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DECENTRALISATION, INTEGRATION AND OUTREACH



**A PUBLIC HEALTH APPROACH TO TESTING, CARE, AND TREATMENT FOR
HCV INFECTION IN PAKISTAN** | *Zahid H., Smiley S., Cunningham N.*

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This guidance document has been developed for National Guidelines for Testing, Care, and Treatment for HCV Infection in Pakistan. The authors would like to acknowledge valuable inputs from MSF operational Centre Brussels (OCB) Karachi Project technical Medical Team – Dr Yuely Capileño and Dr Khawar Aslam. Support and guidance was also provided by MSF OCB co-ordination team – Dr Gul Ghuttai Khalid and Anna Cilliers. Special thanks to MSF OCB Headquarters for reviewing the document and providing valuable input – Jessica Burry, Emmanuel Fajardo and Dr Dmytro Donchuk.

AUDIENCE

This module is relevant for different members of the health workforce working on hepatitis including:

- Ministry of health officials such as hepatitis programme managers, procurement officers and health information system managers at provincial and sub-provincial levels;
- Ministry of health officials of other existing vertical programmes with a capacity to integrate HCV care such as TB, HIV and Polio programmes;
- Staff of the viral hepatitis programme or partner organizations supporting the programme involved with delivery of programmatic care at district and sub-district levels;
- Consultants and staff working at research or public health institutes involved with Hepatitis C testing and treatment within Pakistan.

Glossary of terms

HBsAg

The hepatitis B virus (HBV) surface antigen (HBsAg) is a marker of current infection HBV.

Anti HCV

Antibody against the hepatitis C virus (HCV) that are a serological marker of past or present infection. Persons identified positive for anti HCV must be tested for HCV RNA or HCV core antigen to determine if they are currently infected with HCV.

HCV PCR

HCV Polymerase Chain Reaction (PCR) is a confirmatory test for chronic HCV infection.

SVR12

The Hepatitis C virus PCR done 12 weeks following the completion of treatment. A sustained virological response (SVR) denotes the body is clear of any detectable levels of HCV RNA.

ABBREVIATIONS AND ACRONYMS

Ab	antibody
AST	aspartate aminotransferase
APRI	AST-to-platelet ratio index
ART	antiretroviral therapy
ARV	antiretroviral
DAA	direct-acting antiviral (medicine)
DBS	dried blood spot
FDA	United States Food and Drug Administration
FDC	fixed-dose combination
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HIV	human immunodeficiency virus
LMICs	low- and middle-income countries
MSF	Médecins Sans Frontières or Doctors Without Borders
MSM	men who have sex with men
NAT	nucleic acid testing/test
NSP	needle–syringe programme
OST	opioid substitution therapy
PEG-IFN	pegylated interferon
PWID	people who inject drugs
RBV	ribavirin
RDT	rapid diagnostic test
RNA	ribonucleic acid
SVR12	sustained virological response at 12 weeks post-treatment
TB	tuberculosis
WHO	World Health Organization

NATIONAL PLANNING

The elimination of hepatitis C infection should ideally be based on the local epidemiological context; beginning from current coverage of testing, treatment and prevention; and should be planned to optimise existing healthcare infrastructure and available financial and human resources. In the context of Pakistan, decentralisation of services, followed by community outreach and further improvement of regulated services would broaden access to screening and treatment as well as increase availability of safer health services, all contributing to reduced transmission of hepatitis C.¹ National, provincial and private stakeholders should all use the same plan for service coverage targets in their respective interventions in order to measure progress towards the goal of elimination.

