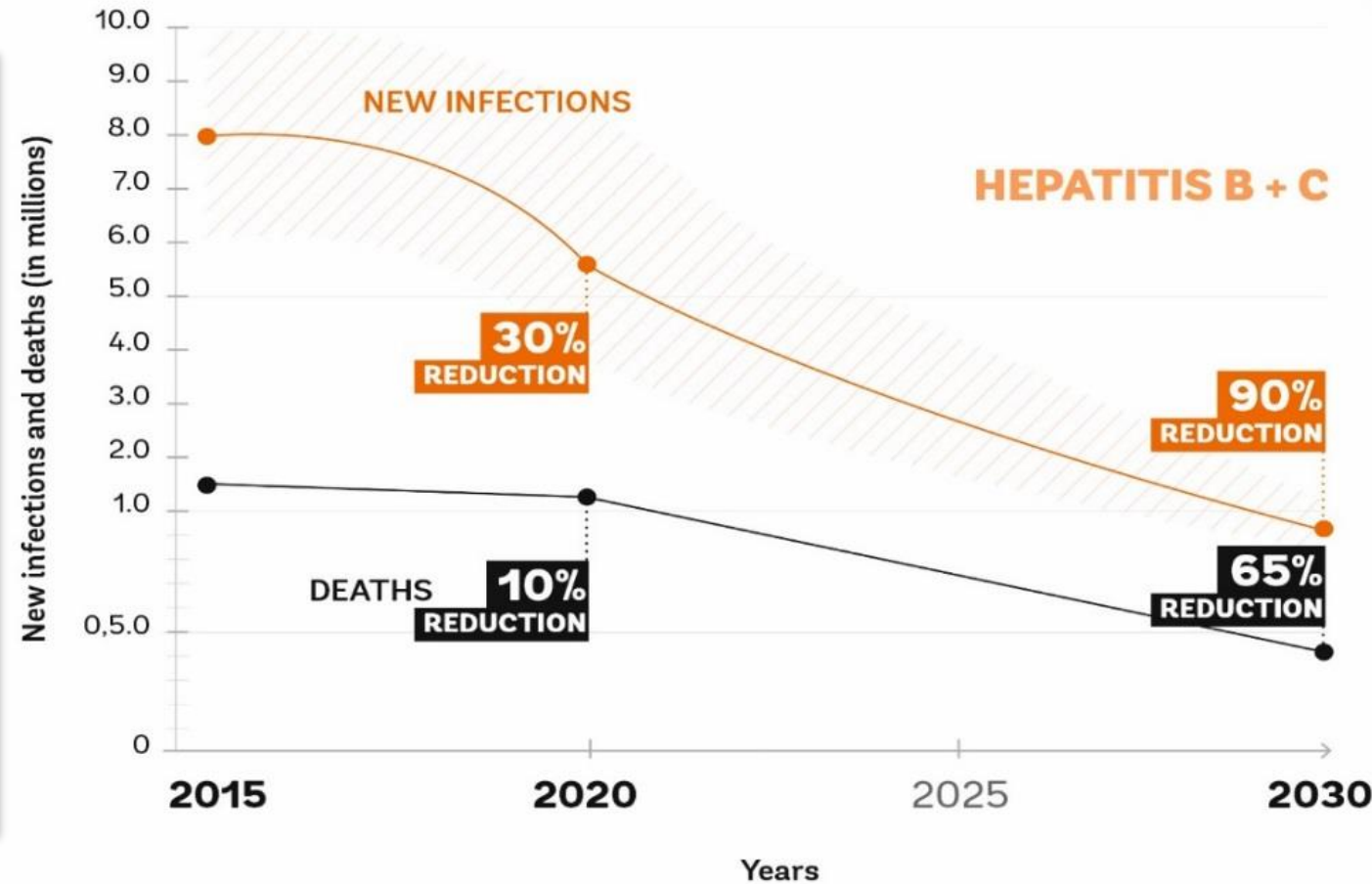
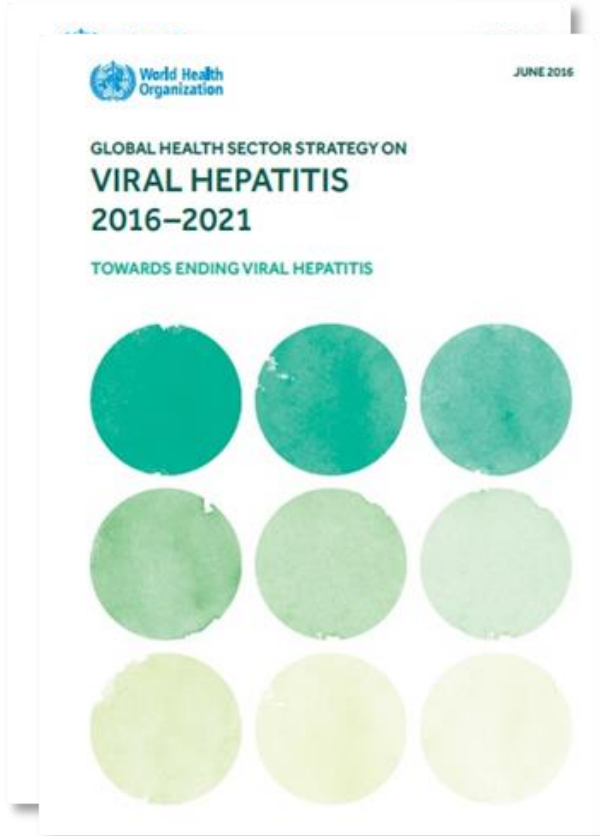


