	No
	Demand Generation Activities	Medium	Medium	Low	Low	Medium	High	Low	Low	Low	Low
	Level of Lab Capacity	Medium	Medium	Low	High	High	Low	Medium	Medium	Medium	Low
Funding	Level of Financing Availability	Medium	Medium	Medium	Low	Medium	Low	Low	Medium	Low	Low
	HCV funding	Low	Medium	Medium	Medium	Low	Low	Low	Low	Low	Low
DBS-specific factors	Size of rural population	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Medium
	Gaps in coverage of existing plasma sample transport system	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
	Current DBS % for HIV VL	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
	Future DBS % for HIV VL	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low

Appendix F: Key data inputs to the HCV VL DBS model

Several data sources informed the market analysis summarized in this report:

- **The 2017 DXMI model and report:** The report is available at https://www.finddx.org/wp-content/uploads/2018/04/HCV-Diagnostics-Market-Intelligence-Report_18APR2018.pdf

- **Publicly-available information on in-scope countries:** Country HCV guidelines and strategic plans, information on laboratory infrastructure and testing capacity, information on DBS policy and implementation across diseases, etc.

- **Country DBS analysis survey:** Collected input from CHAI, FIND, laboratory, and/or public-sector stakeholders in 13 countries to understand country HCV programs, diagnostics landscapes, and the factors that shape potential demand for DBS sampling for HCV VL testing. Specifically, information was collected on:
  - Guidelines for hepatitis, as well as other diseases like HIV
  - Domestic regulatory approval processes for diagnostics
  - NAT platform availability and testing capacity (for hepatitis and other diseases)
  - NAT testing volumes (for hepatitis and other diseases)
  - Funding and procurement processes for HCV diagnostic commodities
  - Specimen transport networks

- **CHAI's Annual Diagnostics Data Request:** Annual data request completed by CHAI diagnostic country teams in collaboration with other in-country stakeholders. Provides useful information on DBS uptake rates for HIV VL testing.

- **Interviews with DBS-experienced countries:** Select interviews were conducted with CHAI staff based in countries that have experience using DBS sampling for HIV VL testing. These interviews were used to gain a deeper understanding of the empirical factors that shape DBS adoption and implementation on the ground.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