DATA SYSTEMS TO MONITOR CASCADE OF CARE

The WHO has developed a monitoring and evaluation framework to allow member states to report on viral hepatitis elimination targets. Three indicators describe the cascade of care in each country: the proportion of infected persons diagnosed (core indicator C6b); treatment initiation rate (core indicator C7b); and the proportion of those treated who are cured (C8b).² These three core indicators may be estimated by compiling and triangulating data from different sources. Programs without a base-line prevalence of their catchment areas cannot generate the complete cascade of care, but should at least be able to generate a cascade of cure for their individual programs. Confidentiality and data security must be ensured at all stages. Aggregating data in national database would allow visualisation of trends which would be the key to identify bottle-necks in the cascade of care, and could help program managers set realistic targets for their programs. Near real-time data would allow them to project resource requirements and aid with a greater decision making capacity to increase the efficiency and cost-effectiveness of their programs.

GENERIC MEDICINES IN PAKISTAN

In Pakistan, several of the most recently-developed DAAs are produced as generics, allowing significant price reductions. Pakistan enjoys some of the lowest prices for DAAs in the world. In order to eliminate cost-related barriers, private and public healthcare providers may avail themselves of inexpensive generic medicines. However, quality should not be compromised in favour of volume. The same holds true for diagnostic and screening tools. Only quality-assured products should be procured from manufacturers, as inefficacious treatments or testing implements could create more problems in the long run that are both harmful to the affected population and very costly to resolve.^{3,4}

COST SAVING STRATEGIES TO SCALE UP DIAGNOSIS AND TREATMENT

Procuring commodities for the screening, diagnosis and treatment of HCV may include competitive tendering in cases of drugs for which multiple manufacturers of generic medicines are registered. Price/volume negotiation with originators could be considered for drugs where generics cannot be procured. Pooled procurement mechanisms may also bring economies of scale in procurement of commodities. Both of these approaches may improve by provincial programmes implementing a single standard regimen allowing for pooled procurement and economies of scale.⁵ Procurement of diagnostics should not be based solely on the lowest available prices: quality should also be given a high priority. All diagnostics should be WHO prequalified or approved by a stringent regulatory authority. Just as WHO has developed an Essential Diagnostic List (EDL) akin to the well-known Essential Medicine List (EML)⁶, Pakistan should also develop its own national essential diagnostics list and, where possible, incorporate access provisions to ensure affordability of diagnostics.

As part of competitive tendering and negotiations with manufacturers, provincial programmes may also consider novel pricing agreements such as: 1) Instrument rental options to avoid making expensive purchases up-front, and becoming 'locked in' to using products from only one company; 2) All-inclusive pricing agreements or a price-per-patient result model whereby reagents, consumables, controls, service and maintenance, and shipment are included as part of a comprehensive pricing scheme.⁷ 3) In the case of multi-disease platforms, bundled pricing discounts across different disease tests based on a volume-based pricing model.

The use of multiplex RDTs for the simultaneous screening of HCV, HBV and HIV holds the potential to streamline the procurement process and be more cost saving. Integrated programs may benefit most from this option as a single point of entry for patients.⁸

ANTICIPATING STOCK-OUTS

To estimate the volume of products required to meet the programme demand, managers must estimate the size of population in need of treatment and expected rate of scale up for testing and treatment activities. Programme managers should ensure that a sufficient volume is accounted for so as to cover a patient's full course of treatment. If drug flow is an issue, care providers may consider dispensing the full course of drugs to the patient of treatment initiation to avoid treatment interruption.

DECENTRALISATION

The 2018 WHO Guidelines for the Care and Treatment of Persons Diagnosed with chronic Hepatitis C Infection defines decentralisation of services as “service delivery at peripheral health facilities, community-based venues and locations beyond hospital sites, bringing care nearer to patients.”⁹ Devolving service delivery to lower-level health facilities reduces transportation, wait times and opportunity costs for patients; improving linkage and adherence to treatment. Decentralisation of HIV treatment services was a key factor in successful global scale-up of ARV coverage, and preliminary research suggests the same of hepatitis C treatment with DAA.^{10,11} Resources that are already engaged as part of primary (or other) healthcare programming may be used toward screening and treatment for HCV, with medications, testing implements and training of staff representing minimal additional costs.

