

第10回肝炎対策推進協議会

平成25年7月25日

WHO HCV Guideline Meeting 報告

*WHO Standard Guidelines for Screening, Care and Chronic
Hepatitis C Virus Infection
at World Council of Churches, Geneva, Switzerland*

(独) 国立国際医療研究センター
肝炎・免疫研究センター
溝上雅史



MM

PICO = Population Intervention Comparative Outcome



World Health
Organization

Second meeting of the Guideline Development Group to develop
WHO Standard Guidelines for Screening, Care and Treatment of
Chronic Hepatitis C Virus Infection

24 - 26 June 2013, Ecumenical Center, Geneva, Switzerland

Co-Chairs: Dr. Bryce Smith, Division of Viral Hepatitis, Centers for Disease Control and
Prevention, Atlanta USA

Dr. Yngve Falck-Ytter, Case Western Reserve University, Cleveland, USA

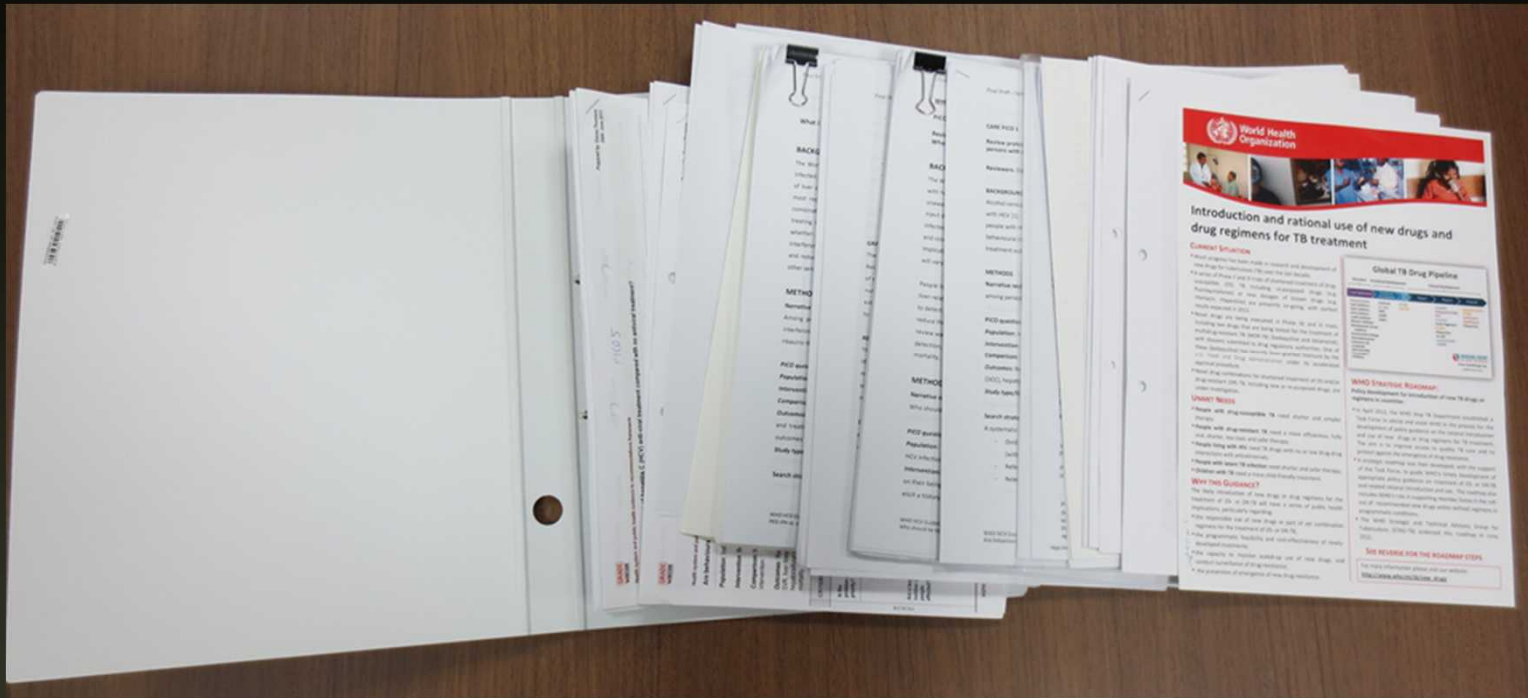
WHO Technical Lead: Dr. Stefan Wiktor, Global Hepatitis Programme, WHO-HQ, Geneva, Switzerland