DARWIN EU in the context of infectious diseases and health emergencies

Erika Duffell, Principal Expert Hepatitis, European Centre for Disease Prevention and Control

**Multi-stakeholder workshop on Real World Data (RWD) quality and experience in use of Real World Evidence (RWE) for regulatory decision-making
27th June 2023**

The hepatitis elimination agenda: elimination of viral hepatitis as a public health threat by 2030



The framework for monitoring viral hepatitis in the EU/EEA



Indicators included in the European monitoring system

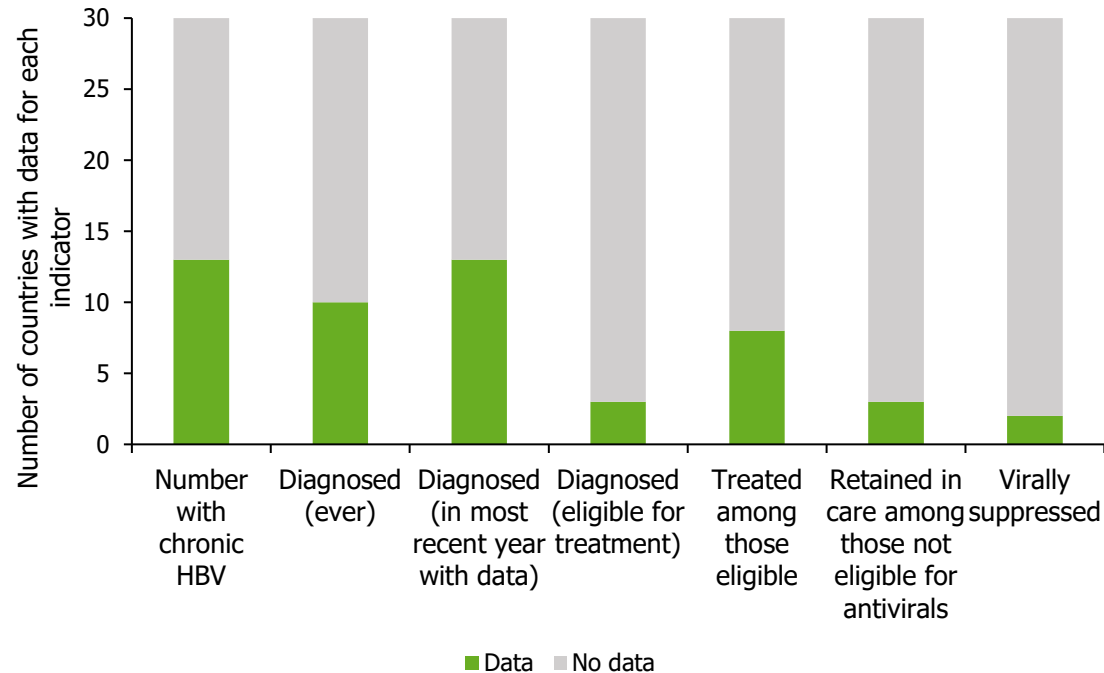


EPIDEMIC CONTEXT
PREVALENCE/MORTALITY
PREVENTION
VACCINATION
PREVENTION OF MOTHER TO CHILD TRANSMISSION
INFECTION PREVENTION AND CONTROL IN HEALTHCARE SETTINGS
BLOOD SAFETY
PREVENTION OF SEXUAL TRANSMISSION
PREVENTION AMONG PEOPLE WHO INJECT DRUGS
THE CARE CASCADE
TESTING
TREATMENT
IMPACT
INCIDENCE
MORTALITY