DECENTRALISATION OF TESTING

Decentralisation of testing services will require access to quality-assured rapid diagnostic tests (RDTs); either qualitative analysis at point-of-care (POC) or specimen referral networks with good centralised diagnostics facilities; and treatment or referral capacity for chronic HCV patients. Comparative studies of WHO-prequalified rapid diagnostic tests (RDTs) available in Pakistan in 2018 have shown over 99% sensitivity and 100% specificity.¹² As RDTs are accurate, safe, and inexpensive, they are recommended for use as first-line tests for anti-HCV in almost all settings. Due to the expense and time required to produce the results, ELISA testing is no longer recommended for use.¹³ Rapid tests are designed to be used by health workers with limited training in outreach and decentralised point-of-care testing.¹⁴

DECENTRALISATION OF DIAGNOSIS

It is now possible to do viral load testing at point-of-care (POC), which may reduce the need for a patient to wait and return for a confirmatory diagnosis.¹⁵ Bringing down such barriers may translate into better patient adherence and a greater efficiency in time and resources.¹⁶ Placing diagnostic facilities within reach of more patients may reduce loss to follow-up between end-of-treatment and SVR12 Viral Load testing. Whether or not an investment in POC diagnostic capacity is financially and programmatically rational depends on the specific context and location of programming. Point-of-care testing should therefore be implemented only when appropriate and where resources allow. In the case where it is not possible or desirable to implement POC testing or to deploy equipment within decentralised setting, quantitative or qualitative (provided assay has acceptable accuracy) diagnostic analysis at centralised laboratories nearest to the decentralised site are an acceptable alternative. Using laboratory services near testing sites speeds processing of samples and reduces risk of loss or destruction during transport. Investment in centralised diagnostic facilities should be optimised to provide efficient multi-disease diagnostic services at a reasonable cost.¹⁷ Locations where decentralised facilities have insufficient sample collection mechanisms in place, dried blood spot (DBS) sampling technique may prove to be a simple and efficient method.

DECENTRALISATION OF TREATMENT

Several models of decentralised HCV testing and treatment service delivery have demonstrated success in high-burden countries, including Pakistan.¹⁸ Task-sharing, the use of a simplified screening and treatment algorithm, and differentiation of care are three approaches that may also facilitate the decentralisation of treatment to peripheral areas.

1. Task-sharing

Effective task-sharing of clinical management of HCV patients between non-specialist doctors or nurses could address the shortage of specialist capacity to cope with the full extent of the disease burden. Experience from several countries including Pakistan demonstrates that very good results can be obtained treating patients with DAA using resources already available at primary healthcare level (general practitioners and nurses).¹⁹ To be successful, such task-sharing would require provision of appropriate training in decentralised settings and support from and/or access to specialised healthcare providers through referrals for more complicated cases.

2. Simple standardized algorithm

WHO HCV Guidelines (2018) recommends the usage of a simplified algorithm.²⁰ The simplified algorithm does not require secondary or tertiary care, and is suited for use in both public and private healthcare settings. The use of a simplified algorithm is the key to the task-sharing, decentralisation and rapid increase in numbers of patients treated necessary to meet elimination targets. Within decentralised clinics, non-specialist doctors can easily refer to the algorithm and provide treatment. Clear case-definitions allow identification of cases warranting referral to higher-level facilities.

3. Differentiation of HCV case management

WHO notes that differentiated care is a “client-centred approach that simplifies and adapts services across the cascade, in ways that both serve the needs of those with more complex problems requiring an urgent care, or a specialised and/or modified clinical care. Such an approach also relieves the overburdened hepatitis clinics and tertiary hospitals.”²¹ In order for differentiation to succeed, point-of-care healthcare practitioners require appropriate training and tools to carry out treatment assessment with clear case-definitions, as well as a good knowledge of referral network. At present, most hepatitis C treatment is facility-based. Delegating case management to different levels of healthcare providers according to patient needs optimises resource use, both for the health system and for the patients.