Rapporteur: Dr. Emma Thomson, University of Glasgow, Glasgow, Scotland



| | | |
|-------|---------------------------------------|-------------------------|
| 6月22日 | 12:00 ~ 18:00 | NCGM 市民公開講座 |
| 6月24日 | 01:00 08:20 09:00 ~ 17:00 | 羽田発 Geneva着 会議一日目 |
| 6月25日 | 09:00 ~ 17:00 | 会議二日目 |
| 6月26日 | 09:00 ~ 17:30 19:00 | 会議三日目 Geneve発 |
| 6月27日 | 15:00 18:00 | 成田着 日本医大 |

送りつけられた約100ページの書類



World Council of Churches, WHO HQ, Geneva, Switzerland



Guidelines Development Group



Guidelines Development Group 22名 (13力国)

WHO Temporary Advisors 9名 (4力国)

WHO Regional Office 1名 (WHO EURO)

WHO HQ Secretariat 15名 (内6名*)

Member of the WHO steering committee for the development of
guideline for the screening, care and treatment of HCV infection

WHO HQ Secretariat Core member 6名

Member of the WHO steering committee for the development of guideline for the screening, care and treatment of HCV infection

Dr. Nicolas Clark
Management of Substance Abuse

Dr. Philippa Easterbrook
HIV Treatment and Care

Mr. Tim Nguyen
Global Hepatitis Programme

Ms. Anita Sands
Essential Medicines & Pharmaceutical Politics

Dr. Marco Vitoria
HIV Treatment and Care

 **Dr. Stefan Wiktor**
Global Hepatitis Programme

Meeting Schedule

Day 1: Monday, 24 June 2013

| Time | Agenda item |
|-------|---|
| 09:00 | Welcome and opening remarks Agenda overview, background of GHP, and introduction of chairpersons |
| 09:30 | Official welcome and charge to participants: Director, Department of Pandemic and Epidemic Diseases |
| 9:45 | Self-introduction of participants |
| 10:15 | Review of Declarations of interest Logistics for group dinner |
| 10:30 | <i>Refreshment Break</i> |
| 11:00 | Overview of WHO Guidelines development process |
| 11:15 | Turning evidence into recommendations |
| 11:45 | Discussion |
| 12:30 | <i>Lunch Break</i> |
| 13:30 | PICO-3: Are behavioural interventions effective at reducing alcohol use among person with chronic HCV infection? - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 15:00 | <i>Refreshment Break</i> |
| 15:30 | Presentation: Cost-effectiveness model of early vs. late treatment of HCV based on Egypt data |
| 16:00 | Discussion |
| 16:15 | PICO-2: When should HCV RNA tests be undertaken to detect viraemia - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 17:45 | Adjourn |
| 19:00 | Group Dinner UN Beach Club, Chaussee de Lausanne |

Day 2: Tuesday, 25 June 2013

| Time | Agenda item |
|-------|--|
| 09:00 | Welcome and housekeeping issues |
| 9:15 | PICO-4 How to assess stage of fibrosis - Presentation: effectiveness and cost of non-invasive fibrosis assessments - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 10:30 | <i>Refreshment Break</i> |
| 11:00 | PICO-1 HCV antibody testing: Targeted vs. symptom based screening - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 12:30 | <i>Lunch Break</i> |
| 13:30 | Presentation: Hepatitis-related recommendations in the updated WHO Consolidated HIV Treatment Guidelines |
| 13:35 | Discussion |
| 13:45 | PICO-5 HCV therapy: Anti-viral therapy versus no treatment - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 15:00 | <i>Refreshment Break</i> |
| 15:30 | Presentation – cost-effectiveness of hepatitis C treatment in injecting drug users |
| 15:45 | PICO-6 HCV therapy: Pegylated interferon vs standard interferon - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 17:30 | Adjourn |

