

MANUAL FOR THE DEVELOPMENT AND ASSESSMENT OF NATIONAL VIRAL HEPATITIS PLANS

A PROVISIONAL DOCUMENT, SEPTEMBER 2015

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ABBREVIATIONS AND ACRONYMS

CLD	chronic liver disease
EIA	enzyme immunoassay
HAV	hepatitis A virus
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HDV	hepatitis D virus
HEV	hepatitis E virus
ICT	information and communication technology
IEC	information, education and communication
Ig	immunoglobulin
IHP+	International Health Partnership+
IPC	infection prevention and control
JANS	Joint Assessment of National Strategies
M&E	monitoring and evaluation
MoH	ministry of health
MSM	men who have sex with men
NAT	nucleic acid testing
NGO	nongovernmental organization
NHA	national health accounts
NSP	needle and syringe programme
OST	opioid substitution therapy
PWID	people who inject drugs
STAG	Strategic and Technical Advisory Group
STI	sexually transmitted infection
SWOT	strengths, weaknesses, opportunities and threats
TB	tuberculosis
UHC	universal health coverage
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHD	World Hepatitis Day
WHO	World Health Organization

PREFACE

This manual is the result of work that started in January 2012 with a World Health Organization (WHO) mission to Egypt. Immediately after establishing the Global Hepatitis Programme in December 2011, WHO staff went to Cairo to support the national hepatitis response. This provided a good opportunity to field-test a “checklist” to look into the status of hepatitis in the country and the national response to it. This checklist had been developed specifically for the mission and was revised many times after this initial field-test with the feedback of many people. It now stands in Annex 4 of this document as the topic guide for the assessment of a national hepatitis programme. The manual was used in its draft format in Pakistan, Saudi Arabia, Oman, Indonesia, Kuwait, Mongolia and Georgia for country assessments and guidance in planning from 2013 to 2015.

As WHO’s work in the area of hepatitis expanded, countries began requesting guidance for devising national hepatitis plans. Since a comprehensive response to viral hepatitis cuts across many areas of work, it was important to pull together all relevant WHO guidance for ease of reference. Thus, the “general” planning section of this manual is kept deliberately short, with references to the currently existing WHO documents in this area of work, and more space is allocated to information and current guidance specific to the hepatitis response. This manual contains extensive references to documents and links in specific areas such as blood safety, injection safety, vaccination and harm reduction, among others.

The purpose of this manual is to provide guidance to public health professionals tasked with managing a response to viral hepatitis. As every country’s needs are different with respect to its epidemiology and the current level of response, people would use this manual in different ways. This manual is intended:

- to help think more comprehensively about the hepatitis response in a country;
- to provide a step-by-step approach to setting up a national hepatitis plan and/or programme;
- to propose a governance structure that can be adapted according to needs; and
- to propose the outline of a national hepatitis plan.

In 2014, the World Health Assembly asked WHO to assess the feasibility of eliminating hepatitis B and C. To address this, WHO is currently developing the first global strategy for hepatitis in broad consultation with global stakeholders. The resulting draft will be presented to the World Health Assembly in 2016 for adoption by Member States. The strategy will then create a common vision, framework and targets for concerted global action against viral hepatitis. This manual will need to be updated when the first global hepatitis strategy is adopted by WHO Member States, in accordance with the strategic directions and targets of the global strategy. Until then, this will be referred to as a provisional document.

1. INTRODUCTION

1.1. Background

Disease burden

Viral hepatitis is a group of infectious diseases that represent a significant global health challenge. Viral hepatitis is caused by five viruses – hepatitis viruses A, B, C, D, E. According to the most recent estimates of the Global Burden of Disease study, viral hepatitis is responsible for approximately 1.5 million deaths each year, which is comparable to the annual deaths from HIV/AIDS (1.3 million), malaria and tuberculosis (TB) (0.9 million and 1.3 million, respectively) (1).

An estimated 240 million persons are chronically infected with hepatitis B virus (HBV), and between 130 and 150 million with hepatitis C (HCV). It is estimated that the majority of persons with chronic hepatitis B and/or hepatitis C are unaware of their infection and do not benefit from clinical care, treatment and interventions designed to reduce onward transmission. Without appropriate diagnosis and treatment, around one third of those chronically infected with viral hepatitis will die as a result of serious liver disease, including cirrhosis, liver cancer and liver failure (2).

In response to this global public health problem, in 2010, the World Health Assembly adopted resolution WHA63.18 on viral hepatitis, urging Member States to recognize and address the issue of viral hepatitis through improved prevention and control efforts (3).

In 2012, the World Health Organization (WHO) issued a framework for global action to prevent and control viral hepatitis infection, which aligned action along four strategic axes of raising awareness, promoting partnerships and mobilizing resources; evidence-based policy and data for action; prevention of transmission; and screening, care and treatment (4).

In 2013, WHO published a global policy report on the prevention and control of viral hepatitis (5), which was based on a survey of Member States. This report noted that implementing a comprehensive national response is a challenge for many governments due to the high burden of hepatitis-related diseases, the different routes of transmission and health outcomes among the population. Fewer than half of the Member States who responded had a written national strategy that focused exclusively or primarily on viral hepatitis, and less than one third had a government unit or department that was solely responsible for viral hepatitis-related activities.

Member States were asked to indicate how WHO could support the development of a robust national response. Fifty-eight per cent requested technical assistance with the development of a national viral hepatitis plan.

At the World Health Assembly in May 2014, resolution WHA67.6 was adopted, which expressed concern about suboptimal access to prevention, screening and treatment interventions, and called for WHO and Member States to take a number of steps to further develop global and national responses to viral hepatitis. The resolution urges Member States to develop and implement coordinated multisectoral national strategies for preventing, diagnosing and treating viral hepatitis based on the local epidemiological context (6).

Resolution WHA67.6 tasks WHO with providing technical support, guidance and specialist advice, and supporting countries in designing, delivering, monitoring and evaluating robust national hepatitis plans (6).

WHO will discuss the first global health sector strategy and targets for viral hepatitis at the Sixty-ninth World Health Assembly in May 2016. A broad consultation is currently ongoing with all relevant stakeholders through a variety of means (virtual and physical meetings, online consultations, surveys) to reach a global consensus on the priorities for action and targets that need to be reached to eliminate viral hepatitis as a public health problem. In order to reach these global targets, countries need stronger hepatitis programmes that are based on comprehensive hepatitis plans.

TABLE 1 Summary of actions in resolution WHA67.6 (6)

Member States are urged:

- **To develop and implement coordinated, multisectoral national strategies for the prevention, diagnosis and treatment of viral hepatitis, including**
 - robust surveillance systems to support evidence-based policy-making,
 - strengthened infection control measures in the areas of food, drinking water, personal hygiene and health-care provision,
 - increased coverage and uptake of vaccination, harm reduction, screening and treatment programmes,
 - increased access to antiviral treatment,
 - administrative and legal measures to address viral hepatitis-related stigma and discrimination;
- **To promote the involvement of civil society in the development of a national response to viral hepatitis.**

1.2 The importance of planning

Planning is the process of thinking about and organizing activities required to achieve a desired goal. It involves making decisions in the present that will result in a positive change in the future. This section is adapted from the currently available WHO guidance on national planning (7).

Within a country, a national health sector plan is developed at the broadest level for all health activities and services, and specific plans are developed for diseases (such as hepatitis or HIV) or for particular priority groups (such as the Maternal and Child Health programme). The appropriate type of plan will depend on the context in which the planning occurs. Countries with a high burden of disease may require disease-specific plans developed at the most focused level for specific projects with time-bound interventions. Alternatively, low-burden countries may include a reference to viral hepatitis in the national health sector plan but choose to appoint a focal point for hepatitis rather than a dedicated unit for oversight and implementation. It should be kept in mind, however, that a low-prevalence country might still have a high burden of hepatitis because chronic hepatitis may be disproportionately prevalent in people over a certain age group or in some key populations and, in such a situation, these people would require specific health-care interventions, such as treatment of chronic disease, transplantation or chemotherapy. Therefore, it might be in the best interest of the country to have a national hepatitis plan targeting this situation specifically.

National health sector plans provide the overall strategic direction for the health sector: it is therefore important that specific planning for priority action areas, such as hepatitis, maternal and child health, infection prevention and control (IPC) or HIV/AIDS, is aligned with national health sector planning. However, there is often a disconnect between planning for disease-specific programmes and national health policies, strategies and plans. This leads to fragmentation and increased transaction costs in the implementation of health programmes. The causes of this disconnect include the following:

1. inadequate situation analysis of and priority setting in programme and system issues;
2. disconnect between operational planning by the various programmes and the policy dialogue on national health policies, strategies and plans – they are often conducted by different constituencies with different planning cycles;
3. donor practice to earmark funds and demand reporting for their – and only their – contributions;
4. competition for available scarce resources; and
5. imbalances in national priority setting.

Health planning at all levels needs to be broad, recognizing the actual and potential inputs of other agencies such as the private sector and nongovernmental organizations (NGOs), and incorporating appropriate actions related to other non-health sector plans.

It is important to note that the terms “strategy”, “policy”, “plan” and “programme” are used in an interchangeable way in the literature and from one country to another, depending on many factors such as regional and national specificities, political culture and history. This also reflects the diversity of approaches and levels at which the process is undertaken.

The same applies to the terms “goals”, “targets” and “objectives”. It is therefore important to take into account this diversity. Definitions of the key terms used in this manual are detailed in Annex 1.

For the purpose of this manual, a national strategy/plan:

- defines national priorities, goals and objectives;
- outlines actions needed to achieve particular objectives and goals;
- enables the effective and efficient use of resources;
- allocates clear roles and responsibilities to various stakeholders;
- enables the measurement of progress and provides a framework for performance assessment.

Some countries may address viral hepatitis within another disease-specific plan (e.g. bloodborne virus infections, communicable/infectious diseases or cancer prevention). If this is the case, we recommend that they use this document to ensure that all points relevant to hepatitis prevention, diagnosis and treatment are addressed in the plan and ensuing programme.

Figure 1 provides an example of a framework for national health policies, strategies and plans.

1.3 Aim and objectives

The aim of this manual is to provide a framework for and guidance on the development or strengthening of national viral hepatitis plans. This manual is aligned with a health systems approach to disease planning and supports an evidence-based decision-making process in order to respond to hepatitis.

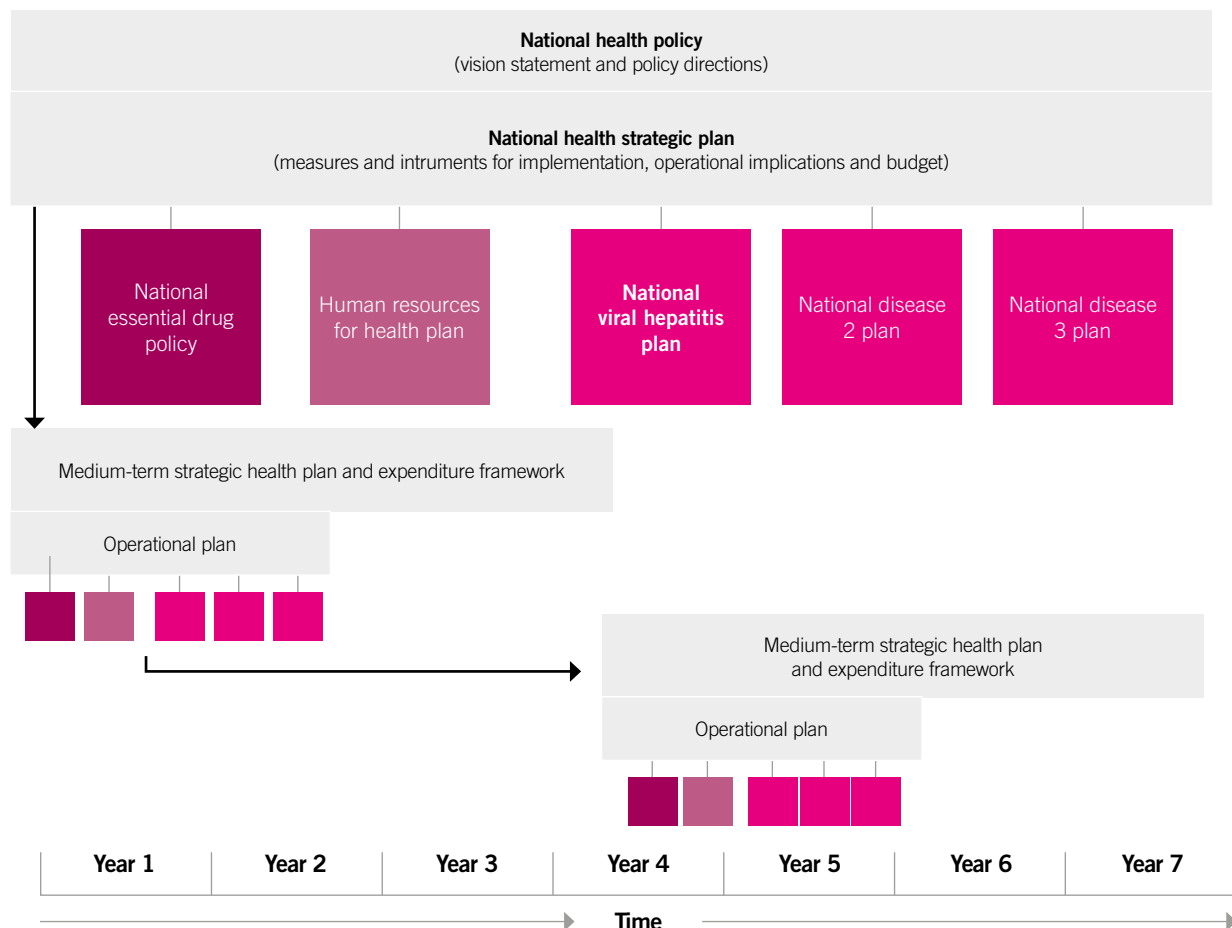
1.4 Target audience

This guide is primarily intended for senior policy-makers and programme managers within the national ministries of health who are responsible for the development and

It should be kept in mind that a low-prevalence country might still have a high burden of hepatitis because chronic hepatitis may be disproportionately prevalent in people over a certain age group or in some key populations and, in such situations, these people would require specific and often more costly health-care interventions.

implementation of national viral hepatitis plans. It is also relevant for all stakeholders involved in the viral hepatitis response, including service providers, academicians, civil society partners and nongovernmental organizations (NGOs).