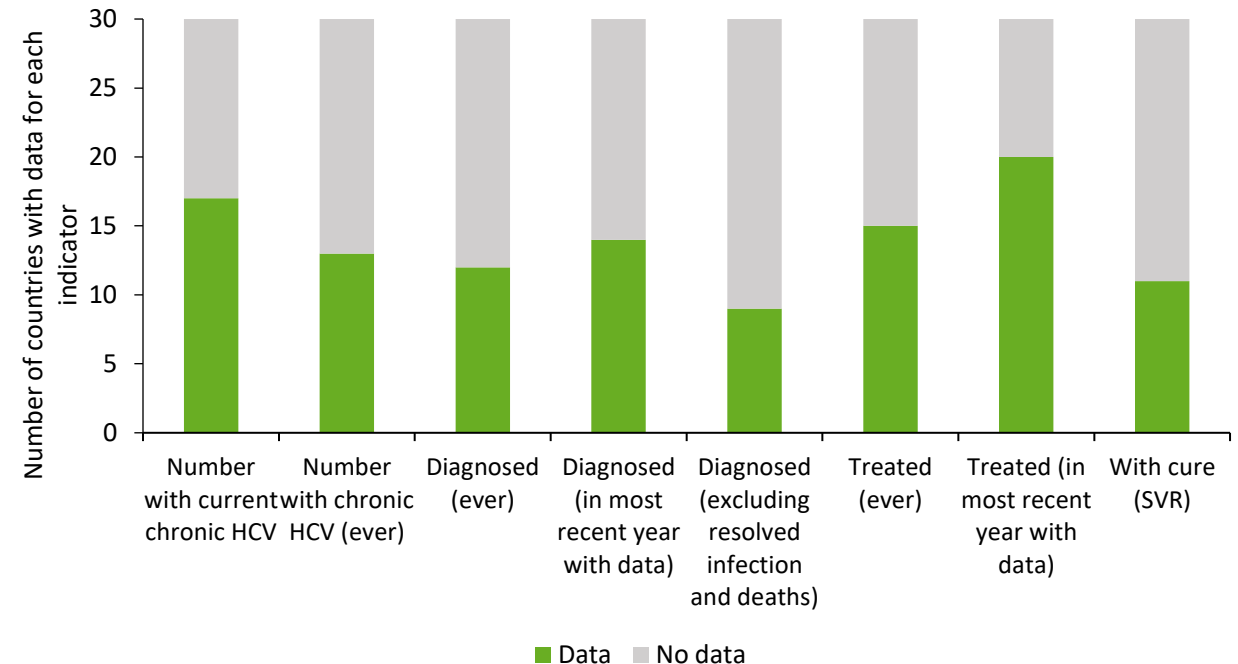
Availability of national-level data along the continuum of care for hepatitis B and C, in EU/EEA countries, 2020