Day 3: Wednesday, 26 June 2013

| Time | Agenda item |
|-------------|---|
| 09:00 | Welcome and housekeeping issues |
| 09:15 | Review of existing recommendations regarding frequency of laboratory monitoring to assess response to and toxicity of HCV therapy |
| 09:45 | PICO-7 HCV therapy: Direct-acting anti-viral therapy versus pegylated interferon treatment - presentation of evidence summary: Burnet Institute - review of decision-making table: co-Chairs - Discussion and formulation of recommendation: All |
| 10:30 | <i>Refreshment Break</i> |
| 11:00 | Continuation of discussion and review of HCV treatment recommendations |
| 12:30 | <i>Lunch Break</i> |
| 13:30 | Review of all draft recommendations |
| 15:00 | <i>Refreshment Break</i> |
| 15:30-15:45 | Sharing best practice: WHO interim guidance on the use of bedaquiline to treat MDR-TB |
| 15:45 | - Discussion of process to update recommendations when new medications are approved - Next steps |
| 17:00 | Closure of the meeting |

Lunchの間もDiscussion



PICO = Population Intervention Comparative Outcome

人口 介入 比較 結果

PICO = 集団介入による対費用効果

PICO-1: HCV antibody testing: Targeted vs. symptom based screening

PICO-2: When should HCV RNA tests be undertaken to detect viraemia

PICO-3: Are behavioural interventions effective are reducing alcohol use among person with chronic HCV infection?

PICO-4: How to assess stage of fibrosis

PICO-5: HCV therapy: Anti-viral therapy vs. no treatment

PICO-6: HCV therapy: Peggylated interferon vs. standard interferon

PICO-7: HCV therapy: Direct-acting anti-viral therapy vs. pegylated interferon treatment



PICO QUESTIONS for the WHO Hepatitis C Treatment Guidelines Evidence Reviews

Testing PICO question 1:

Population: People with a history of behaviors or exposures that place them at increased risk of hepatitis C infection.

Intervention: Targeted HCV antibody testing. “Targeted” means testing of individuals based either on their being part of a defined risk group (e.g. injecting drug user, person with HIV) or through questions to elicit a history of HCV-risk behaviors (see CDC document [need to get reference]).

Comparison: Symptomatic HCV antibody testing. “Symptomatic”, means antibody testing based on the presence of liver-related signs or symptoms •

Outcomes: Number of referrals to care/treatment for HCV, number of cases of HCV transmission, HCV disease progression (liver cirrhosis, HCC, DCC), SVR, quality of life, all-cause mortality.

Study type/limits: Experimental or observational studies published between 1994 and the present.

Testing PICO question 2:

Population: People who are HCV antibody positive

Intervention: HCV RNA testing at the time of receipt of an positive HCV antibody result

Comparison: HCV RNA test in the context of HCV care as part of assessment for HCV therapy

Outcomes: Number of cases of HCV transmission, number achieving sustained virological response to HCV treatment (SVR), number of cases of decompensated liver disease/hepatocellular carcinoma/liver-related deaths/all-cause mortality, quality of life

Study type/limits: Experimental or observational studies published between 1994 and the present.

Care PICO question 1 :

Population: Individuals with chronic HCV infection

Intervention: Behavioral alcohol-reduction interventions

Comparison: No behavioral alcohol-reduction intervention

Outcome : Reduction or cessation of alcohol intake, SVR, liver fibrosis, decompensated liver, cirrhosis, hepatocellular carcinoma, quality of life, All-cause mortality –since LR mortality isn't always accurately identified.

Study type/limits: Experimental studies (human) published between 1994 and the present

PICO 1のTestingを訳してみると

Testing PICO question 1:

Population: People with a history of behaviors or exposures that place them at increased risk of hepatitis C infection.

Intervention: Targeted HCV antibody testing. “Targeted” means testing of individuals based either on their being part of a defined a risk group (e.g. injecting drug user, person with HIV) or through questions to elicit a history of HCV-risk behaviors (see CDC document [need to get reference]).

Comparison: Symptomatic HCV antibody testing. “Symptomatic”, means antibody testing based on the presence of liver-related signs or symptoms.

Outcomes: Number of referrals to care/treatment for HCV, number of cases of HCV transmission, HCV disease progression (liver cirrhosis, HCC, DCC), SVR, quality of life, all-cause mortality.

Study type/limits: Experimental or observational studies published between 1994 and the present.