FIGURE 1. A framework for national health policies, strategies and plans (7)



1.5 Structure of the manual

The manual is organized into the following parts:

Part 1. Introduction

This section describes the background and gives an overview of the current status of national planning for hepatitis globally; it highlights the importance of planning, and describes the purpose and structure of the manual.

Part 2. Guiding principles for effective development of a national hepatitis plan

This section describes the key principles that should be considered in developing a plan. Careful consideration and inclusion of these principles in the planning process will help ensure that the national plan is effective and appropriate.

Part 3. National planning for hepatitis within the universal health coverage framework

This section develops national planning within the framework of universal health coverage (UHC) principles.

Part 4. Process and steps for developing a national hepatitis plan

This section focuses on the planning process, including assigning governance and management roles, situational analysis, prioritization, defining objectives, identifying synergies with relevant global and national policies and programmes, identifying opportunities for integration, and costing and funding the plan.

Part 5. Contents of the national hepatitis plan

This section focuses on the content of the plan. Detailed information and guidance has been provided for each relevant area: awareness-raising, workforce development, data for policy and action, primary prevention, screening, diagnostic testing, and clinical care and treatment. Part 5 also contains summaries of available WHO guidance relevant to the hepatitis response, including prevention, testing and treatment. Links to the original documents are provided for more detailed information.

Part 6. Template for developing a national plan for viral hepatitis

Part 6 provides a national plan template with exemplary goals and objectives, and proposes activities from a country perspective. The template is for providing examples and is not comprehensive. It should be thought of as a helpful starting point for a plan adapted to the country context.

Part 7. Monitoring and evaluation framework

This framework is designed with the four levels of monitoring and evaluation (M&E) in mind: inputs, outputs, outcomes and impacts. The importance of M&E is highlighted in terms of the implementation and effectiveness of the plan and associated programme.

Annex 1. Definition of terms

This contains definitions of some of the terms used in this manual.

Annex 2. Process for review and update of a national plan and the associated programme

Reviewing and updating the national plan is key to maintaining progress. This section provides examples of different review activities that can be conducted at specific points in the programme cycle.

Annex 3. Planning tools

This part contains references to the JANS and OneHealth tools.

Annex 4. Topic guide for the assessment of a national programme

The topic guide is a tool for assessing a viral hepatitis programme. It is useful for identifying gaps and areas of need, and will therefore assist in the planning process and review of existing plans.

Annex 5. Checklist for initiating or scaling up hepatitis treatment services

This checklist provides a quick assessment of programme readiness for implementing hepatitis treatment.

1.6 How to use the manual, topic guide and template

This manual has been written as a resource to support the process of developing hepatitis plans at the national level. It is intended for countries that wish to strengthen an existing plan and for those that are at the initial stages of planning. Where relevant, examples have been provided. The examples serve as a guide for developing a plan that is context-specific, relevant and adapted to local conditions.

2. GUIDING PRINCIPLES FOR EFFECTIVE DEVELOPMENT OF A NATIONAL HEPATITIS PLAN

The primary objective of WHO is “the attainment by all peoples of the highest possible level of health”. This document has been developed with this principle in mind, and that of the United Nations Universal Declaration of Human Rights (8). Countries that are planning to embark on national planning should take into account the following guiding principles.

2.1 Leadership and governance

The leadership and governance of health systems is arguably the most complex but critical building block of any health system. It is about the role of the government in health and its relation to other actors whose activities impact on health. This involves overseeing and guiding the whole health system – private as well as public – in order to protect the public interest. It requires both political and technical action, because it involves reconciling competing demands for limited resources, in changing circumstances, for example, with rising expectations, more pluralistic societies, decentralization or a growing private sector. There is increased attention to corruption, and calls for a more human rights-based approach to health. There is no blueprint for effective health leadership and governance. While ultimately it is the responsibility of the government, this does not mean that all leadership and governance functions have to be carried out by central ministries of health. Experience suggests that there are some key functions common to all health systems, irrespective of how these are organized.

- Policy guidance: formulating sector strategies and specific technical policies; defining goals, directions and spending priorities across services; identifying the roles of public, private and voluntary actors; and the role of civil society;
- Intelligence and oversight: ensuring generation, analysis and use of intelligence on trends and differentials in inputs, service access, coverage, safety; on responsiveness, financial protection and health outcomes, especially for vulnerable groups; on the effects of policies and reforms; on the political environment and opportunities for action; and on policy options;
- Collaboration and coalition-building: across sectors in the government and with actors outside the government, including civil society, to influence action on the key determinants of health and access to health services; to generate support for public policies; and to keep the different parts connected – so-called “joined-up government”;
- Regulation: designing regulations and incentives and ensuring that they are fairly enforced;
- System design: ensuring a fit between strategy and structure, and reducing duplication and fragmentation;

- **Accountability:** ensuring that all health system actors are held publicly accountable. Transparency is required to achieve real accountability.

For more information, please refer to “Everybody’s business: strengthening health systems to improve health outcomes: WHO’s framework for action” (9).

2.2 Human rights and equity

Viral hepatitis is likely to have a disproportionate impact on some groups in society, including those with low socioeconomic status, those with poor access to health care, indigenous people, migrants and marginalized groups, such as people who inject drugs (PWID), men who have sex with men (MSM), sex workers and people in prison. In addition, comorbidities with HIV, TB and poor mental health are also more prevalent in these groups. In order to promote equity in health and to reduce the burden of disease among these groups, several human rights issues such as stigma, discrimination, social exclusion and poor access to services need to be addressed from a social justice perspective. For example, detainment in closed settings such as prisons should not impede the right to the highest attainable standard of health. It is also important that efforts are undertaken to ensure that the relevant workforce in each setting understands the issues affecting at-risk populations, and how to effectively engage with and support them.

Finally, the design and provision of culturally appropriate information about viral hepatitis, and its prevention, treatment and care options are crucial to overcoming the barrier caused by poor health literacy in some settings.

2.3 Health systems strengthening and integration

A health system consists of all the organizations, institutions, resources and people whose primary purpose is to improve health. A health systems strengthening approach seeks to increase the capacities of individuals and of the systems and organizations that constitute the

TABLE 2 The six building blocks of health systems strengthening

Six building blocks for health systems strengthening	Expected outcome for hepatitis programmes
Effective and transparent leadership and governance	Strong political commitment, enabling national policy, leadership and accountability, a coordinated response
Fair and sustainable financing mechanisms	Timely availability of financial resources for implementation, prevention of burdensome costs for people who need and cannot afford required interventions
Human resources for health	An adequate number of appropriately trained staff to deliver high-quality, culturally competent interventions
Essential medicinal products, infrastructure and technology	Procurement and supply of cost-effective medicines, commodities and tools for prevention, diagnosis and treatment of hepatitis
Service delivery	Delivery of comprehensive hepatitis interventions to those that need them
A functioning health information system for monitoring, evaluation and for informing decision-making	Timely production, analysis and dissemination of reliable information

health sector. Table 2 gives the essential components of an effective health system response to viral hepatitis.

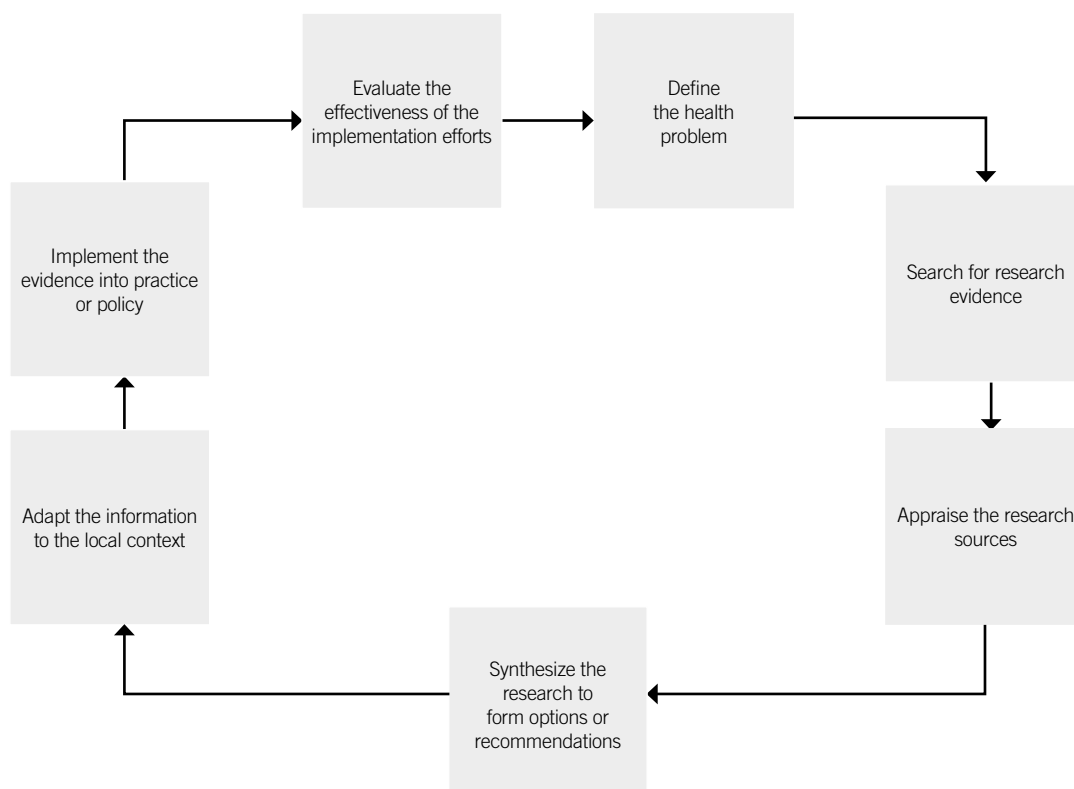
A national hepatitis plan will include a set of integrated and comprehensive actions to be implemented at a national level under defined objectives to be achieved within a specific time frame. Of paramount importance is integration of disease-specific planning in national health sector planning, and integration of disease-specific services within the currently existing health services. This is the only way to maximize synergies, avoid duplication, achieve sustainability and promote cost-effectiveness. In the context of hepatitis, prevention, diagnosis and treatment services could be delivered via different means, for example, through community-based multipurpose health-care facilities (such as primary-level health-care centres), or through HIV, sexually transmitted infection (STI), antenatal services, and others.

Of paramount importance is integration of disease-specific planning in national health sector planning, and integration of disease-specific services within the currently existing health services. This is the only way to maximize synergies, avoid duplication, achieve sustainability and promote cost-effectiveness.

2.4 Evidence-informed policy and planning

Evidence-informed health policy-making is an approach to policy decisions that aims to ensure that decision-making is well informed by the best available evidence. It is characterized by the systematic and transparent access to, and appraisal of, evidence as an input into the policy-making process. Figure 2 outlines the stages in the process of evidence-informed policy-making.

FIGURE 2. Stages in the process of evidence-informed policy-making (10)



2.5 Feasibility, cost–effectiveness and impact

Assessing the feasibility of a proposed health programme involves an evaluation of the programme in order to determine if it can be implemented using the existing technical capacity within the country. Feasibility assessments also include cost–effectiveness considerations. For example, can the proposed programme be implemented using the estimated budget and have interventions been prioritized based on their having the biggest impact on mortality and morbidity? Where a health system's reach is limited or weak, activities and support for capacity building should be included in the national strategic plan.