Hepatitis B



Hepatitis C



Major gaps in availability of data, especially for hepatitis B

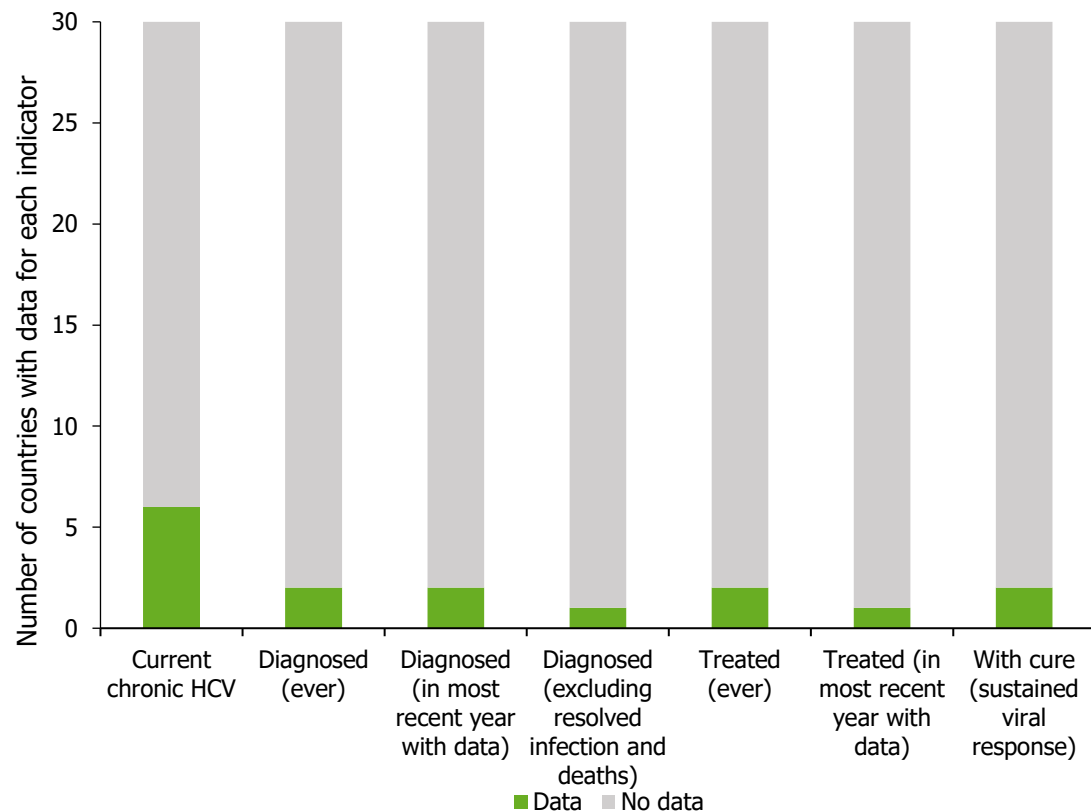
- Reduction since 2017/18 data collection round

Variation in data quality and age

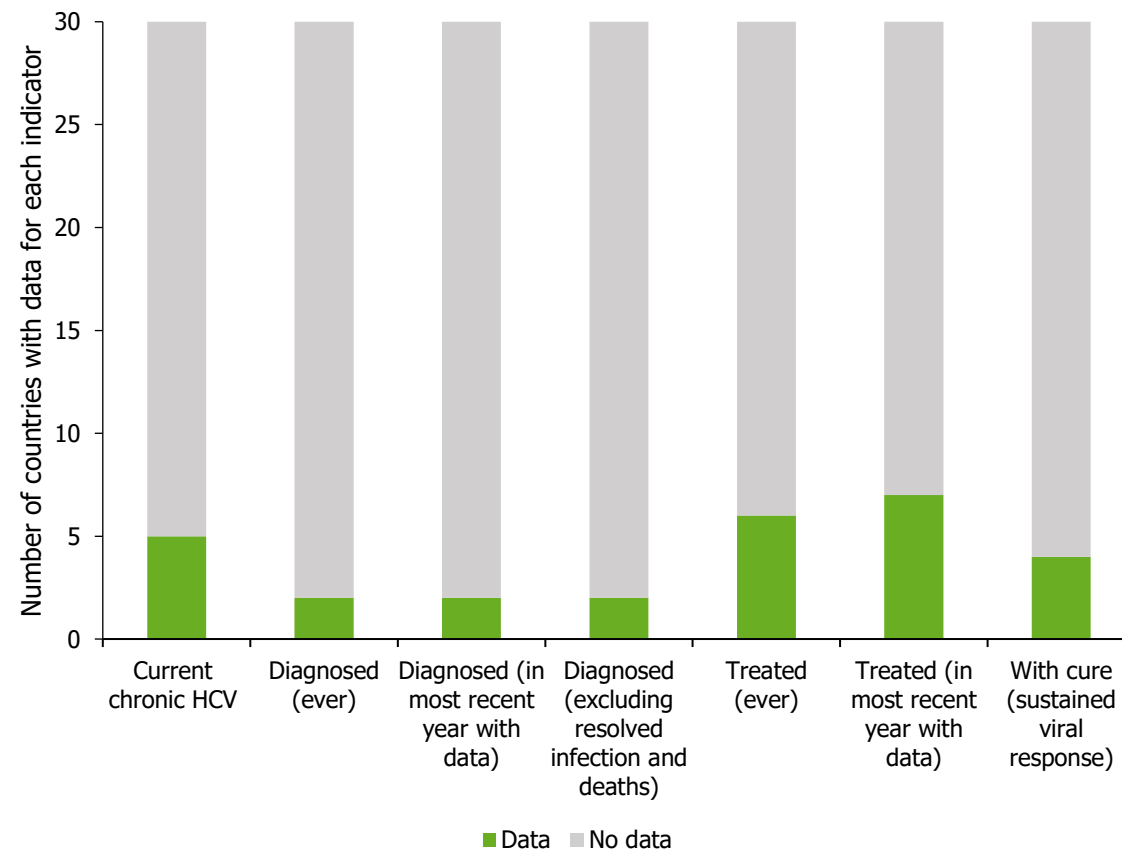
- Data collected ranged from 2001 - 2020