対象： C型肝炎感染リスクのある行動、あるいは、曝露歴のある人達

介入： 目標を定めたHCV抗体検査。「目標を定めた」とは、HCV感染可能性の高いリスクグループ（例えば注射している麻薬常用者、HIVを持っている人）を定義し、または、質問を通してHCV-リスク行動の歴史を引き出す（CDCドキュメントを見る[参考文献を入れる必要があります]）

比較： 症状のある人達のHCV抗体検査。「症状のある」とは、肝臓 - 関連した徴候あるいは症状のある人達との比較

結果： HCVのケア/治療した患者数、HCV感染した患者数、HCVで肝硬変、肝がんに行なった数、完治した人の数、QOLの改善率、すべての死亡した人の数を照会

HCV抗体の検査を勧めるのは良いが、確認試験は出来ない

子供に対する治療文献のsummaryとその評価

Table 2: Indirect evidence from systematic reviews of HCV treatment in Children and PWID

| Study, methods | No of studies (numbers and population) | Intervention Outcomes | Summary of primary findings (95% confidence interval) | Review conclusions |
|---|---|--|--|---|
| Druyts <i>et al.</i> (2013) Systematic review Cochrane/PRISMA compliant | 1 RCT, 7 non-randomised trials (n=438, 3-18 year children/adolescents) | PEG+RBV for all patients Measured SVR, treatment discontinuation due to AE | Among children: <ul style="list-style-type: none"> SVR: 58% (95%CI 53-64) Treatment discontinuation due to AE: 4% (1-7%) | Treatment is effective and safe in treating children and adolescents with HCV |
| Aspinall <i>et al.</i> (2013) Systematic review Cochrane/PRISMA compliant | 6 observational studies (n=314 PWID, 45% active PWID in last month) | PEG+RBV for all patients Measured SVR, adherence, treatment discontinuation (all-cause) | Among PWID: <ul style="list-style-type: none"> SVR 61% (51-72%) Adherence 82% (74-89%) Treatment discontinuation (all-cause, not AE specific) 22% (16-27%) | Treatment among active PWID has a comparable SVR and adherence rates among studies to former or non-PWID. |

Definitions for ratings of the certainty of the evidence (GRADE)**

| Ratings | Definitions | Implications |
|------------------|--|---|
| ⊕⊕⊕⊕ High | This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different* is low. | This evidence provides a very good basis for making a decision about whether to implement the intervention. Impact evaluation and monitoring of the impact are unlikely to be needed if it is implemented. |
| ⊕⊕⊕○ Moderate | This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different* is moderate. | This evidence provides a good basis for making a decision about whether to implement the intervention. Monitoring of the impact is likely to be needed and impact evaluation may be warranted if it is implemented. |
| ⊕⊕○○ Low | This research provides some indication of the likely effect. However, the likelihood that it will be substantially different* is high. | This evidence provides some basis for making a decision about whether to implement the intervention. Impact evaluation is likely to be warranted if it is implemented. |
| ⊕○○○ Very low | This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different* is very high. | This evidence does not provide a good basis for making a decision about whether to implement the intervention. Impact evaluation is very likely to be warranted if it is implemented. |

*Substantially different: large enough difference that it might have an effect on a decision

**The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group began in the year 2000 as an informal collaboration of people with an interest in addressing the shortcomings of present grading systems in health care. The working group has developed a common, sensible and transparent approach to grading quality of evidence and strength of recommendations. Many international organizations have provided input into the development of the approach and have started using it.

Peg-IFN治療のEvidence Levelの評価とその纏め

Evidence profile [title]

Authors: David Hunt, Esther Aspinall, and Hamish Innes

Date: 2013-05-16

Question: What is the effectiveness of PEG-interferon and ribavirin versus standard interferon and ribavirin for chronic HCV treatment

Settings: Individuals with chronic HCV infection

Bibliography: [Citation text]