2.6 A public health approach

The principles of a public health approach provide a useful framework to guide a response to viral hepatitis. The classic steps can be translated into a public health approach to viral hepatitis, as follows:

1. Define the problem through the systematic collection of information about the magnitude, scope, characteristics and consequences of viral hepatitis.
2. Establish why viral hepatitis infections occur, using research and epidemiological evidence to identify the social determinants of infection, the factors that increase or decrease individual risk, and the factors that can be modified through appropriate interventions.
3. Identify and produce evidence on what works to prevent and control viral hepatitis by designing, implementing and evaluating interventions.
4. Implement the most effective, evidence-based interventions in a range of settings. The effects of these interventions on both risk factors and desired outcomes should be monitored, and their impact and cost–effectiveness evaluated.

Practically speaking, a public health approach to designing and delivering hepatitis interventions must be based on the following four concepts: are the interventions affordable, acceptable, accessible and appropriate (11)?

3. NATIONAL PLANNING FOR HEPATITIS WITHIN THE UNIVERSAL HEALTH COVERAGE FRAMEWORK

It is important to conceptualize national hepatitis planning within the UHC framework. UHC has been defined as the desired outcome of health system performance, whereby all people who need health services (promotion, prevention, treatment, rehabilitation and palliation) receive them, without undue financial hardship. UHC has two interrelated components: the full spectrum of good-quality, essential health services according to need, and protection from financial hardship, including possible impoverishment due to out-of-pocket payments for health services. Both components should benefit the entire population (12).

For a community or country to achieve UHC, several factors must be in place, including the following:

- A strong, efficient, well-run health system that meets priority health needs through people-centred integrated care (including services for hepatitis, HIV, TB, malaria, noncommunicable diseases, maternal and child health) by
 - informing and encouraging people to stay healthy and prevent illness (health promotion and prevention);
 - detecting health conditions early (early diagnosis);
 - having the capacity to treat disease (treatment); and
 - helping patients with rehabilitation.
- Affordability – a system for financing health services so that people do not suffer financial hardship when using them. This can be achieved in a variety of ways.
- Access to essential medicines and technologies to diagnose and treat medical problems.
- A sufficient number of well-trained, motivated health workers to provide services to meet patients' needs based on the best available evidence.

In keeping with the UHC framework, national hepatitis plans could be structured as follows:

- providing essential services for hepatitis within the continuum of care;
- covering populations and achieving equity;
- covering costs.

There is no single universal model for UHC; countries will need to adapt their own strategies and see how to include hepatitis within the framework.

4. PROCESS AND STEPS FOR DEVELOPING A NATIONAL HEPATITIS PLAN

National health planning refers to the process of defining the health problem, gathering and synthesizing evidence, and formulating and organizing the activities required to achieve a stated goal relevant to the health problem. In other words, planning for a specific disease requires the use of evidence and expertise to analyse the country's burden and patterns of that disease; setting of priorities to reduce that burden; generation of a series of focused, costed and achievable actions; and confirmed arrangements for monitoring and evaluating delivery of the plan.

The steps outlined in Figure 3 are discussed in detail in the following sections.

FIGURE 3. Steps for developing, implementing and evaluating a national plan



4.1. Step 1: Preparation

4.1.1 Establish a management structure and governance arrangements

In many countries, hepatitis is not explicitly mentioned in the job definition of any ministry of health (MoH) staff. An important first step is to assign one person, at least part time initially, to take on the responsibility of the preparation phase. If, by the end of the situation analysis, it is deemed feasible and necessary to have a more visible management structure, staffing could then be evaluated and adjusted to needs.

This person should have the authority to initiate and manage the preparation phase, including proposing a Strategic and Technical Advisory Group (STAG) (see Section 4.3), act as its secretariat and report the developments to the minister or a designated senior official.

4.1.2 Develop a workplan for the planning process

The designated official, in collaboration with STAG, should develop a workplan with a clear time frame, milestones and budget, and identify roles and responsibilities. If technical assistance is required for the development of a national plan, help must be sought early in the process.

4.1.3 Conduct a situation analysis

A situation analysis is an assessment of the current health situation and is fundamental to designing and updating national policies, strategies and plans.

A strong situation analysis is not just a collection of facts describing the epidemiology, demography and health status of the population. Instead, it should be comprehensive, encompassing the full range of current and potential future health issues relevant to hepatitis and their determinants. The situation analysis should also be disaggregated by specific hepatitis viruses (A, B, C, D and E) to ensure that all relevant aspects of prevention and control are addressed. It should also assess the current situation and compare it with the expectations and needs of the country. A situation analysis serves as a basis for priority setting and should include an assessment of the following:

- the social determinants of health, including current and projected disease burdens;
- expectations, including current and projected demand for services;
- health system performance;
- capacity of the health sector;
- health system resources (including national health policies, strategies and plans) (13).

a. Epidemiological context

Understanding the transmission, distribution, drivers and impact of viral hepatitis is at the core of the situation analysis. Countries should use the most reliable and recent data available. This will include the collection and analysis of information on overall prevalence, incidence, disease progression, morbidity and mortality associated with viral hepatitis. Where possible, these data should be disaggregated by subpopulation, mode of transmission and geographical location. Any gaps identified in the available epidemiological information should be addressed.

Essentially, the analysis of the epidemiological context will answer the following questions:

1. Who is affected by hepatitis? *At-risk populations, trends in age distribution of incidence, prevalence and mortality*
2. When are they affected? *Under what circumstances is transmission occurring and in what populations and age groups?*
3. Where are they affected? *Geographical distribution of hepatitis disease burden, outbreaks and high-prevalence settings*

4. How are they affected? *Analysis of the population, and individual impact and outcomes of the disease*

b. Social determinants

The social determinants of health are the conditions in which people are born, grow, live, work and age (14). These circumstances are shaped by the distribution of money, power and resources at the global, national and local levels. The determinants are partly responsible for inequitable health outcomes and can increase a person's vulnerability to and risk of viral hepatitis.

It is demonstrated that various factors play a role in people's risk of acquiring hepatitis, seeking testing or medical care. The burden of hepatitis is greater in some ethnic groups and indigenous communities. Settings such as prisons accelerate transmission, and may hamper access to appropriate care and treatment. Marginalized groups such as sex workers, PWID and MSM are at increased risk of hepatitis as well as other sexually transmitted diseases.

Taking a social determinants' approach to planning a response to hepatitis requires governments to coordinate and align different sectors and different types of organizations in the pursuit of health and development.

c. Stakeholder analysis

Stakeholder analysis is a process of systematically gathering and analysing information to determine whose interests should be taken into account when developing and/or implementing a policy or programme (15). Persons or organizations who have a vested interest in the programme are considered stakeholders and this will include various levels of the MoH and other relevant ministries; related programmes; provincial and district leaders; academic and research institutions; civil society; community-based organizations, NGOs, the private sector and, in some cases, donors/development partners, including philanthropic foundations.

Involving stakeholders at various stages in the preparation and validation of a national plan will ensure that all relevant and effective activities and actors are incorporated in the plan and programme. This directly impacts the strength of the plan; it ensures that the plan is in line with national strategies and priorities, and is more likely to be endorsed and implemented.

d. Policy and legal context

A policy review includes a description of the existing regulations, legislations and policies that impact on the determinants of viral hepatitis and the people most at risk for and affected by the condition. At this point, it is important to identify other policy documents and strategies that address relevant areas of work (e.g. national blood safety policy, national injection safety policy, national immunization policy). The mention of hepatitis in the current national health plan would give a stronger reason for the technical programme to develop a national plan for this disease. It is also important to identify which supportive technical documents, such as treatment, surveillance or screening guidelines, exist within the country.

In addition, policies regarding infection control in health-care facilities, harm reduction, prenatal care, etc. should be considered, along with antidiscrimination, human rights and patient confidentiality policies.

A number of legal and policy changes may be required to support delivery of the national plan. These may include administrative and legal means:

- to promote access to prevention, diagnosis, and treatment services and technologies, including harm reduction services;
- to prevent and address stigma and discrimination against people living with and affected by viral hepatitis in the areas of employment, education, housing and access to health care.

Countries should consider identifying and resolving barriers to the effective implementation of their plan with complementary regulatory and legislative areas, including infection control in health-care and other settings (e.g. where tattooing and piercing are done), criminal justice, drug addiction and recovery, welfare rights, equality and human rights.

After identifying all the relevant policies in the country, a reference can be made to them in the national plan.

e. Existing capacity, infrastructure and service provision

In addition to existing services relevant to viral hepatitis, the capacity (human and financial), structures, systems, programmes and management for the prevention and treatment of viral hepatitis should also be assessed. This is key, especially if countries are to integrate the prevention, testing, care and treatment of viral hepatitis into existing health-care systems, and make the best use of existing infrastructure and strategies. Special consideration should be given to services working with the most affected communities. Field visits, interviews, published and unpublished reports would be the sources of this information. Opportunities where existing health system policies and programmes can be reshaped or extended to include hepatitis-related activities must be identified and described.

The topic guide in Annex 4 provides a good framework for this assessment.

4.2 Step 2: Plan development

4.2.1 Define priorities (goals, objectives, targets, activities); assign lead and partner agencies

Programme goals and objectives establish criteria and standards against which programme performance can be assessed.

Goal is a broad statement about the long-term expectation of what should happen as a result of the programme (the desired result). It serves as the foundation for developing programme objectives.

Objectives are statements describing the results to be achieved, and the manner in which they will be achieved. Multiple objectives are usually needed to address a single goal. SMART attributes are used to develop a clearly defined objective (see Box 1).

The situation analysis, including the epidemiology and burden of disease, and status of the current response, will provide an overview of the key issues and needs in the country for the prevention, diagnosis and treatment of hepatitis. This will provide evidence to inform the development of a set of

SMART criteria

Objectives should meet the following SMART criteria (16):

- Specific: includes the “who”, “what” and “where”. Use only one action verb in order to avoid issues with measuring success.
- Measurable: focuses on “how much” change is expected.
- Achievable: defines realistic action, given programme resources and planned implementation.
- Relevant: relating directly to programme/activity goals.
- Time bound: focuses on “when” the objective will be achieved.

priorities, which will, in turn, be translated into the headings of goals, objectives, targets and activities.

For each activity, one or more performance indicators should be defined. These are quantitative measures that will be used to measure progress towards meeting the actions. In special circumstances, qualitative measures may be used. The required timescale for delivery of each action should be specified. Performance indicators and timescales are essential components of programme monitoring and evaluation.

Finally, each action should state the lead agency responsible for ensuring delivery, and partner agencies who are tasked with supporting effective implementation.

BOX 2. Defining priorities

Example. Extract from South Australian Department of Health Hepatitis C Action Plan 2009–12 (17)

Strategy	Improve access to hepatitis C testing and treatment services in metropolitan and rural areas for all people with hepatitis C.
Activity	Establish hepatitis C Clinical Nurse Consultant positions attached to tertiary treatment services to support treatment provision. Develop community-based treatment services for priority population groups, including through Aboriginal Health Worker-accredited training.
Performance indicators	Eight Clinical Nurse Consultant positions established and distributed across metropolitan specialist treatment centres, with emphasis on outer metropolitan hospitals and incorporating outreach services to Warinilla, Nunkuwarrin Yunti, the O'Brien St Practice and at The Parks Medical Centre.
Timeline	2012
Lead agency	Statewide Services Strategy
Partner agencies	HIV/HCV policies and programmes HCV Council of South Australia Specialist treatment centres Adelaide University Nunkuwarrin Yunti Aboriginal Health Council of South Australia

4.2.2 Cost and allocate a budget for the national plan

The national plan should be fully costed and include an expenditure framework that outlines how the proposed actions will be resourced for the duration of the plan. Costing means how much will need to be spent to implement the activities proposed in the plan. Resourcing refers to where this money will come from. Costing a plan is important because it guides the management in making decisions, allows for comparisons with other plans or activities, and helps with monitoring. It is also the first step to getting a budget allocated for the activities outlined in the plan.

Experience in developing national plans shows that costing is often not done in a rigorous manner and with the required expertise. It is recommended that the costing exercise be undertaken using appropriate expertise. Furthermore, costing the commodities and operational costs related to procurement and supply is of critical importance and also requires specific expertise.

There are tools available to guide the development of a financial framework, for example, the OneHealth tool (18), which supports the costing, budgeting, financing and national strategy development of the health sector in developing countries, with a focus on integrating planning and strengthening health systems.

The OneHealth tool is a software designed to strengthen health system analysis and costing, and to develop financing scenarios at the country level. The primary purpose of the tool is to assess health investment needs in low- and middle-income countries. While most costing tools take a disease-specific approach, OneHealth is the first tool to present the detailed components of each programme area in a uniform format and link them with a view to strengthening the overall capacity of national health systems. Planners have a single framework for planning, costing, impact analysis, budgeting and financing of strategies for all major diseases and health system components. The tool is modular in format and can easily be adapted to the country context, allowing for programme-disease-specific costing as well as overall health sector costing. The tool is designed for use by experts involved in national health planning, including government health planners, United Nations (UN) agencies, NGOs, donors, researchers and consultants (18).