Continuum of care for hepatitis C for key populations

People who inject drugs



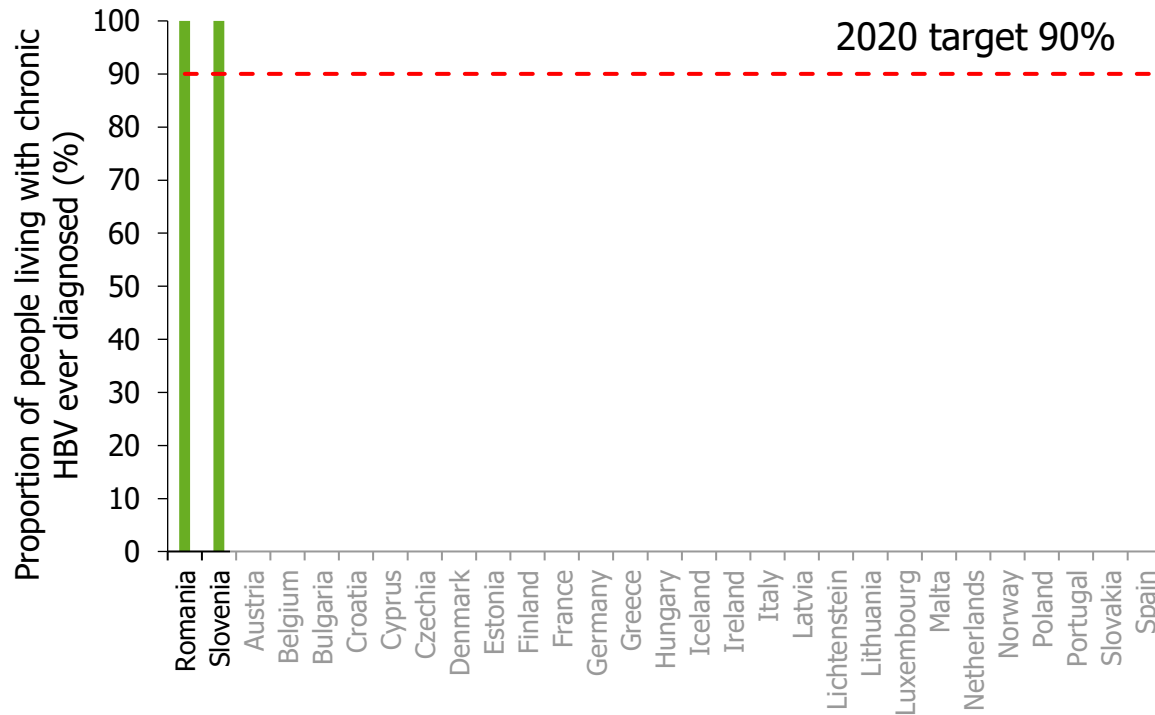
People in prisons



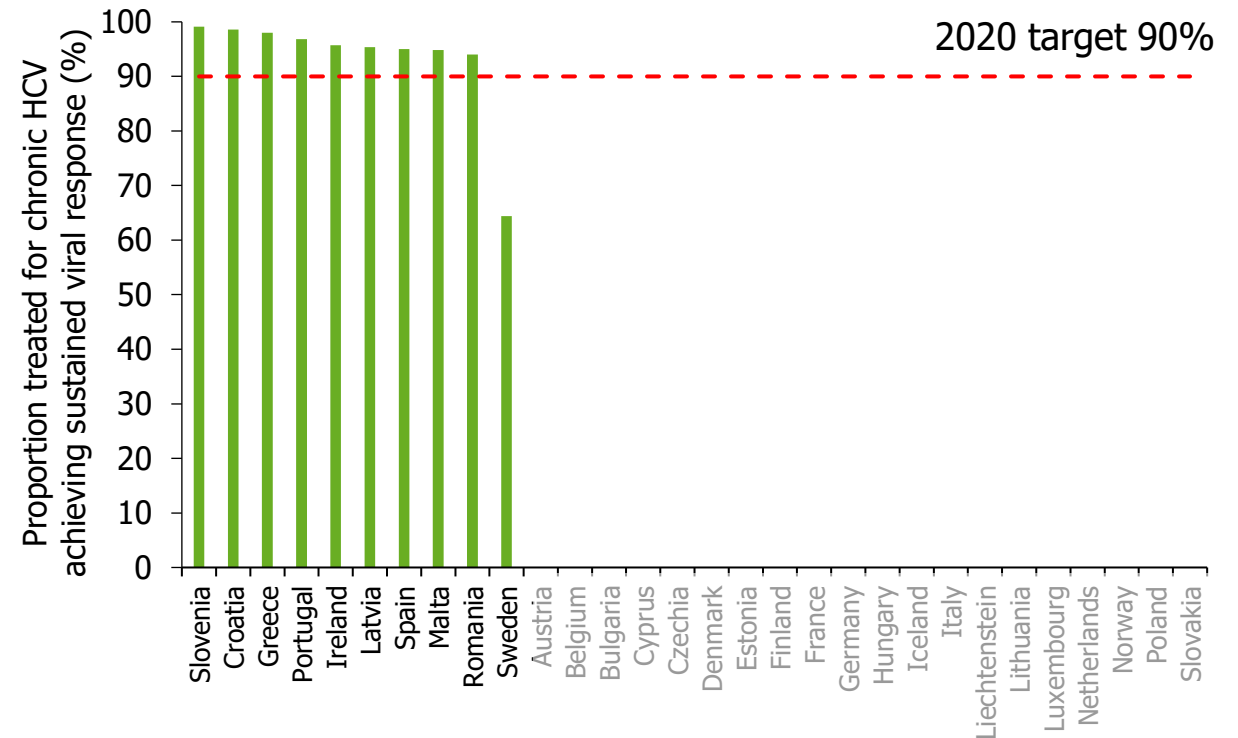
Data availability for key populations was very limited

Proportion HBV and HCV cases achieving viral suppression/SVR of those receiving antiviral treatment during 2020*

Hepatitis B



Hepatitis C



* Among those with documented treatment outcome

Current sources of treatment data

1. National data collected on biennial basis from ECDC Hepatitis Focal Points through the **EU Hepatitis Monitoring System**
2. **European Surveillance of Antimicrobial consumption Network** (ESAC-Net) data on antivirals
3. Data collected from sentinel sites in clinical centres through the **EU Hepatitis Sentinel Surveillance System**

Limitations of current sources of treatment data

1. EU Hepatitis monitoring system

- Data lacking from many countries and often not up to date
- Limited data on key populations
- Data from a variety of different sources of varying quality

2. European Surveillance of Antimicrobial Consumption Network data

- Data expressed in defined daily doses (DDDs) which does not equate easily to number of individuals on treatment/treated

3. EU Hepatitis Sentinel Surveillance System

- System currently in development phase and will take time to yield results

Potential use for treatment data from DARWIN EU

Type data	Key applications
National data on treatment hepatitis B and C	• Measurement of national progress towards elimination targets • For HCV adjustment of national prevalence estimates for cases who are treated and cured
Local data on treatment hepatitis B and C	• Measurement of local progress towards elimination targets
Data on treatment for different settings	• Assessment of gaps in service provision and of progress towards decentralisation
Data on treatment for different population groups	• Assessment of inequities in service provision