Table 1: GRADE summary of findings

| Question: Should pegylated interferon and ribavirin vs standard interferon and ribavirin be used for HCV? | | | | | | | | | | | |
|---|--------------------------------------|--------------------------|-------------------------|------------------------|------------------|---|--|---|--------------------------|---|--|
| Quality assessment | | | | | | | Summary of Findings | | | | |
| Participants (studies) Follow up | Risk of bias | Inconsistency | Indirectness | Imprecision | Publication bias | Overall quality of evidence | Study event rates (%) | | Relative effect (95% CI) | Anticipated absolute effects | |
| | | | | | | | With Standard interferon and ribavirin | With Pegylated interferon and ribavirin | | Risk with Standard Interferon and ribavirin | Risk difference with Pegylated Interferon and ribavirin (95% CI) |
| Failure to achieve sustained virological response (CRITICAL OUTCOME) | | | | | | | | | | | |
| 6350 (25 studies) 72 weeks | no serious risk of bias ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | undetected | ⊕⊕⊕⊕ HIGH ¹ | 1889/2858 (66.1%) | 1855/3492 (53.1%) | RR 0.81 (0.76 to 0.86) | 661 per 1000 | 126 fewer per 1000 (from 93 fewer to 159 fewer) |
| Terminated study due to adverse events (CRITICAL OUTCOME) | | | | | | | | | | | |
| 5013 (16 studies) 72 weeks | no serious risk of bias | serious ² | no serious indirectness | no serious imprecision | undetected | ⊕⊕⊕⊖ MODERATE ² due to inconsistency | 264/2231 (11.8%) | 340/2782 (12.2%) | OR 1.01 (0.79 to 1.29) | 118 per 1000 | 1 more per 1000 (from 22 fewer to 29 more) |
| All-cause mortality during study (CRITICAL OUTCOME) | | | | | | | | | | | |
| 1402 (5 studies) 72 weeks | no serious risk of bias | no serious inconsistency | no serious indirectness | serious ³ | undetected | ⊕⊕⊕⊖ MODERATE ³ due to imprecision | 9/701 (1.3%) | 11/701 (1.6%) | OR 1.26 (0.52 to 3.07) | 13 per 1000 | 3 more per 1000 (from 6 fewer to 26 more) |
| Liver-related mortality during study (CRITICAL OUTCOME) | | | | | | | | | | | |
| 533 (2 studies) 72 weeks | no serious risk of bias | no serious inconsistency | no serious indirectness | serious ⁴ | undetected | ⊕⊕⊕⊖ MODERATE ⁴ due to imprecision | 4/268 (1.5%) | 2/265 (0.75%) | OR 0.63 (0.12 to 3.27) | 15 per 1000 | 5 fewer per 1000 (from 13 fewer to 32 more) |
| Hepatic decompensation during study (IMPORTANT OUTCOME) | | | | | | | | | | | |
| 694 | serious ³ | no serious | no serious | serious ⁴ | undetected | ⊕⊕⊖⊖ | 6/346 | 5/348 | OR 0.84 | 17 per 1000 | 3 fewer per 1000 |

ReviewとSummaryは有難いが――

| CRITERIA | JUDGEMENTS | RESEARCH EVIDENCE | ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|---------------------------|---------------------|---------------------------|-----|--|------|-------------------------------------|--|--------------|--------------------------------|--|-----|---------------------|--|----------|---|--|----------|-----------------|--|-------------|---|
| VALUES | <p>How certain is the relative importance of the desirable and undesirable outcomes?</p> <p> <input type="checkbox"/> Important uncertainty or variability <input type="checkbox"/> Possibly important uncertainty or variability <input type="checkbox"/> Probably no important uncertainty or variability <input type="checkbox"/> No important uncertainty or variability <input type="checkbox"/> No known undesirable outcomes </p> | <p><i>The relative importance or values of the main outcomes of interest:</i></p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Relative importance</th> <th>Certainty of the evidence</th> </tr> </thead> <tbody> <tr> <td>SVR</td> <td></td> <td>High</td> </tr> <tr> <td>Decompensated liver cirrhosis (DCC)</td> <td></td> <td>Low-moderate</td> </tr> <tr> <td>Hepatocellular carcinoma (HCC)</td> <td></td> <td>Low</td> </tr> <tr> <td>All-cause mortality</td> <td></td> <td>Moderate</td> </tr> <tr> <td>Adverse events leading to discontinuation</td> <td></td> <td>Moderate</td> </tr> <tr> <td>Quality of life</td> <td></td> <td>No evidence</td> </tr> </tbody> </table> | Outcome | Relative importance | Certainty of the evidence | SVR | | High | Decompensated liver cirrhosis (DCC) | | Low-moderate | Hepatocellular carcinoma (HCC) | | Low | All-cause mortality | | Moderate | Adverse events leading to discontinuation | | Moderate | Quality of life | | No evidence | <p>The data survey carried out prior to the second guidelines meeting contained opinions on the relative importance of each outcome. These opinions were gathered from patients and healthcare workers.</p> |
| | Outcome | Relative importance | Certainty of the evidence | | | | | | | | | | | | | | | | | | | | | |
| SVR | | High | | | | | | | | | | | | | | | | | | | | | | |
| Decompensated liver cirrhosis (DCC) | | Low-moderate | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocellular carcinoma (HCC) | | Low | | | | | | | | | | | | | | | | | | | | | | |
| All-cause mortality | | Moderate | | | | | | | | | | | | | | | | | | | | | | |
| Adverse events leading to discontinuation | | Moderate | | | | | | | | | | | | | | | | | | | | | | |
| Quality of life | | No evidence | | | | | | | | | | | | | | | | | | | | | | |
| <p>Are the desirable effects large relative to undesirable effects?</p> <p> <input type="checkbox"/> No <input type="checkbox"/> Probably No <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably Yes <input type="checkbox"/> Yes <input type="checkbox"/> Varies </p> | <p>Side effects: 14 fewer cases of HCC per 1000 with pegylated IFN (baseline 21 per 1000); 3 fewer cases of hepatic decompensation (from 17 per 1000) and 5 fewer liver related mortality cases (from 15 per 1000). One more patient per 1000 terminated treatment due to adverse events (from 118 per 1000).</p> | | | | | | | | | | | | | | | | | | | | | | | |