4.3 Step 3: Implementation

4.3.1 Sign off, launch and disseminate the national plan

After the national plan is prepared and adopted by STAG, it is important for it to be formally endorsed by the MoH, and published and disseminated to stakeholders and the community. Websites provide an excellent venue for this. The official adoption of the plan also designates the start of the implementation process.

4.3.2 Review the management structure and governance arrangements

The implementation of a national viral hepatitis plan through the associated programme will require leadership, commitment, a clearly defined budget and meaningful engagement with stakeholders. One of the first steps should be a review of the programme management and governance structure.

The management structure and governance arrangements necessary for effective implementation will be defined by the existing management culture and leadership structure within the country. Based on national planning experience in some countries, the following management structures and governance arrangements have proven effective. Though the names of the different groups will vary, the functions will essentially be similar.

It is important to remember the essence and reasons behind the proposed structure rather than seeing this as a prescription. Depending on the burden of hepatitis, structures may be expanded or scaled down.

1. Oversight function

- a. *Steering Committee*: This is the group responsible for programme oversight. A senior official within the MoH, appointed by the minister, generally chairs it. Depending on the burden of hepatitis within the country, it may include representatives from other ministries or sectors. It meets at least annually to review the programme indicators.

2. Advisory function

- a. *Strategic and Technical Advisory Group*. STAG comprises experts on various aspects of viral hepatitis prevention and control. It convenes at least annually to advise the MoH on strategic directions, priorities and activities.

This group is responsible for assessing the hepatitis burden in the country by collecting, organizing and making sense of data, and using evidence to inform their recommendations. It consists of a broad range of stakeholders including, but not limited to, the academia (teaching and research), national professional organizations (doctors, nurses, midwives, etc.), civil society, patient groups and service provider groups (laboratories, blood banks, hospitals, etc.). In some countries, WHO and other international technical agencies are also asked to join this group. The technical unit (or the hepatitis focal point) within the MoH acts as the secretariat to this group. If, at the end of the situational analysis, STAG considers it necessary to create a national hepatitis plan, this is also the group to approve its final draft before official adoption. After the launch of the national plan, STAG meets at least annually to review the programme indicators and the disease burden, and makes recommendations to the Steering Committee and implementing units.

3. Implementation function

- a. *Ministry of Health Hepatitis Unit.* This is the unit responsible for implementing the programme based on recommendations from STAG and leadership of the Steering Committee. The unit could be as small as a part-time official or a multiperson team, depending on the country needs. They could draft the national plan with the Planning Technical Working Group (see item b below) and present it to STAG for further discussion, revision and adoption. They develop the M&E framework for the national programme. They convene and lead the Internal Coordination Unit within the MoH to ensure comprehensive and concerted action.
- b. *MoH Internal Coordination Group* consists of the relevant units within the MoH. Its main purpose is to coordinate the activities of these different units. The groups would consist of representatives from immunization, blood safety, IPC (including injection safety), occupational health, laboratory, water and sanitation (if hepatitis A and E are included in the programme), public education and communication, disease surveillance, drug and commodities procurement, health-care facilities, screening programmes (e.g. premarital, antenatal care, etc.) and relevant treatment services for hepatitis or other programmes (e.g. HIV, TB programmes).
- c. *Technical Working Groups* are those that are established as needed to find solutions to specific problems. The first technical working group is usually the one to draft the national plan, i.e. the Planning Technical Working Group. Its members are technical experts from the MoH, patient groups, civil society, representatives of professional organizations, research groups, representatives of other sectors providing health-care services, and others as needed. It is important for this group to be inclusive in order to ensure adoption of the national plan by all stakeholders. Other technical working groups may be established (and disassembled) as specific problems are encountered during the implementation of the national plan, or they may be permanent to address specific problem areas such as prevention, public education, strategic information, etc. (Figure 4).

FIGURE 4. Implementation of the plan

4.4 Step 4: Monitoring and evaluation

Each national hepatitis plan should include an M&E framework that describes how the implementation and effectiveness of the programme will be measured and assessed. Most countries will already have arrangements for M&E of the wider national health sector plan that can be adapted to the viral hepatitis plan. Please see Part 7 for a more detailed discussion on this topic.

5. CONTENTS OF A NATIONAL HEPATITIS PLAN

This section of the guide outlines key sources of information that countries should consider when developing the content of their national viral hepatitis plans. The information is grouped according to UHC action areas of health statistics and information systems, providing essential health services, covering populations and covering costs. The content and weight given to each area in each country will depend on the epidemiological context, and degree and quality of existing services.

Wherever possible, information and links to key WHO and other international guidance has been provided. In the absence of global policy, key evidence-based documents have been referenced.

5.1 Health information systems

All viral hepatitis meet the criteria for conditions suitable for surveillance: they can be diagnosed through sensitive and specific laboratory tests, addressed through appropriate prevention and control mechanisms, and monitored using available epidemiological tools. Surveillance also produces data that can be used to monitor and evaluate progress towards implementation of the national plan.

Robust and effective surveillance systems are needed to detect outbreaks and monitor trends in incidence and risk factors; assess the burden of chronic hepatitis and disease outcomes (including liver cirrhosis, cancer, transplants, deaths); monitor the coverage and outcomes of antiviral treatment; and evaluate the efficacy of interventions designed to prevent and control viral hepatitis (e.g. vaccination coverage, response to testing campaigns, etc.). In addition to surveillance, data for policy and action could be obtained from qualitative and quantitative social-behavioural and clinical research to identify barriers and enablers to prevention, diagnosis and treatment of people with or at risk of infection.

WHO has developed technical guidance that describes the key components of a national viral hepatitis surveillance system.^a Although primarily aimed at middle- and low-income countries, the principles are generally applicable to all countries and can be used to develop the hepatitis component of any national surveillance programme.

It is important to develop surveillance methods to match the needs and purpose of surveillance.

5.2 Providing essential services

The package of essential services needs to be regularly reviewed to ensure that, as new evidence emerges, and new technologies and approaches are developed, innovations are rapidly integrated and new opportunities are taken.

^aViral hepatitis surveillance: technical guidance for middle- and low-income settings (draft). Geneva: World Health Organization. (Unpublished)

Hepatitis prevention and control strategies are most effective when they prioritize quality-assured, high-impact interventions, and address the conditions and risk behaviours that place people at risk of hepatitis infection, and the contexts that facilitate those conditions and behaviours. An enabling environment that promotes health equity and human rights is therefore essential, as is strong collaboration with partners, especially those in civil society.

5.2.1 Health promotion

Global public health campaigns raise awareness and understanding of health issues and mobilize support for action, from the local community to the international stage. Around 240 million people are chronically infected with hepatitis B and around 130–150 million people have chronic hepatitis C infection, but most are unaware of their status (2,6). Awareness-raising activities can encourage people to access diagnostic testing, and those infected to engage with clinical care and treatment. These activities can also be used to engage those at risk of infection, informing them about routes of transmission, and providing important advice on harm reduction and other preventive measures.

It is also important to raise awareness of viral hepatitis among policy-makers and health-care providers. Key aims include increasing general awareness of viral hepatitis, increasing support for prevention and control measures, and reducing stigma and discrimination, which can be associated with the condition.

RAISING AWARENESS: KEY RECOMMENDATIONS AND RELATED GUIDANCE

World Hepatitis Day

WHO has endorsed 28 July as World Hepatitis Day (WHD), providing a focus for awareness-raising events across the world. Each year, millions of people take part in WHD activities to raise awareness about viral hepatitis among policy-makers, health-care professionals and the public, strengthening prevention and control measures while removing discrimination against those who are infected. The World Hepatitis Alliance supports national campaigns through the provision of a range of themed resources that countries can adapt with locally specific messages. Member States should consider how they can use WHD to support awareness-raising efforts, including promoting key points and achievements from their national viral hepatitis plans. (For more information, visit <http://www.worldhepatitisday.org/>.)

Targeted hepatitis health promotion activities

National efforts to raise awareness and understanding of viral hepatitis should include, but not be limited to, WHD. Throughout the year, there are opportunities to promote prevention and control issues to priority groups such as health-care workers and at-risk populations. These could include campaigns and interventions to encourage health-care workers to discuss viral hepatitis with patients, promote diagnostic testing to at-risk populations, and highlight the importance of engaging with clinical care and treatment among those who have been diagnosed with HBV and HCV.

When developing awareness-raising campaigns, countries should consider the following:

- Identify evidence for the most effective messages and media for the target population.
- Create partnerships with a range of media and civil society groups to ensure the appropriateness of messages and effective coverage.
- Support community-based organizations working with at-risk populations to increase the reach of campaign materials among these specific groups.
- Ensure that campaigns do not contribute to the stigmatization of at-risk populations or those living with viral hepatitis.

5.2.2 Prevention

Viral hepatitis is preventable through a combination of evidence-based interventions. The mix of interventions that are required will depend on the local and national epidemiology, and ongoing development of innovative prevention interventions. Policy-makers could consider the following when formulating the prevention component of their national plan.

Vaccination

Safe, effective and affordable vaccines are currently available against HAV, HBV and HEV. It is important to consider that the HBV vaccine also prevents HDV disease, which causes substantial mortality in some countries. There is currently no vaccine against HCV.

HEPATITIS B VACCINATION: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- All infants should receive a dose of HBV vaccine as soon as possible after birth, preferably within 24 hours, followed by 2 or 3 doses to complete the primary series.
- HBV vaccination should be included in national childhood immunization schedules.
- Catch-up vaccination should be considered for cohorts of children with low coverage as a way to increase the number of protected children.
- Catch-up strategies targeted at adolescents could be considered as a supplement to routine infant vaccination, depending on the epidemiological setting.
- HBV vaccination should also be offered to those at increased risk of acquiring or transmitting the virus, including:
 - people who frequently require blood or blood products, dialysis patients, recipients of solid organ transplantations;
 - people interned in prisons;
 - PWID;
 - household and sexual contacts of people with chronic HBV infection;
 - people with multiple sexual partners;
 - health-care workers and others who may be exposed to blood and blood products through their work;
 - persons travelling to areas where the virus is endemic.

HEPATITIS A VACCINATION: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- Vaccination against HAV should be part of a national plan for the prevention and control of viral hepatitis.
- Inclusion of HAV vaccination in routine childhood immunization programmes should be informed by the local context, including the proportion of susceptible people in the population, level of exposure to the virus and consideration of cost-effectiveness.
- Vaccination of the following groups should be considered in low- and very low-endemicity settings to provide individual health benefits:
 - persons travelling to areas where the virus is endemic;
 - MSM;
 - PWID;
 - persons requiring lifelong treatment with blood products;
 - people with chronic liver disease, including those with active HBV or HCV infection;
 - workers in contact with non-human primates.

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Blood safety

In many countries, transmission of viral hepatitis via transfusion of unsafe blood and blood products continues to occur. Countries failing to implement rigorous standards for blood donor recruitment and selection, blood screening and processing, and clinical transfusion face an unacceptable risk of transmission of infections that could easily be prevented. Blood safety encompasses actions aimed at ensuring that everyone has access to safe blood and blood products that are appropriate to their needs, transfused only when necessary, and provided as part of a sustainable blood programme. WHO guidance recommends that countries implement key strategies that ensure the provision of an adequate and safe national blood supply, such as a nationally coordinated blood transfusion service, fully integrated into the national health system with sufficient and continuous resources.

BLOOD SAFETY: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- Establish systems to increase blood donations from regular voluntary non-remunerated donors; assessing donor suitability prior to blood collection on each occasion, and deferring donors at high risk of transmission of hepatitis infections.
- Develop and implement appropriate national policy and strategies for screening of donated blood for transfusion-transmissible infections, including hepatitis B and C, and also for confirmatory testing of those with reactive results.
- Establish systems for a continuous supply of high-quality screening assays with the appropriate sensitivity and specificity for blood screening.
- Develop effective quality systems to ensure the reliability and consistency of blood screening.
- Provide services for notification, counselling, referral for care and follow up of donors with positive infectious markers for their timely treatment and care, and for minimizing the risk of further spread of infection.
- Reduce unnecessary transfusions and minimize patients' exposure to blood and blood products through active patient blood management, appropriate clinical use and use of alternatives.

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Infection prevention and control, including injection safety

Injections are one of the most common health-care procedures. Every year, at least 16 billion injections are administered worldwide. Around 90% are given for curative care. Immunization injections account for around 5% of all injections, with the remaining covering other indications, including transfusion of blood and blood products, intravenous administration of drugs and fluids, and the administration of injectable contraceptives.

The Sixty-seventh World Health Assembly noted that there is a need to strengthen injection safety as an important component of IPC in health-care settings to reduce the risk of transmission of viral hepatitis. The new WHO Injection Safety Policy launched in 2015 (20) recommends that by 2020, governments transition to the exclusive use, where appropriate, of safety-engineered injection devices with reuse prevention and sharps (needle) injury prevention. These devices should meet WHO quality standards.