Integration

WHO 2018 guidelines recommend integrating HCV services into existing health services where possible according to characteristics and capacity. Integrating services reduces the overall resources required with an incremental return on investment. It also improves health equity for the population.²² With the availability of highly quality RDTs designed to be used at POC by lay health workers, screening for HCV can now more easily be integrated into existing services. However, integration of HCV testing requires additional attention in linkage to care.

Service delivery	Screening and testing services	Outreach services	Diagnostic testing services
<ul style="list-style-type: none"> ■ Primary healthcare clinic ■ Basic Health Unit ■ Rural Health Unit ■ TB Clinic ■ Drug rehabilitation clinic ■ Postnatal services ■ ART Clinics Prison health service ■ Mental health services 	<ul style="list-style-type: none"> ■ Primary healthcare clinic ■ Basic Health Unit ■ Rural Health Unit ■ Blood bank ■ Antenatal care clinic ■ HIV/ART services ■ Dental clinic ■ TB Clinics ■ Harm-reduction drop-in centre 	<ul style="list-style-type: none"> ■ Harm reduction for people who use drugs ■ TB mobile testing units ■ Maternal and child health outreach ■ Hepatitis B vaccination ■ EPI vaccination ■ Polio vaccination ■ Gender-based violence outreach ■ Street children outreach 	<ul style="list-style-type: none"> ■ GeneXpert capacity within existing TB programme
Existing healthcare services with the capacity to integrate			

INTEGRATION OF SCREENING

Integrating HCV screening with existing outreach for TB, HIV and hepatitis B is simplified by the similarity of the testing and counselling procedures as well as the population screened. The addition of RDTs and counselling for HCV requires only a minor increase in training, equipment (RDTs), and human resources, for a far greater benefit through efficient resource use. Multiplex RDTs for the simultaneous screening of HCV, HBV and HIV maybe the future of integrated screening as a single point of entry for patients.²³

INTEGRATION OF DIAGNOSIS

Increased screening with RDTs will create an increased demand for confirmatory PCR testing. In Pakistan, most of this testing is carried out with HCV Real-time RNA detection assays which require fully functioning laboratories. Many GeneXpert machines which have the capacity to perform HCV, HBV as well as HIV PCR Viral Load testing on the same platform are dedicated to vertical programmes like the National TB programme. Resource-sharing and round-the-clock optimal utilisation of existing GeneXpert capacity on a large scale could ease the burden of a greater demand for HCV PCR testing.

INTEGRATION OF TREATMENT AND LINKAGE TO CARE

The ease of use of a simplified treatment algorithm, decentralisation of diagnostic testing, and safety of DAAs allows for integration of treatment services within general out-patient care sites like primary health care clinics (PHC), Basic Health Units (BHU) and Rural Health Centres (RHC). However, this may require additional resources and capacity building of existing staff. At minimum, screening services should be implemented followed by linkage to care which becomes an integral part of health service delivery. Health facilities should only incorporate HCV screening services once a referral mechanism is put in place. The referring facility should retain responsibility for follow-up of patients until their treatment by the referral facility is confirmed.

INTEGRATION WITHIN SPECIALISED FACILITIES

Specialised and limited healthcare services such as those provided in prisons, drug rehabilitation clinics, and mental health facilities should be included. In addition, RDTs and linkage to care should be offered wherever screening and testing services are already available, even if they are not the main purpose of the facility; e.g. blood banks, dental clinics, drop-in centres for IVDUs etc. The ease of use and low-price of HCV RDT kits makes it viable for integration within almost any form of health service delivery with minimal addition of resources.