私の評価表 — 迷いに迷って —

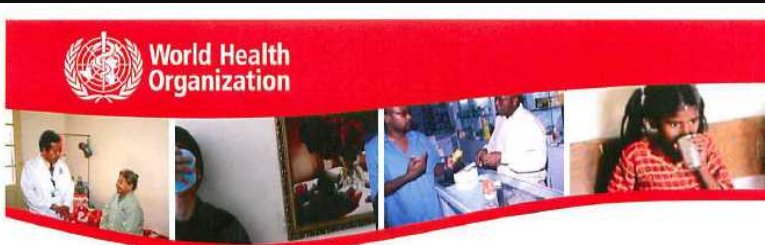
| CRITERIA | JUDGEMENTS | RESEARCH EVIDENCE | ADDITIONAL INFORMATION | | | | | | | | |
|---|--|--|------------------------|----------|----------|---------------------------|----------------------------|--|----------|---------------------|--|
| RESOURCE USE | Are the resources required small? | <p><i>Main resource requirements</i></p> <table border="1"> <tr> <th>Resource</th> <th>Settings</th> </tr> <tr> <td>Training</td> <td>Doctors/specialist nurses</td> </tr> <tr> <td>Supervision and monitoring</td> <td>Treatment given for 1 year and fol months thereafter</td> </tr> <tr> <td>Supplies</td> <td>IFN/RBV/DAA therapy</td> </tr> </table> | Resource | Settings | Training | Doctors/specialist nurses | Supervision and monitoring | Treatment given for 1 year and fol months thereafter | Supplies | IFN/RBV/DAA therapy | |
| | Resource | Settings | | | | | | | | | |
| Training | Doctors/specialist nurses | | | | | | | | | | |
| Supervision and monitoring | Treatment given for 1 year and fol months thereafter | | | | | | | | | | |
| Supplies | IFN/RBV/DAA therapy | | | | | | | | | | |
| Is the incremental cost small relative to the net benefits? | <p>Cost benefit analysis</p> | | | | | | | | | | |
| EQUITY | What would be the impact on health inequities? | <p>An intervention targeted at patients most at risk e.g. IDUs and prisoners is likely to improve health inequities.</p> | | | | | | | | | |
| | Is the option acceptable to key stakeholders? | <p>Discussion in meeting</p> | | | | | | | | | |

