An Introduction to Access to Diagnostics

14:00-14:45 BST
17 June
Chair:
Dr Greg Martin, Specialist Registrar, Public Health Medicine and Editor-in-Chief of *Globalization and Health*

@drgregmartin

Speakers:
Raquel Peck, CEO, World Hepatitis Alliance,

@RaqPeck

Anita Sands, Prequalification Team, Diagnostics, World Health Organisation

Jilian Sacks, HCV Scientist, Lab Services Team, Clinton Health Access Initiative

Elena Ivanova, Scientific Officer, HCV & TB, FIND
Viral Hepatitis B and C

- 400m people affected
- 7th global leading cause of death
- Largely neglected until recently
- Needs intensified and expanded response now (scale up of interventions incl. testing)

69th WHA: 194 govts commit to eliminating viral hepatitis by 2030
Access to diagnostics - challenges

• Around 5% diagnosed (in low-income settings, <1% are likely to be aware of their diagnosis)

ELIMINATION GOAL = 90% diagnosed by 2030

• Facilities or services for hepatitis testing are few
• Hepatitis surveillance programmes to inform the epidemiological situation are weak or non-existent
• Laboratory capacity is poor
• Diagnostic assays and algorithms are costly and complex
• There is limited patient and community engagement
WHO guidance: Guidelines for HBV and HCV testing
Prequalification of in vitro diagnostics

Anita Sands
Prequalification Team – Diagnostics
Essential Medicines and Health Products
WHO guidelines for HBV and HCV testing

- New WHO guidelines for countries - *in draft*

- Aim: to expand access to testing for hepatitis B and C
  - Who to test
  - How to test
  - When to start treatment
  - Was the treatment effective

- Where: in laboratories and at point-of-care
Testing strategies for HCV

● Step 1: Detect HCV exposure
  – Presence of antibodies to HCV (the body's reaction to seeing HCV)
  – May be past infection that is resolved, or active infection that requires treatment

● Step 2: Diagnose active HCV infection that requires antiviral treatment
  – Presence of the hepatitis C virus itself

● Step 3: Confirm that treatment worked – a cure!
  – Absence of the hepatitis C virus itself
Testing strategies for HBV

- Step 1: Detect chronic HBV infection
  - Presence of surface antigen of hepatitis B virus (HBsAg)
  - Why not look for antibodies to HBV – because of immunization!

- Step 2: Determine if antiviral treatment is needed
  - Presence of hepatitis B virus itself and functionality of liver

- Step 3: Confirm that treatment worked
  - Suppression of the hepatitis B virus itself to undetectable and functionality of liver
Where does WHO prequalification fit?

1. Testing strategy
2. Product selection
3. National registration
4. Procurement of IVDs
5. Quality assurance
6. Training/proficiency
7. Change notification

Post-market surveillance
Measuring performance of diagnostics

- Sensitivity - the ability of the test to identify a person as positive who is truly positive
  - if a test has poor sensitivity, it will have many false negative results

- Specificity - the ability of the test to identify a person as negative who is truly negative
  - If a test has poor specificity, it will have many false positive results

- Stability – how long is the test stable and at what temperature
What is WHO prequalification?

- WHO PQ independently reviews **safety, quality, performance** of diagnostics for hepatitis C and B
- WHO PQ is similar to regulatory approval, it can be used in settings where regulation of diagnostics is poorly implemented
- WHO PQ is also used by UN agencies and governments to make procurement decisions
WHO prequalification process

Pre-submission form

Priority diagnostic

Yes

No

Dossier review

Site inspection

Laboratory evaluation

Prequalification decision. UN procurement eligibility.
What happens after WHO PQ listing

- Joint UN tender for agreed price per test/per instrument
  - Countries use UN price to negotiate their own prices, usually based on the expected volumes of tests procured

- WHO makes sure the manufacturer conducts post-market surveillance, including dealing with complaints and vigilance

- WHO is notified if any changes are made to the product or the manufacturing site = partial re-assessment
WHA Webinar: An Introduction to Access to HCV Diagnostics

17 June 2016

Jilian A. Sacks, Ph.D.
To facilitate “Access,” health systems need to provide:

- The right **products**
- At the right **price**
- In the right **quantities**
- In the right **places**
- At the right **time**

CHAI’s major access programs include HIV, TB, Malaria, Maternal and Child Health…and most recently Viral hepatitis
CHAI’s approach to diagnostics access addresses both demand and supply-side challenges.

**Demand-side needs**

Products that meet the **needs** of resource limited settings in terms of quality, efficacy, useability and price.

- **Insight**

  - Volumes

**Supply-side needs**

A reliable, transparent, **marketplace** for commodities that provide ongoing growth opportunities.
Key challenge: imbalance in where diagnostic tests are performed and where health care is accessed

- Conventional technologies
- Simple tests
- Point of care (POC) or near POC tests
Rates of HCV diagnosis are much lower in LMIC/UMIC compared to HIC and generally correlate with treatment rates.