INJECTION SAFETY: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- Strengthen or reinforce and sustain routine infection control practices in health-care and other settings, including hand hygiene, safe handling and disposal of used sharps and clinical waste, and safe cleaning of equipment that is designed for reuse.
- Develop and implement national policies to ensure best practices in phlebotomy, blood collection and management of occupational risk to bloodborne pathogens.
- Develop standards for rational use and national policies to support the transition to the exclusive use, where appropriate, of safety-engineered injection devices, including reuse-prevention syringes and sharps injury protection devices for therapeutic injections by 2020.
- Set health-systemwide policies and standards for procurement, use and safe disposal of disposable syringes in situations where they remain necessary, including in syringe programmes for people who inject drugs.
- Develop an implementation strategy for the procurement of safety syringes, training and education of health workers, and sound waste management. Establish a targeted communications programme and a framework for evaluating overall progress.

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Harm reduction for people who inject drugs

Existing guidance from WHO, United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) defines and recommends a series of core interventions that Member States should provide to PWID as an evidence-based public health response. It is also recommended that countries set targets to enable universal access to these interventions for PWID among their populations.

PEOPLE WHO INJECT DRUGS: KEY RECOMMENDATIONS AND RELATED GUIDANCE

Nine core interventions for HIV prevention, treatment and care that should be made available to all PWID

1. Needle and syringe programmes (NSPs), including provision of other drug-using paraphernalia
2. Opioid substitution therapy (OST) and other drug dependence treatment
3. HIV testing and counselling
4. Antiretroviral therapy
5. Prevention and treatment of STIs
6. Condom programmes for PWID and their sexual partners
7. Targeted information, education and communication for PWID and their sexual partners
8. Vaccination, diagnosis and treatment of viral hepatitis

9. Prevention, diagnosis and treatment of tuberculosis.

Additional recommendations for the prevention of viral hepatitis infections among PWID

- Offer the rapid hepatitis B vaccination regimen.
- Offer incentives to increase uptake of and complete the hepatitis B vaccination schedule.
- Implement sterile NSPs that also provide low dead-space syringes for distribution.
- Offer peer interventions to reduce the incidence of viral hepatitis.
- Offer OST to treat opioid dependence; reduce risk behaviour for acquisition and transmission of hepatitis C through injecting drug use; and increase adherence to HCV treatment.
- Integrate the treatment of opioid dependence with medical services for hepatitis.

Additional recommendations for men who have sex with men, transgender people, sex workers, and people in prisons and other closed settings

- Catch-up hepatitis B immunization strategies should be instituted in settings where infant immunization has not reached full coverage.

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Sexual transmission

Hepatitis B is transmitted through exposure to infectious blood, semen and other body fluids, and is considered in many countries as an STI. There is low or no risk of sexual transmission of HCV among heterosexual couples or MSM who are not infected by HIV. However, recent data indicate that sexual transmission of HCV can occur, especially among HIV-infected persons.

PREVENTION OF SEXUAL TRANSMISSION: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- Promotion of safer sex practices, including effective use of, and access to, condoms and water-soluble lubricant for those at higher risk
- Targeted catch-up hepatitis B vaccination for MSM, sex workers and other at-risk groups in settings where infant immunization has not reached full coverage
- Interventions targeted at key and vulnerable populations, such as adolescents, sex workers, MSM and PWID
- Integrated action to eliminate discrimination and gender violence, and to increase access to medical and social services for vulnerable persons.

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Sanitation, clean water and food safety

Food- and waterborne transmission of HAV and HEV is common in many parts of the world, and is responsible for sporadic outbreaks and epidemics that result in illness and deaths. There is a wide range of global publications relating to sanitation, clean water and food safety, and it is beyond the scope of this document to summarize all the recommendations. For more information, please see the bibliography in the box below.

SANITATION, WATER AND FOOD SAFETY: KEY RECOMMENDATIONS AND RELATED GUIDANCE

Development and implementation of national standards and guidance on:

- Water and food hygiene
- Safe disposal of clinical and other health-care waste
- Safe management of human and other potentially infectious waste.

Bibliography

Water quality and health strategy 2013–2020. Geneva: WHO; 2013 (http://www.who.int/water_sanitation_health/publications/2013/water_quality_strategy.pdf, accessed 08 July 2015).

Management of solid health-care waste at primary health-care centres: a decision-making guide. Geneva: WHO; 2005. (<http://www.who.int/iris/bitstream/10665/43123/http://apps.who.int/iris/bitstream/10665/43123/1/9241592745.pdf>, accessed 08 July 2015).

Principles and guidelines for the conduct of microbiological risk management (MRM). Codex Alimentarius Commission; 2007 [CAC/GL 63-2007]. http://www.codexalimentarius.org/download/standards/10741/CXG_063e.pdf, accessed 08 July 2015).

5.2.3 Testing

Proactive, targeted diagnostic testing approaches can reduce the proportion of undiagnosed cases, provide opportunities to prevent onward transmission, and increase access to clinical care and treatment. Testing needs to be of primary benefit to the person being tested. In many countries, people infected with HBV and HCV have limited access to diagnostic testing and remain undiagnosed until they present at a health centre with symptoms of advanced disease, such as cirrhosis and liver cancer. Late presentation with chronic viral hepatitis is associated with suboptimal outcomes and fewer treatment options for the patient. Testing should be easily accessible and confidential. When a person receives a positive diagnosis of viral hepatitis, it is imperative that comprehensive information is provided regarding the disease, its management, treatment options and harm reduction opportunities.

TESTING: KEY RECOMMENDATIONS AND RELATED GUIDANCE

- Diagnostic testing strategies based on epidemiological evidence should be developed. Priority populations who should be considered for screening include:
 - individuals who are part of a population with high HCV or HBV prevalence. Some countries could consider birth cohort screening, depending on the local epidemiology;
 - individuals with a history of hepatitis risk exposure or behaviour, such as
 - » previously incarcerated persons,
 - » persons who have received medical or dental interventions in health-care settings where infection control practices are substandard,
 - » PWID,

- » persons who have received blood transfusions before the start of serological testing of blood or in countries where serological testing of blood donations is not routinely performed;
- those at increased risk of morbidity and mortality due to pre-existing medical conditions or treatment (e.g. people living with HIV, those receiving cytotoxic or immunosuppressive therapy);
- Policies that support public health approaches to contact notification and management of diagnosed cases should be developed and implemented.

Bibliography

Guidelines for the screening, care and treatment of persons with hepatitis C infection. Geneva: WHO; 2014 (http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1, accessed 08 July 2015).

Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva: WHO; 2015 (<http://www.who.int/hiv/pub/hepatitis/hepatitis-b-guidelines/en/>, accessed 08 July 2015).

5.2.4 Clinical care and treatment

Efforts to expand access to, and uptake of, clinical assessment and antiviral treatment can play a key role in determining health outcomes of people affected by hepatitis. Expanded access may be achieved by enabling the delivery of treatment in primary care settings and by engaging community stakeholders. Clinical care and treatment should be delivered in line with evidence-based guidelines.

It is important to identify and use the most feasible procurement strategies to ensure availability of the best medicines at the best possible prices within the country. This necessitates clarification of the patent situation and, if there is only one provider, exploration of different options to reduce the price.

Effective clinical management of viral hepatitis reduces the individual, social and health burden related to the infection. WHO has published guidelines for the care and treatment of persons with HBV and HCV infection (20,21).

WHO also noted the need to increase access to antiviral therapy among infected populations, and has highlighted opportunities for care and treatment to be provided in a range of community settings, as part of partnerships between specialist services and primary health-care providers.

CARE AND TREATMENT: KEY RECOMMENDATIONS AND RELATED GUIDANCE

Develop national clinical guidelines for the management and treatment of persons with chronic HBV and HCV infection, based on available WHO or other evidence-based guidelines. National guidelines should address the following components.

- Initial clinical assessment, including:
 - assessment of liver disease stage based on clinical criteria or non-invasive tests;
 - assessment to reduce individual risk of disease progression, including screening for alcohol use and counselling to reduce moderate and high levels of alcohol intake.
- Assessment for starting antiviral treatment, including:
 - screening and testing for comorbidities such as renal impairment, high body mass index and smoking, in order to inform treatment plans (drug–drug interactions, potential hepatotoxicity and others);
 - screening and testing for coinfections such as HIV, TB;
 - prioritization for treatment of individuals according to clinical criteria;

- reducing the risk of transmission using appropriate methods, for example, harm reduction interventions for PWID;
- monitoring patients for whom treatment has been deferred.
- Provision of antiviral treatment, including:
 - optimal first-line therapeutic regimen;
 - monitoring response to treatment;
 - monitoring for, and managing, adverse effects such as toxicity;
 - well-defined goals and end-points of therapy, and stopping rules.

Develop detailed treatment access plans addressing the following issues: communication, leadership and advocacy; staffing and human resources; drugs and supplies; system organization; infrastructure; costs; funding; and monitoring and evaluation. (See Annex 5 for a checklist.)

Bibliography

Guidelines for the screening, care and treatment of persons with hepatitis C infection. Geneva: WHO; 2014 (http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1,, accessed 01 May 2014).

Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva: WHO; March 2015 (<http://www.who.int/hiv/pub/hepatitis/hepatitis-b-guidelines/en/>, accessed 08 July 2015).

5.3 Covering populations and achieving equity

Large proportions of people at high risk for, or living with, viral hepatitis infection, do not have access to prevention services, remain undiagnosed, or do not use or adhere to treatment therapies. Yet existing approaches seldom address the underlying factors – such as discrimination and criminalization, drug dependence and poor mental health – that can generate health inequities. Interventions and services are often poorly targeted and fail to reach those at greatest risk or most affected, which lessens their impact.

Recent innovations in technology and delivery methods make it easier for countries to identify at-risk populations and service gaps, and achieve equitable provision of high-impact services and interventions. It is equally important to address the underlying factors – such as discrimination and criminalization, poverty and social exclusion – that help generate health inequities. This is best achieved by actively involving people living with or at high risk for viral hepatitis in developing strategies and programmes.

Populations that are especially vulnerable to viral hepatitis include newborns and infants, recipients of blood and blood products or tissues and organs, people exposed to unsafe injections, health-care workers, PWID, people who undergo skin-piercing procedures such as tattooing, prisoners and detainees, indigenous communities, migrants, sex workers and MSM.

At-risk populations may be exposed to stigma and discrimination, social marginalization or face legal barriers (such as age-of-consent laws for adolescents and criminalization of behaviours such as drug use and sex work) that impede their access to services for preventing or treating infection. Some of these barriers can be overcome if existing models of service delivery are assessed and improved to ensure that all viral hepatitis programmes and services are delivered in an equitable manner. Others may require the reform or repeal of certain laws or legal provisions.

WHO has issued guidance on HIV prevention, diagnosis, treatment and care for key populations (22) and defined a package of interventions that also address viral hepatitis.

ACHIEVING EQUITY: KEY RECOMMENDATIONS

- Make special provision in policies for equitable access to prevention, diagnosis and treatment services for populations most affected by viral hepatitis.
- Develop, adopt and evaluate models of decentralized and integrated services that are suited to priority settings and key populations, including providing hepatitis prevention, screening and treatment services in services for PWID.
- Act to eliminate stigma and discrimination against people living with or affected by viral hepatitis, including through the development of programmes in community and health-care settings.
- Support the implementation and expansion of viral hepatitis prevention and treatment services in custodial settings, refugee camps and places of humanitarian concern.

Bibliography

Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. Geneva: WHO; 2014 (<http://www.who.int/hiv/pub/guidelines/keypopulations/en/>, accessed 08 July 2015).

5.4 Covering costs

Countries face the challenge of enhancing their hepatitis services by investing along the entire continuum of interventions and promoting UHC. Financing for a sustainable response requires action in three areas:

- raising funds to pay for the programmes, including through public and private domestic funding and external sources, such as donor grants;
- establishing equitable mechanisms to pool funds for providing financial risk protection related to health, including viral hepatitis, such as through taxation and health insurance schemes; and
- optimizing the use of resources by improving the efficiency and effectiveness of services, and reducing the costs of medicines, diagnostics and other commodities.

The national health financing system in each country should address all priority health needs of that country, avoiding fragmented funding channels and aiming to achieve health equity.

6. TEMPLATE FOR A NATIONAL HEPATITIS PLAN

This section includes a template indicating the sections of a national plan and suggested content for each section, which would be useful for people drafting a national hepatitis plan. It is important to note that each national plan would be unique, reflecting the disease burden, readiness to respond and the governance structures. However, the template provided here has been used and found useful in many countries.