WHO should be treated ----

WHO recommend to treat ----

WHO recommend to consider treat ----

世界の3大感染症は、結核・マラリア・HIV



Introduction and rational use of new drugs and drug regimens for TB treatment

CURRENT SITUATION

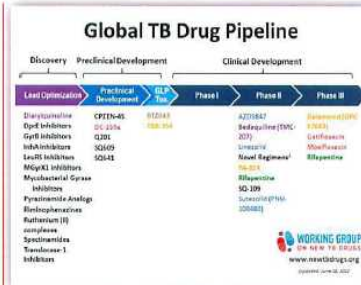
- Much progress has been made in research and development of new drugs for tuberculosis (TB) over the last decade.
- A series of Phase II and III trials of shortened treatment of drug-susceptible (DS) TB including re-purposed drugs (e.g. fluoroquinolones) or new dosages of known drugs (e.g. rifamycin, rifapentine) are presently on-going, with earliest results expected in 2013.
- Novel drugs are being evaluated in Phase IIb and III trials, including two drugs that are being tested for the treatment of multidrug-resistant TB (MDR-TB) (bedaquiline and delamanid), with dossiers submitted to drug regulatory authorities. One of these (bedaquiline) has recently been granted licensure by the U.S. Food and Drug Administration under its accelerated approval procedure.
- Novel drug combinations for shortened treatment of DS and/or drug-resistant (DR) TB, including new or re-purposed drugs, are under investigation.

UNMET NEEDS

- People with drug-susceptible TB need shorter and simpler therapy;
- People with drug-resistant TB need a more efficacious, fully oral, shorter, less toxic and safer therapy;
- People living with HIV need TB drugs with no or low drug-drug interactions with antiretrovirals;
- People with latent TB infection need shorter and safer therapy;
- Children with TB need a more child-friendly treatment.

WHY THIS GUIDANCE?

- The likely introduction of new drugs or drug regimens for the treatment of DS- or DR-TB will have a series of public health implications, particularly regarding:
- the responsible use of new drugs as part of set combination regimens for the treatment of DS- or DR-TB;
 - the programmatic feasibility and cost-effectiveness of newly-developed treatments;
 - the capacity to monitor scaled-up use of new drugs, and conduct surveillance of drug-resistance;
 - the prevention of emergence of new drug resistance.



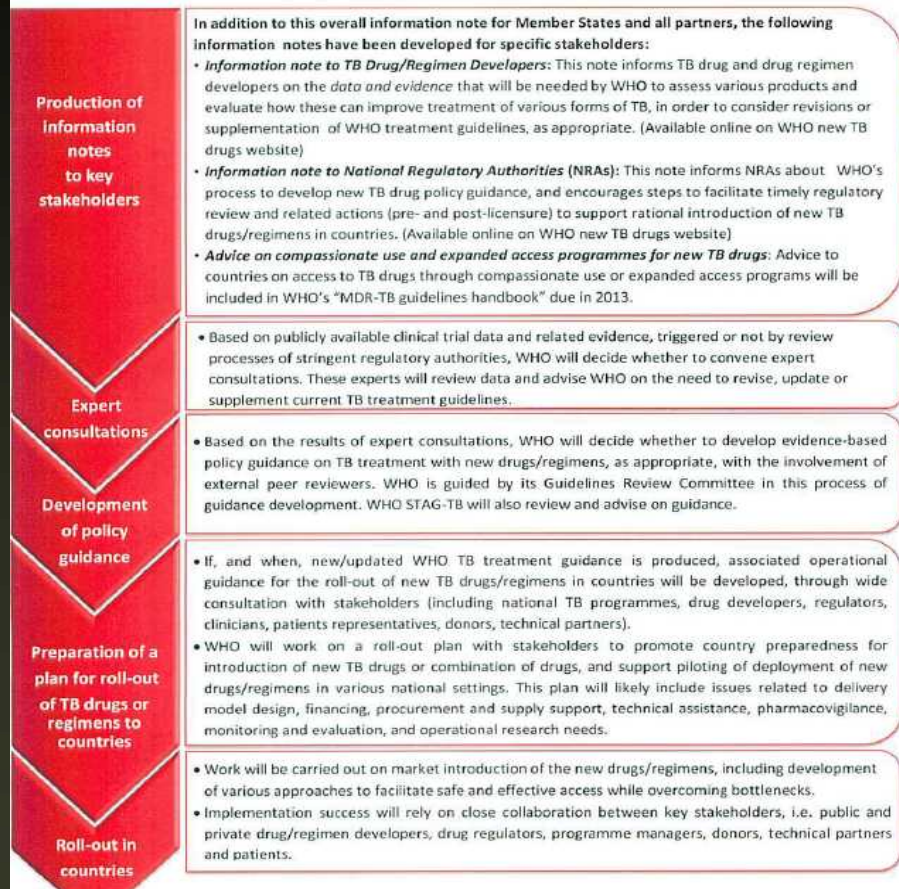
WHO STRATEGIC ROADMAP: Policy development for introduction of new TB drugs or regimens in countries