Dore GJ et al. (2014) Journal of Viral Hepatitis, 21 (Suppl. 1): 1–4
CHAI aims to catalyze HCV treatment scale-up in LMIC by demonstrating the feasibility of public sector programs in 7 countries. Goal = Cure patients and generate evidence for scale-up.
CHAI’s country support for HCV addresses major in-country bottlenecks

- Training health care workers in HCV prevention, screening, diagnosis and treatment
- Developing M&E tools that integrate into existing country systems
- Mapping current treatment and laboratory capacity
- Developing plans to leverage existing or build new networks for screening, diagnosis and treatment
- Supporting country test selection
- Promote uptake of novel technologies
- Encourage and expedite national registration processes
- Identification of procurement channels and promoting order placement
- Commodity forecasting

- Developing treatment guidelines based around simplified testing and treatment
- Developing realistic costed operational plans for governments to launch programs
All oral anti-HCV treatment enables simpler and fewer diagnostic requirements, which ultimately promotes increased access to care.

- Fewer lab tests needed to initiate treatment
- Simpler decisions on who, how, and how long to treat
- Less toxicity so no need for complex laboratory monitoring during treatment
- Fewer patients lost to follow up
- De-specialization of care
- Less laboratory system burden

Feasible for LMIC to increase access to treatment!
What can members of WHA do to promote access to HCV Diagnosis?

• Demand diagnosis of HCV infection, because curative treatment is available!

• Activism and Advocacy
  - Demand availability of simple, affordable, high quality screening and diagnostic tests
  - Demand clear and appropriate linkage to diagnosis and care
  - Health Systems should integrate diagnosis and management of viral hepatitis into existent programs, rather than create new vertical programs
  - Health care workers: demand screening, diagnosis and treatment availability in their health facility
  - The public: know your status and demand access to affordable treatment!
DISCUSSION / QUESTIONS AND ANSWERS

How to ask a question

You can submit a question by typing it in the ‘Questions’ section in your meeting control panel.
WHA Webinar: An Introduction to Access to Diagnostics

FIND HCV programme overview

Elena Ivanova
Scientific Officer for HCV & TB

Elena.Ivanova@finddx.org
17 June 2016
Turning complex diagnostic challenges into simple solutions to transform lives

- Dynamic needs definition
- S4S: Support programme for manufacturers

Guide use & policy
- Clinical trials
- WHO evidence & guideline development

Accelerate access
- National policy
- Rollout planning
- Gap analysis and solutions
- QA tools and strategies

Shape the agenda
- Impact of diagnostics
- Diagnostic ecosystem changes
- Emerging diagnostics topics
From strategy to reality

FIND programmes:

- Tuberculosis
- Malaria
- Neglected Tropical Diseases
- Hepatitis C
- HIV

Cross-cutting themes:

- Outbreak management and surveillance
- Syndromic Disease Management and AMR
- Electronic Health and Connectivity

Working with 185 partners globally

- Universities and Research Institutes: 44 partners
- Industry: 46 partners
- Government/multilateral agencies: 35 partners
- Advocacy: 2 partners
- Clinical Trial Sites: 32 partners
- Implementing partners: 26 partners
FIND’s strategy is focused on addressing challenges around diagnosis to meet global goals

**Long-term vision**

Enable a world free of Hepatitis C

**5-year goal**

To support the Global Hepatitis Programme in its goals: to reduce transmission, reduce the morbidity and mortality, and reduce the socio-economic impact of viral hepatitis at individual, community and population levels

**Strategy objectives**

1. Enable affordable and fit-for-purpose diagnosis
2. Enable access to diagnosis
3. Support the prevention of infection
4. Demonstrate the need and benefit of interventions for HCV
HCV diagnostics can be transformed to become available for everybody

I. Current diagnostic continuum:

1. Screening
   - Serological RDTs

2. Confirmatory testing
   - HCV RNA
   - HCV-cAg

3. Genotyping
   - Line probe RT PCR

4. Fibrosis staging
   - Blood biomarkers
   - Imaging

5. Prognostic markers
   - IL-28B

6. Treatment monitoring
   - HCV RNA

7. Test of cure
   - HCV RNA

One-step diagnostics: Low-cost virologic test

Not needed with DAA therapy

II. Mid-term diagnostic continuum (with DAA therapy):

1. Virologic test
   - HCV RNA
   - HCV-cAg

2. Fibrosis staging
   - Blood biomarkers
   - Imaging

3. Test of cure
   - HCV RNA
   - HCV-cAg

Low-cost virologic test
One vs two step diagnostic strategy (depending on prevalence, cost, ease-of-use, LTFU etc)

**TWO-STEP DIAGNOSIS**

- RDT for HCV antibodies
  - Screening: high sensitivity, low specificity
- HCV virological test
  - Confirmatory testing: centralized laboratory

**ONE-STEP DIAGNOSIS**

- HCV virological test
  - POC test: high sensitivity, high specificity

One step solution: point-of-care HCV RNA test and point-of-care HCV core antigen test
Principal of FIND development work

Prioritization & development of the target product profiles

Landscaping & opportunity description & partner building

Drive project to success: inform R&D; accelerate trial pathway; country rollout
DISCUSSION / QUESTIONS AND ANSWERS

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THANK YOU FOR ATTENDING

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