6.1 Situational analysis, stakeholder mapping and priority setting

- Provide an overview of the situation, including disease epidemiology, burden, existing response activities and projected future changes to the current situation.
- Describe the health needs of the population, including possible sources of inequalities in specific populations with regard to viral hepatitis.
- Identify the priorities of a national response to viral hepatitis, including a justification of how efficiency (interventions likely to achieve the maximum health gain with the available resources), equity (the absence of avoidable differences between groups of people) and public demands will be taken into consideration.
- Map national stakeholders involved in the viral hepatitis response (professional organizations, patient groups, other ministries).

6.2 Governance and organizational structure

- Describe the national leadership and governance roles in response to viral hepatitis, including the national management structure and an overview of the process of national policy formulation and coordination.
- Elaborate on the key contributors to policy formulation, such as steering groups, technical advisory groups, implementation groups and technical working groups.
- Indicate partnerships essential to plan implementation, such as community organizations, doctors, nurses and academia.

6.3 Relationship to other policies, strategies, plans and programmes

- Identify potential and existing synergies between the response to viral hepatitis and other health system and/or disease-specific strategies and plans. Possible synergies could include the following:
 - common priority populations, for example, PWID, incarcerated persons and pregnant women;

- shared or similar priority action areas, for example, blood safety, immunization and infection control;
- common workforce development, monitoring and surveillance, and health system strengthening needs.
- Make clear references to other relevant policies or plans (e.g. policies on blood safety, injection safety, vaccination).
- Link the viral hepatitis plan to the national health sector plan, if relevant.

6.4 Viral hepatitis response

This section is where detailed activity planning will be done according to goals, objectives and targets.

The tabular format used here is for ease of visualizing the plan with the goals and objectives in mind. As every country's circumstances will require country-specific goals, objectives, targets, activities, responsible groups and other stakeholders, Table 3 should be taken as an example. As the actual plan will need to be much more detailed, this page format will probably not allow for sufficient space. It should also be kept in mind that there might be additional items to add to this table, such as costs and resource needs.

When the global strategy for hepatitis is adopted, this section of the manual will be revised to reflect the strategic directions and interventions within the global strategy.

6.5 Integration and implementation

- Identify opportunities where existing health system policies and programmes can be reshaped or extended to include hepatitis-related activities.
- Make a special effort to link service delivery pathways to existing structures to increase efficiencies (e.g. HIV treatment facilities, antenatal care clinics).

6.6 Financial framework

- Describe planned internal resource allocation.
- Describe internal and external funding and financing mechanisms.
- Indicate planned budgeting and expenditure.

TABLE 3 Example of a national plan structure

Strategic aim: Reduce the impact of viral hepatitis on people, society and the economy.

Goals	Objectives	Targets (by end 2020)	Activities	Responsible group(s)	Other stakeholders
1. Raise awareness of viral hepatitis	1.1. Increase knowledge of the general population and key populations on risks and protection from viral hepatitis	<ul style="list-style-type: none"> 80% of university students know who is at risk, and how to protect from viral hepatitis 80% of secondary school teachers know who is at risk, and how to protect from viral hepatitis 	<ul style="list-style-type: none"> Commemorate World Hepatitis Day on 28 July Develop printed information material for elementary schools and universities 	<ul style="list-style-type: none"> Led by information, education and communication (IEC) by MoH and media groups with technical support from the MoH hepatitis group 	<ul style="list-style-type: none"> Teachers' associations, patient groups, civil society groups, others
	1.2. Increase awareness of health-care providers in screening high-risk populations	<ul style="list-style-type: none"> All primary-level health-care workers have received information on hepatitis All primary-level doctors know how to interpret hepatitis serology for referral 	<ul style="list-style-type: none"> Prepare information material for primary-level health-care workers Prepare information material on hepatitis serology for primary-level doctors Introduce hepatitis sessions in national/regional meetings 	<ul style="list-style-type: none"> Led by national doctors' and nurses' associations with support from MoH hepatitis group 	<ul style="list-style-type: none"> Patient groups, other health worker associations, others
	1.3. Reduce stigma and discrimination associated with hepatitis in the community	<ul style="list-style-type: none"> Enhance the social environment in favour of people living with or affected by hepatitis 	<ul style="list-style-type: none"> Remove all legal language that may result in stigma and discrimination such as mandatory tests for employment 	<ul style="list-style-type: none"> MoH policy group 	<ul style="list-style-type: none"> Other relevant ministries, civil society
2. Monitor health sector response to hepatitis	2.1. Estimate the national burden due to chronic hepatitis	<ul style="list-style-type: none"> Determine prevalence of chronic hepatitis B by [year] Determine prevalence of chronic hepatitis C by [year] Estimate number of hepatitis-related cirrhosis, liver failure, liver transplants and deaths by [year] Estimate incidence of hepatitis infections per year 	<ul style="list-style-type: none"> Nationally representative serosurveys for hepatitis B and C held 5–10 years apart Sentinel surveillance for cirrhosis in biggest five hospitals National data repository for liver cancer and liver transplantation Serosurveys in high-risk groups such as PWID, MSM, and others 	<ul style="list-style-type: none"> Led by MoH hepatitis group in collaboration with national statistics institute 	<ul style="list-style-type: none"> Academia, civil society
	2.2. Monitor trends in chronic hepatitis over time	<ul style="list-style-type: none"> 50% reduction in hepatitis B and C prevalence 	<ul style="list-style-type: none"> Analysis and annual reporting of national surveillance and research data 	<ul style="list-style-type: none"> Led by MoH hepatitis group in collaboration with national statistics institute 	<ul style="list-style-type: none"> Academia, civil society

Goals	Objectives	Targets (by end 2020)	Activities	Responsible group(s)	Other stakeholders
3. Reduce new infections with viral hepatitis	3.1. Stop mother-to-child transmission of hepatitis B	<ul style="list-style-type: none"> Zero babies born with hepatitis B infections 	<ul style="list-style-type: none"> Develop or add to the currently available antenatal care guidelines recommendations on hepatitis B testing of pregnant women Test all pregnant women for hepatitis B Manage all hepatitis B-positive pregnant women according to national guidelines Vaccinate all infants with the hepatitis B vaccine in the first 24 hours of life 	<ul style="list-style-type: none"> MoH immunizations group in collaboration with maternal and child health group and hepatitis group 	<ul style="list-style-type: none"> Nurses' and midwives' associations, relevant medical associations, civil society, media
	3.2. Prevent health-care related transmission of hepatitis B and C	<ul style="list-style-type: none"> Zero health-care related transmission of hepatitis B and C 	<ul style="list-style-type: none"> Organize campaigns to reduce unnecessary injections and blood transfusions Establish strong infection prevention and control (IPC) programmes in all public and private health-care facilities. 	<ul style="list-style-type: none"> MoH and patient groups 	<ul style="list-style-type: none"> MoH public communications group, professional associations, media communications group, professional associations, media
	3.3. Reduce the number of susceptible people in the community	<ul style="list-style-type: none"> Increase coverage with hepatitis B vaccine third dose to 98% 	<ul style="list-style-type: none"> Vaccinate all infants with 2 or 3 doses of hepatitis B vaccine in addition to the birth dose to complete the series 	<ul style="list-style-type: none"> MoH immunization group in collaboration with hepatitis group 	<ul style="list-style-type: none"> National professional associations, media, civil society
	3.4. Decrease HCV incidence among PWID	<ul style="list-style-type: none"> Increase number of syringes distributed to 200/PWID/year 	<ul style="list-style-type: none"> Increase the number of NSP centres to 10 Establish OST/NSP centres in the biggest two provinces with strong linkages to care and treatment services 	<ul style="list-style-type: none"> MoH harm reduction group 	<ul style="list-style-type: none"> MoH hepatitis unit, local PWID NGO

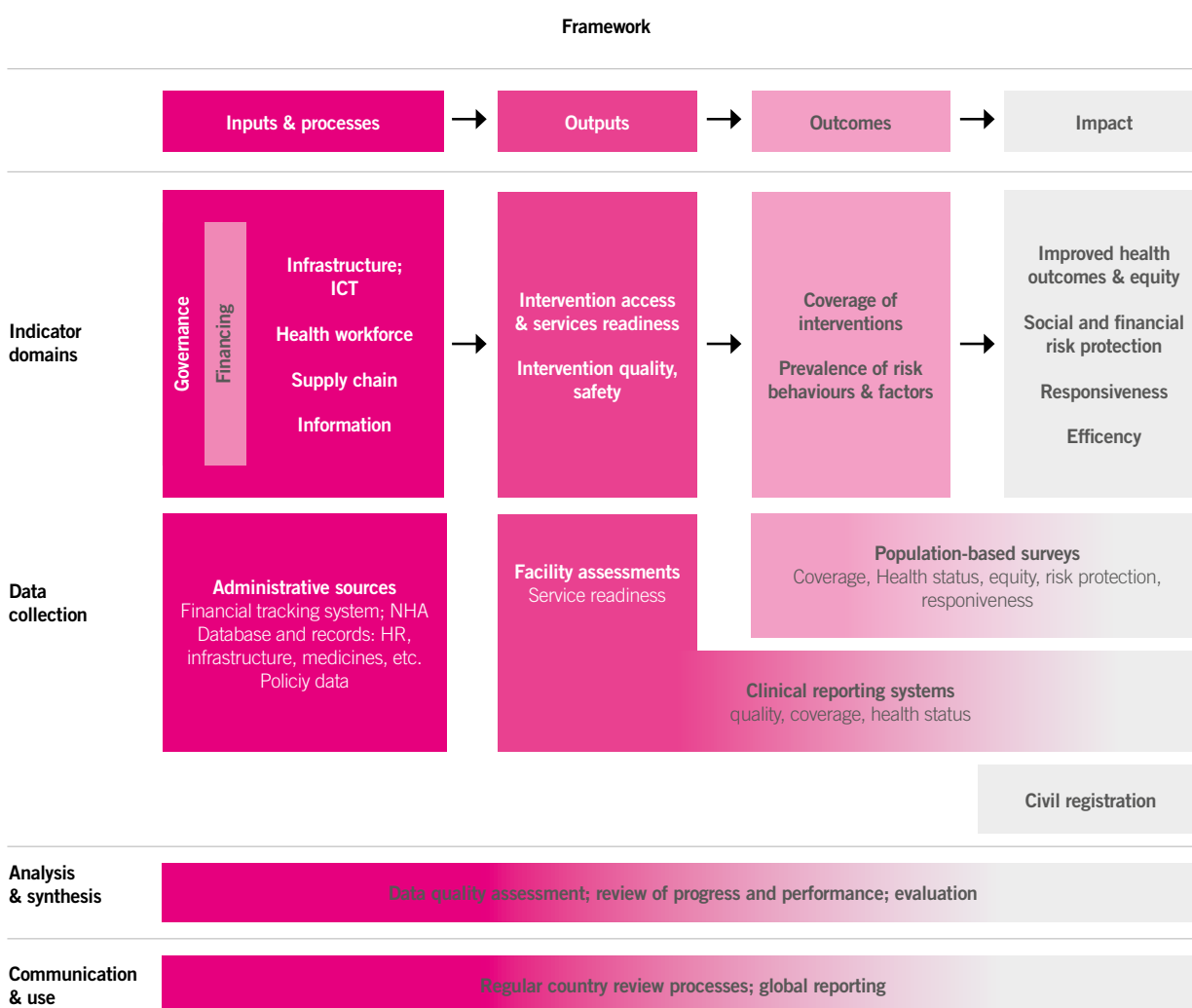
Goals	Objectives	Targets (by end 2020)	Activities	Responsible group(s)	Other stakeholders
4. Reduce deaths due to viral hepatitis	4.1. Increase proportion of people diagnosed with chronic hepatitis	<ul style="list-style-type: none"> • Increase number of diagnostic tests performed for hepatitis by 100% • Test 50% of PWID for hepatitis B and C • Test 80% of all health-care workers for hepatitis B and C 	<ul style="list-style-type: none"> • Offer free testing to all PWID through NSPs • Offer free testing to all health-care workers 	<ul style="list-style-type: none"> • Led by MoH hepatitis unit in collaboration with HIV and other relevant groups 	<ul style="list-style-type: none"> • Other sector hospitals, professional societies, NGOs
	4.2. Ensure adequate follow up and management of diagnosed people	<ul style="list-style-type: none"> • 100% of people with chronic hepatitis are given appropriate counselling • 50% of eligible people are started on treatment 	<ul style="list-style-type: none"> • Ensure that appropriate counselling messages reach people with chronic hepatitis • Reduce loss to follow up of people diagnosed with chronic hepatitis • Translate and adapt WHO guidelines on hepatitis B and C testing and treatment • Train treating physicians in the new guidance 	<ul style="list-style-type: none"> • MoH hepatitis unit 	<ul style="list-style-type: none"> • MoH health-care delivery unit, counselling group, chronic diseases group or other relevant units; nurses' associations

IEC information, education and communication, IPC infection prevention and control, MoH ministry of health, MSM men who have sex with men, NGO nongovernmental organization, NSP needle-syringe programme, OST opioid substitution therapy, PWID people who inject drugs

7. MONITORING AND EVALUATION FRAMEWORK

Each national hepatitis plan should include an M&E framework that describes how the implementation and effectiveness of the programme will be measured and assessed. Most countries will already have arrangements for the M&E of the wider national health sector, which can be adapted to the viral hepatitis plan.