Outreach

Decentralisation and integration with existing services could greatly expand the coverage of HCV testing and care. However, in order to achieve the goal of elimination, dedicated outreach may still be required to reach patients who experience barriers to access these services. Hepatitis C oriented outreach may be necessary for full coverage within high-risk groups, high-prevalence settings and difficult-to-reach populations. Barriers to access vary with time and place, but may include disability, marginalisation, language barriers and lack of social support or autonomy in seeking healthcare. Many of these can be addressed by dedicated outreach. Well-designed monitoring combined with community mapping and epidemiological surveillance can reveal underserved population groups. Outreach should support systematic general screening and linkage to treatment. Dedicated outreach may need to be adapted to the characteristics of the population group e.g. health knowledge, cultural practices, transmission risks and health-seeking behaviour.

Considerations for dedicated outreach in Pakistan

- | | |
|---|---|
| ■ Informal healthcare settings | ■ Physically disabled |
| ■ Haemodialysis facilities | ■ Mentally disabled |
| ■ Thalassemia facilities | ■ Untreated drug addicts |
| ■ Prisons | ■ Transgender population (Hijra) |
| ■ Drug-rehabilitation centres | ■ Sex workers |
| ■ Blood donors of unregulated blood banks | ■ Homeless persons |
| ■ IVDUs not in harm reduction | ■ Bonded labourers |
| ■ Patients with known health facility-acquired transmission | ■ Migrant, displaced, and undocumented populations, including street children |

COUNSELLING

Pre- and post-test counselling is necessary for both RDT and confirmatory tests. Counselling can be provided by trained lay health workers, who also support and prepare the patient for counselling at treatment initiation. Where possible, it should be conducted by peers. Counselling should be in the preferred language of the person tested and adapted according to the prior knowledge and education level of the patients. Evaluation of counselling should be differentiated by audience and should measure message retention so that counselling can be adapted to convey messages that are difficult for the audience to understand.

COMMUNITY ENGAGEMENT AND PEER SUPPORT

The known risk factors for a majority of hepatitis C infections and re-infections in Pakistan are related to community behaviour and practices: unnecessary invasive healthcare interventions, barber and beautician services with unsterilised equipment, use of unregulated blood services and re-use of equipment by unregulated healthcare providers being the most common.^{24,25,26} Peer-led interventions have been effective in promoting access to care and supporting adherence to treatment for both hepatitis and other communicable diseases.²⁷ This is particularly true within marginalised population groups such as people who inject drugs.²⁸ Peer-led interventions may include patient support groups, volunteer outreach, and peer-to-peer support for behaviour change. It should be adapted for risk practices within the community. In addition to providing services, peers can act as role models and offer non-judgmental support that may contribute to reducing stigma and promote the acceptability of services. Community engagement and peer-led efforts are particularly important for prevention strategies which may be the key to changing the behaviour of consumers, patients, and providers alike.^{29,30}

Summary of Recommendations

- Monitor nationwide elimination targets with a central data reporting mechanism
- Use quality-assured generic drugs for rapid scale-up of treatment
- Procure quality-assured drugs and diagnostics through competitive tendering, pool-procurement and other access strategies
- Assure uninterrupted treatment, if necessary by dispensing full-course at initiation
- Decentralise screening, diagnosis and treatment to the primary health care level wherever possible
- Implement point-of-care testing and diagnosis where appropriate and resources allow
- Distribute a standard, simplified treatment algorithm for use by public and private healthcare providers
- Refer to specialised treatment facilities for differentiated care where needed
- Broaden coverage of screening, by including HCV screening in existing vertical programs with an existing outreach component wherever possible
- Reduce barriers to diagnosis and treatment for patients by integrating horizontally to provide services for multiple diseases e.g. HCV, HBV, HIV and TB at a single point of care.
- Ensure linkage to care by all screening facilities
- Linkage to care should be ensured by all screening facilities
- Use Community mapping and epidemiological surveillance to identify underserved populations
- Broaden screening to high prevalence service delivery settings
- Increase access with dedicated outreach for screening and treatment of high-risk and underserved population groups
- Engage community and empower peers for behaviour change and prevention of HCV infection and re-infection

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