FIGURE 5. Monitoring and evaluation results framework



HR human resources, ICT information and communication technology, NHA national health accounts

The M&E framework will include details of the qualitative and quantitative data that are required to assess progress against key performance indicators. All data that are collected should clearly relate to the goals and actions set out in the national plan. Everyone involved in M&E activities should understand what data are required, the frequency of data collection, how they will be analysed, and the process for reporting findings.

The International Health Partnership+ (IHP+) M&E results framework (23) provides a useful foundation to guide the rationalization and selection of a core set of indicators. It also puts the indicators in a broader perspective of a framework for M&E. This framework comprises four major indicator domains: system inputs and processes, outputs, outcomes and impact. The framework illustrates the directionality of how inputs to the system (e.g. financing, health workforce) and processes (e.g. supply chain) contribute towards outputs (such as availability of quality services and interventions) and eventual outcomes (e.g. intervention coverage and the prevalence of health-related behaviours), which finally result in impact (e.g. improved health outcomes). This results-chain framework can be used to demonstrate the performance of both disease-specific and health systems interventions (Figure 5).

WHO is developing a set of monitoring indicators alongside the global strategy for hepatitis. When published, they will provide a framework for countries to monitor the implementation and effectiveness of their hepatitis response.

7.1 Monitoring

Programme monitoring is the ongoing tracking and reporting of the actions set out in the national hepatitis plan. It brings together data from all relevant sources to describe what is happening, where, and to whom. Monitoring activities focus on the process of implementation, measuring both the level of investment into the programme (inputs) and the resulting service delivery activities (outputs).

Monitoring requires the development of robust administrative systems to capture and report indicators from all delivery partners. These data will be reported to a central coordinating agency in an agreed format to support analysis and interpretation. Monitoring reports allow all stakeholders to check that prevention and control activities are appropriately resourced, and that delivery is in line with agreed targets and milestones.

Programme monitoring activities should include both quantitative and qualitative dimensions. As well as measuring the volume and coverage of interventions, quality should also be assessed. The accessibility and scope of viral hepatitis services can be assessed against existing service standards and guidelines. User satisfaction surveys can provide valuable information on the acceptability of services to their target populations and indicate where improvements are required to engage with specific subgroups. Monitoring should be transparent for all stakeholders to be able to follow national activities.

WHO will publish a set of indicators to assess the global response to hepatitis. Countries may wish to adopt these as early as possible in order to be able to report on their response.

7.2 Evaluation

Evaluation is the episodic assessment of the effectiveness of programmes. It builds on monitoring activities, but the analysis takes into account contextual changes, addressing questions of attribution, and exploring counterfactual situations (25). Programme outcomes can be assessed through population surveys that focus on changing patterns of behaviour and attitudes among target populations, including assessment of public awareness, service uptake rates, and the prevalence of risk factors and behaviours. In addition to individual-level changes, research into changes in the structural barriers to health services should also be undertaken.

Evaluation is also concerned with describing the longer-term impacts on population health. Disease surveillance data and epidemiological studies provide evidence of changing rates of infection and health-seeking behaviours among at-risk populations. These findings can then be modelled to provide estimates of the long-term impact of the national plan on disease burden, including morbidity and mortality rates, health inequities and socioeconomic costs.

ANNEX 1.

DEFINITION OF TERMS

Policies, strategies and plans are words that cover a wide spectrum of dimensions and hierarchies; they range from values and vision, policy direction, strategy and strategic planning to detailed operational plans; from comprehensive health planning to disease-specific programme planning; from a long-term time horizon to the 5-year plan, the 3-year rolling plan and the yearly operation plan; from national to regional and district plans; from the highest level of endorsement of the vision and the policy directions, to approval of operational plans. It is then not surprising that even a cursory glance at the actual country process and the literature reveals an interchangeable use of terms such as policy, plan, strategy and programme. There seems to be a lack of consensus and consistency in the way core terms are used; such differential uses reflects a diversity of approaches and levels at which the process is undertaken, as well as the different aims that countries have. In any given country, the partitioning between different products and the terminologies used are largely determined by regional and national specificities, by the political culture and history, and by the concrete challenges faced. Therefore, the intercountry and interregional diversity in terminology and practice has to be acknowledged. Meanwhile, it remains important to have a common understanding of terms used in this manual, as proposed below^a:

Activities: actions that need to be undertaken to deliver an intervention or service

Efficiency: better use of resources to produce results

Equity: principle of being fair to all, with reference to a defined set of values

Goal: a general objective related to the impact on the main problem in terms of cases, deaths or transmission

Guiding principle: a rule or ethical standard that guides the work of the programme

Indicator: a measurable or tangible variable that helps to assess the goals, objectives and targets, and to show the changes over time

Objective: a statement of a desired future status related to the expected outcomes the hepatitis programme wants to reach

Policy: an expression of national goals/objectives for improving the health situation, the priorities among the goals/objectives, and the main directions for attaining the goals/objectives

^a Adapted from Manual for developing a national malaria strategic plan. Brazzaville: WHO Regional Office for Africa; September 2011. (http://www.afro.who.int/index.php?option=com_docman&task=doc_download&gid=7232, accessed 5 August 2015).

Plans:

Strategic plan: a process of organizing decisions and actions to achieve particular goal(s) and objectives within a policy. It sets up precise priorities and activities, as well as the means to achieve them.

Implementation plan: a detailed multiple-year rolling action plan that converts the specific objectives into targets/milestones, describes interventions and activities with the relevant timeframe and sequences, identifies responsibilities and resource allocation

Action plan or workplan: annual detailed plan that guides the day-to-day work

Situation analysis is the process of analysing and interpreting all information available from the health systems, including that on hepatitis. Analysis of the situation involves identifying strengths, weakness, opportunities and threats in the form of risks or assumptions (SWOT analysis) of the existing health delivery systems and of the hepatitis programme.

Strategy: the approach to implement an intervention or a combination of interventions in order to maximize the impact on hepatitis cases and deaths

Targets: an intermediate result towards an objective that a programme seeks to achieve

Vision: a statement expressing a mind picture of a desired better future

ANNEX 2.

PROCESS FOR REVIEW AND UPDATE OF A NATIONAL PLAN AND THE ASSOCIATED PROGRAMME

Programme reviews provide an assessment of how the viral hepatitis programme has performed during a given period of time. Information from a range of sources, including monitoring and evaluation activities, is used to establish whether the programme and its components are proceeding in the right direction and producing the desired results.

A series of programme review activities are usually conducted at defined points in the programme cycle (24):

- **Annual reviews** are used to assess progress in implementing the national viral hepatitis plan, and to identify any emerging challenges to the delivery of the programme. This typically includes a review of programme monitoring data against targets set out in the national plan. The findings of annual reviews help to inform any adjustments that are required to strengthen implementation of the viral hepatitis programme. Examples of best practice can be identified and adapted to improve delivery in underperforming areas.
- **Mid-term reviews** are typically conducted around the mid-point of a multi-year programme. The purpose is to determine whether the implementation of the national programme is going in the right direction and is on course to meet the targets set out in the national plan. As well as supporting improvements in implementation, a mid-term review also examines progress in the services being delivered (outputs) and how the relevant populations engage with these services (outcomes). They might also review the impact of prevention and control activities where data are available or sufficient time has passed to demonstrate impact. Mid-term review findings provide evidence for stakeholders to consider the need for any adjustments to the national viral hepatitis plan. These adjustments could include modifying targets, priority population groups or treatment strategies, or types of interventions.
- **End-term reviews** are carried out at the end of the multi-year programme. The aim is to determine how well the programme has performed overall. This comprehensive review is informed by an examination of all M&E outputs, with particular emphasis on those relating to programme outcomes and impacts. The end-term review will provide evidence to inform the situation analysis component of the subsequent national viral hepatitis plan.

Specific reviews are those concerned with discrete components of the national programme, including the following:

- **Thematic reviews** generally focus on specific interventions (e.g. vaccination, testing, harm reduction) or populations (e.g. PWID, MSM, health-care workers). They could also focus on issues such as decentralization of clinical care, public awareness or procurement.
- **Project reviews** are conducted for specific projects, such as those focusing on particular population subgroups or those concerned with specific geographical areas.

ANNEX 3.

PLANNING TOOLS

Joint Assessment of National Strategies (JANS)

This tool provides a systematic and deliberately generic framework for reviewing the essential elements of any sound national strategy. While its prime use is to review national health sector strategies or plans, it can equally be used to review multisectoral or programme-specific strategies. It was developed by a multistakeholder Working Group on National Policies, Strategies and Plans convened in 2008 under the auspices of the IHP+ (25).

OneHealth

The OneHealth Tool is a software tool designed to strengthen health system analysis and costing, and to develop financing scenarios at the country level. The primary purpose of the tool is to assess health investment needs in low- and middle-income countries (26).

ANNEX 4.

TOPIC GUIDE FOR THE ASSESSMENT OF A NATIONAL PROGRAMME

The following topic guide is used by WHO in joint reviews of Member States' national hepatitis programmes. It is used as a reminder during interviews with the people responsible for the relevant services. By adding the information collected here to the disease status and burden within the country, it is possible to identify the gaps and make programme recommendations.

Assessment area	Yes/No/Not applicable and additional info.
1. Programme management and governance arrangements	
a. Is there a national steering committee responsible for setting the high-level strategic direction, funding, oversight and governance of the national plan and programme?	
b. Is the steering committee led by a relevant minister or a high-level official appointed by the minister?	
c. Is there a Strategic and Technical Advisory Group (STAG) for hepatitis?	
d. Does STAG include representation from: <ul style="list-style-type: none"> • MoH; • other relevant ministries; • national professional medical societies; • academia; • senior leaders from organizations involved in operational delivery of the plan; • civil society, including groups most at risk for or affected by viral hepatitis? 	
e. Is there a designated unit or person within the MoH responsible for the national hepatitis response?	
f. If yes, how many whole-time equivalent staff work on viral hepatitis? If no, who is responsible for it?	
g. Does the government have a current national viral hepatitis plan? If yes, what is the title of the document and for what period is it valid? If no, are there strategies that cover the areas of hepatitis services?	
h. Which stakeholders are involved in <ul style="list-style-type: none"> • development of the national plan and programme; • provision and review of technical advice; • coordinating implementation of the plan; • provision of monitoring and evaluation? 	

Assessment area	Yes/No/Not applicable and additional info.
i. How have the plan and programme been communicated to key stakeholders in the country, including health-care providers, those responsible for setting health-care policy, prevention services, at-risk populations, and the general population?	
j. Is the national plan costed and funded?	
k. Which national laws, ministerial decrees and other legislation, if any, regulate the awareness, prevention and control of viral hepatitis in the country? l. Does the national plan include a framework that describes the process and content of monitoring, evaluation and review activities?	
m. What is the process and time scale for the mid-term/end-of-term review and updating of the national plan?	
2. Awareness-raising and community engagement	
a. Are specific national activities and events held on or around World Hepatitis Day? If yes, who is involved in awareness-raising activities: MoH, national civil society organizations, others? (Please specify.)	
b. Other than World Hepatitis Day-related activities, how are the issues surrounding the prevention and control of viral hepatitis promoted to the following groups: <ul style="list-style-type: none"> • health- and social-care providers; • at-risk populations; • general public; • others? (Please specify.) What topics do these activities address: <ul style="list-style-type: none"> • general information about viral hepatitis and its routes of transmission; • sanitation, safe water and food safety; • safer sexual practices; • harm reduction activities for PWID; • importance of knowledge of status; • availability and benefits of clinical care and treatment for those with chronic HBV and HCV infection; • stigma and discrimination? 	
c. Is viral hepatitis awareness and information embedded within school/university curricula? If yes, which curricula (primary school/secondary school/university) and who provides quality assurance of this information?	
3. Workforce development	
a. Which cadres of health-care professionals are being trained in viral hepatitis prevention, care and treatment as part of their professional education/training?	
b. Is viral hepatitis a component of the continuing education of health-care workers?	
c. Is there a programme of training and development for the provision of HBV and HCV clinical assessment and treatment in primary care and other community settings? If yes, who are the partners in this programme?	
4. Data for policy and action	
4.1 Surveillance and monitoring	
a. Is there a national surveillance system for <i>acute</i> hepatitis infection?	
b. What hepatitis does this system cover?	
c. Does this surveillance system report cases and deaths to a central registry?	
d. What is the case definition of acute hepatitis?	

Assessment area	Yes/No/Not applicable and additional info.
e. Is there a registry for <i>chronic</i> hepatitis infection? <ul style="list-style-type: none"> • At the national level? • At the regional/subnational level? • At sentinel sites? 	
f. What is the case definition of <i>chronic</i> hepatitis infection?	
g. Are there standard case definitions/diagnostic criteria for outbreak investigation purposes? <ul style="list-style-type: none"> • Case definition for <i>confirmed</i> case • Case definition for <i>possible</i> case 	
h. Are suspected hepatitis outbreaks reported and further investigated? If yes, to which people is this information reported to, and do they follow standard operating procedures for investigation and management of the outbreak?	
i. Is there a national cancer registry? If yes, is it possible to identify liver cancer cases associated with viral hepatitis infection?	
j. Are aggregated data on viral hepatitis cases and deaths routinely published? If yes, how often and where is this information published, and how is the confidentiality of data protected?	
k. Which information is collected on new hepatitis cases and recorded in the case notification system?	
l. Is the major viral genotype of new HBV and HCV cases confirmed?	
m. Are performance indicators used to assess the quality and performance of surveillance systems (e.g. completeness, timeliness). If yes, please give examples.	
4.2 Implementing a public health research agenda	
a. Is there a national research agenda for viral hepatitis? If yes, please outline its components and the lead researchers/institutions.	
b. Are there national standards/operating procedures for conducting biomarker surveys (e.g. standard survey protocols)?	
c. Which information is collected as part of biomarker surveys?	
4.3 Ensuring adequate laboratory capacity and performance	
a. Is there adequate laboratory capacity to support outbreak investigations and other surveillance activities (e.g. enzyme immunoassay [EIA], nucleic acid testing [NAT])?	
b. Is there adequate laboratory capacity in the country for scaling up testing and diagnosis services?	
5. Prevention of transmission	
5.1 Vaccination	
a. Is there a strategy for preventing mother-to-child transmission of HBV? <ul style="list-style-type: none"> • Is post-exposure prophylaxis (hepatitis B immunoglobulin [Ig] and HBV vaccine) provided to all infants born to hepatitis B surface antigen (HBsAg)-positive mothers? • Do all health-care facilities have standing orders to vaccinate all newborns with hepatitis B vaccine within 24 hours of life? • Are strategies in place to provide hepatitis B vaccination to all newborns delivered at home within 24 hours of birth or as soon as possible? 	
b. Is HBV vaccination part of the routine infant immunization schedule?	
c. Is there a policy to vaccinate all health-care workers with hepatitis B vaccine before starting work?	

Assessment area	Yes/No/Not applicable and additional info.
<p>d. What is the national strategy for routine HBV vaccination of the following groups, and who funds their vaccination (government, self, other)?</p> <ul style="list-style-type: none"> • Military personnel • Commercial sex workers • PWID • MSM • People with HIV or chronic HCV • Others (please specify) 	
<p>e. What is the national strategy for routine HAV vaccination of the following groups, and who funds their vaccination (government, self, other)?</p> <ul style="list-style-type: none"> • Travellers to areas of high endemicity • Military personnel • Ecological and sanitary workers • People with HIV or chronic HCV • Others 	
5.2 Blood safety	
<p>a. Is there a national blood safety strategy and associated policies governing the collection of blood from donors?</p>	
<p>b. Are donors assessed for suitability prior to collection and on each occasion?</p>	
<p>c. Is all donated blood screened for HBV, HCV, HIV, syphilis and other transfusion-transmissible infections?</p>	
<p>d. Do systems exist for the notification, counselling and onward referral of donors if any abnormalities are found?</p>	
<p>e. What is the national approach to the reduction of unnecessary transfusions?</p>	
5.3 Infection prevention and control, including injection safety	
<p>a. Are there national infection prevention and control guidelines for health-care facilities (public and private) that address the following:</p> <ul style="list-style-type: none"> • hand hygiene; • handling and disposal of used sharps; • management of clinical waste; • safe cleaning of equipment that is designed to be reused? 	
<p>b. How are health-care workers informed and trained about infection control guidelines?</p>	
<p>c. Are single-use syringes and needles used in all health-care facilities?</p>	
<p>d. Is there a process for recording shortages/failures in the following equipment?</p> <ul style="list-style-type: none"> • Personal protective equipment • Single-use syringes and/or needles • Boxes for the disposal of used sharps and other equipment • Facilities/equipment for the decontamination of reusable medical/dental equipment 	
<p>e. Are there national guidelines for the management of occupational exposure to HBV and HCV among:</p> <ul style="list-style-type: none"> • health-care workers; • prison staff and those working in other residential settings; • others? 	
<p>f. What measures are taken to ensure the safe disposal of medical waste?</p>	
<p>g. What are the challenges or shortcomings associated with ensuring effective infection control at the national level, and in specific regions or settings?</p>	

Assessment area	Yes/No/Not applicable and additional info.
5.4 Harm reduction (injecting drug use)	
<p>a. Are there national guidelines for prevention of transmission of viral hepatitis and other bloodborne viruses among PWID that address the following:</p> <ul style="list-style-type: none"> • vaccination of PWID against HBV (rapid schedule); • HBV, HCV and HIV testing and counselling; • programmes to provide PWID with sterile needles, low-dead space syringes and other injecting equipment; • peer-to-peer interventions for harm reduction; • OST to treat opioid dependence (and integration of OST services with those providing hepatitis care and treatment)? 	
5.5 Harm reduction (sexual risk)	
<p>a. Is there a national policy for the promotion of safer sex practices, and access to condoms and appropriate lubricant for high-risk groups?</p>	
<p>b. Is HBV vaccination recommended and provided to MSM, sex workers and other at-risk groups?</p>	
<p>c. Is this work supported by targeted information campaigns for at-risk and other vulnerable groups, such as adolescents, sex workers, MSM and PWID?</p>	
<p>d. Is there a national policy and action to eliminate discrimination and gender violence, and to increase access to medical and social services for vulnerable persons?</p>	
5.6 Sanitation, clean water, food safety	
<p>a. Are there national policies and guidance on:</p> <ul style="list-style-type: none"> • water safety; • food hygiene; • safe disposal of clinical and other health-care waste; • safe management of human and other potentially infectious waste? 	
6. Screening and diagnostic testing	
<p>a. Are there national guidelines for screening, diagnostic testing and referral for specialist clinical assessment for HBV and HCV?</p>	
<p>b. Do these guidelines include pre- and post-test information for people who will be and have been tested, and for those who have been diagnosed with viral hepatitis?</p>	
<p>c. Is HBV and HCV serology testing routinely offered to individuals from populations with a high prevalence or who have a history of risk exposure/behaviour? These include:</p> <ul style="list-style-type: none"> • children born to mothers infected with HBV or HCV; • people who received medical/dental interventions in health-care settings where infection control practices are suboptimal (including countries with a high prevalence of HBV and HCV); • people who received transfusions of blood/blood products before screening was initiated, or in countries where screening is not routinely performed; • PWID; • people who have had tattoos, body piercings or scarification in settings where infection control practices are suboptimal; • people with HIV infection; • people who use or have used intranasal drugs; • prisoners and previously incarcerated persons; • sex workers; • indigenous people; • migrants; • military personnel; • health-care workers; • other (please specify). 	

Assessment area	Yes/No/Not applicable and additional info.
d. Which health-, social-care and other facilities (e.g. prisons) offer affordable and confidential HBV and HCV testing?	
e. What percentage of the population has access to affordable and confidential screening services?	
f. Is there a national policy of screening pregnant women for HBV? If yes, are pregnant women routinely tested for the following antigens: <ul style="list-style-type: none"> • HBsAg • Hepatitis B e antigen (HBeAg)? 	
g. Are pregnant women with active HBV or HCV infection routinely referred to specialist care?	
7. Clinical care and treatment	
a. Are there national guidelines for the assessment and treatment of: <ul style="list-style-type: none"> • acute hepatitis; • chronic hepatitis; • cirrhosis; • liver cancer? If yes, do they address issues relating to the following: <ul style="list-style-type: none"> • assessment of disease severity; • risk of disease progression to cirrhosis and primary liver cancer; • assessment and management of comorbidities and coinfections; • assessment for antiviral treatment, including precautions and contraindications, consideration of special groups (e.g. children, persons coinfecting with TB and other bloodborne viruses, persons with renal impairment or advanced liver disease); • treatment, including monitoring response to therapy, management of adverse effects, goals and end-points of therapy, stopping rules? 	
b. Is there a national strategy for monitoring resistance to antiviral treatment?	
c. What mechanisms are there for ensuring a secure supply of affordable therapeutic agents for the treatment of chronic HBV and HCV?	
d. What are the financing arrangements for the treatment of chronic HBV and HCV? <ul style="list-style-type: none"> • Funded by the government, free of charge for all patients • Funded by public insurance schemes • Funded by private insurance schemes • Funded as out of pocket expenses by patients. 	
e. What drugs are available in the country for treating <ul style="list-style-type: none"> • chronic hepatitis B, and • chronic hepatitis C? 	
f. Which cadres of health professionals are permitted to prescribe drugs to treat chronic hepatitis?	
g. How many of these health professionals (mentioned in item “7f” above) are practising in the country?	
8. Monitoring and evaluation	
a. Is there a monitoring and evaluation framework for the national viral hepatitis plan?	
b. Are arrangements in place for reviewing and updating the plan and programme (both mid-term and end-of-term)?	

ANNEX 5.

CHECKLIST FOR INITIATING OR SCALING UP HEPATITIS TREATMENT SERVICES

Communication, leadership and advocacy	Check if present	Comments
1. There is a person responsible for developing or updating national guidelines or protocols for patient management and monitoring.	<input type="checkbox"/>	
2. There is a person responsible for developing training materials for health-care workers.	<input type="checkbox"/>	
3. There is a plan to communicate the service scale-up recommendations to <ol style="list-style-type: none"> health-care facilities, including public, not-for-profit and private institutions, health-care workers, other relevant stakeholders, such as people with chronic hepatitis. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
4. There is a person responsible for advocacy with stakeholders, such as political leaders, health personnel and the mass media.	<input type="checkbox"/>	
Staffing and human resources		
5. The number of additional health-care workers needed to implement the scaling up of services is calculated.	<input type="checkbox"/>	
6. It is identified which cadres of health-care workers (physicians, health officers, nurses, midwives, community health workers, laboratory assistants, etc.) are needed.	<input type="checkbox"/>	
7. How these cadres of health-care workers can be recruited is identified.	<input type="checkbox"/>	
8. Task-shifting is being considered as a strategy to optimize available human resources for health and expanding service delivery.	<input type="checkbox"/>	
9. Training needs for various cadres of health-care providers are assessed.	<input type="checkbox"/>	
10. Capacity-building plans are in place, including how training will be delivered and paid for.	<input type="checkbox"/>	
Drugs and supplies		
11. Systems are in place for forecasting treatment needs.	<input type="checkbox"/>	
12. Systems are in place for procuring recommended drugs and other commodities at the best possible prices.	<input type="checkbox"/>	
13. The patent situation within the country is identified for globally available treatment options.	<input type="checkbox"/>	

Drugs and supplies (continued)	Check if present	Comments
14. There is a transition plan to phase out suboptimal medicines.	<input type="checkbox"/>	
15. Supply management systems are strengthened to manage the increased demand for diagnostics and medicines.	<input type="checkbox"/>	
16. A regulatory process is in place to approve and register medicines and diagnostics in a timely manner.	<input type="checkbox"/>	
17. Laboratory quality control and external quality assurance systems are in place and fully functional.	<input type="checkbox"/>	
18. National laws allow for the purchase and importation of all necessary commodities.	<input type="checkbox"/>	
System organization		
19. Linkages and referral systems between testing and treatment services are adequate.	<input type="checkbox"/>	
20. Services are integrated and/or decentralized to support the implementation of recommendations for scaling up.	<input type="checkbox"/>	
21. Treatment access plans are developed in consultation with managers of other relevant programmes (e.g. HIV, TB, maternal and child health, harm reduction).	<input type="checkbox"/>	
22. Strategies at the policy and service delivery levels are in place to address possible disparities in access to care and treatment.	<input type="checkbox"/>	
23. Interventions are in place to promote and reinforce adherence to treatment and retention in care.	<input type="checkbox"/>	

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Manual for the development and assessment of national viral hepatitis plans: a provisional document

As WHO's work in the area of hepatitis expanded, countries began requesting guidance for devising national hepatitis plans. Since a comprehensive response to viral hepatitis cuts across many areas of work, it was important to pull together all relevant WHO guidance for ease of reference. This manual contains references to the currently existing WHO documents, both specific and relevant to the global hepatitis response.

The purpose of this manual is to provide guidance to public health professionals tasked with managing a response to viral hepatitis. As every country's needs are different with respect to its epidemiology and the current level of response, people would use this manual in different ways. However, this manual is intended to help think more comprehensively about the hepatitis response in a country; to provide a step-by-step approach to setting up a national hepatitis plan and/or programme; to propose a governance structure that can be adapted according to needs; and to propose the outline of a national hepatitis plan.

Feedback and suggestions for improvement may be sent to: hepatitis@who.int.

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