- In April 2012, the WHO Stop TB Department established a Task Force to advise and assist WHO in the process for the development of policy guidance on the rational introduction and use of new drugs or drug regimens for TB treatment. The aim is to improve access to quality TB care and to protect against the emergence of drug resistance.
- A strategic roadmap was then developed, with the support of the Task Force, to guide WHO's timely development of appropriate policy guidance on treatment of DS- or DR-TB and related rational introduction and use. The roadmap also includes WHO's role in supporting Member States in the roll-out of recommended new drugs within defined regimens in programmatic conditions.
- The WHO Strategic and Technical Advisory Group for Tuberculosis (STAG-TB) endorsed this roadmap in June, 2012.

SEE REVERSE FOR THE ROADMAP STEPS

For more information please visit our website:
http://www.who.int/tb/new_drugs

THE ROADMAP



- In addition to this overall information note for Member States and all partners, the following information notes have been developed for specific stakeholders:
- **Information note to TB Drug/Regimen Developers:** This note informs TB drug and drug regimen developers on the *data and evidence* that will be needed by WHO to assess various products and evaluate how these can improve treatment of various forms of TB, in order to consider revisions or supplementation of WHO treatment guidelines, as appropriate. (Available online on WHO new TB drugs website)
 - **Information note to National Regulatory Authorities (NRAs):** This note informs NRAs about WHO's process to develop new TB drug policy guidance, and encourages steps to facilitate timely regulatory review and related actions (pre- and post-licensure) to support rational introduction of new TB drugs/regimens in countries. (Available online on WHO new TB drugs website)
 - **Advice on compassionate use and expanded access programmes for new TB drugs:** Advice to countries on access to TB drugs through compassionate use or expanded access programs will be included in WHO's "MDR-TB guidelines handbook" due in 2013.
- Based on publicly available clinical trial data and related evidence, triggered or not by review processes of stringent regulatory authorities, WHO will decide whether to convene expert consultations. These experts will review data and advise WHO on the need to revise, update or supplement current TB treatment guidelines.
 - Based on the results of expert consultations, WHO will decide whether to develop evidence-based policy guidance on TB treatment with new drugs/regimens, as appropriate, with the involvement of external peer reviewers. WHO is guided by its Guidelines Review Committee in this process of guidance development. WHO STAG-TB will also review and advise on guidance.
 - If, and when, new/updated WHO TB treatment guidance is produced, associated operational guidance for the roll-out of new TB drugs/regimens in countries will be developed, through wide consultation with stakeholders (including national TB programmes, drug developers, regulators, clinicians, patients representatives, donors, technical partners).
 - WHO will work on a roll-out plan with stakeholders to promote country preparedness for introduction of new TB drugs or combination of drugs, and support piloting of deployment of new drugs/regimens in various national settings. This plan will likely include issues related to delivery model design, financing, procurement and supply support, technical assistance, pharmacovigilance, monitoring and evaluation, and operational research needs.
 - Work will be carried out on market introduction of the new drugs/regimens, including development of various approaches to facilitate safe and effective access while overcoming bottlenecks.
 - Implementation success will rely on close collaboration between key stakeholders, i.e. public and private drug/regimen developers, drug regulators, programme managers, donors, technical partners and patients.

A NEW ERA IN TB TREATMENT

The pipeline for new TB drug and regimens is advancing, with new drugs becoming available now. Building on this progress, it is critical to ensure that new drugs/regimens for the treatment of all forms of TB are effectively introduced in countries in a way that guarantees access to the best treatment for all those in need and avoids inappropriate use of new drugs. WHO will develop evidence-based policies and strategy guidance for introduction of regulatory-approved drugs to ensure affordability and access while preserving drug efficacy. Programmatic implementation should be aligned with ongoing efforts that aim to maximize the efficiency and effectiveness of TB treatment by optimizing drug regimens, advancing point-of-care and other simplified platforms for diagnosis and monitoring, reducing costs, adapting delivery systems, and mobilizing communities.



世界の3大感染症に共通するのは薬剤耐性の問題

A NEW ERA IN TB TREATMENT

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February 2018

7月24日7:30 PMにWHOのViral Hepatitis Global Policy for World Hepatitis Day 2013が発表

Dear CEVHAP Members,

WHO is launching the Viral Hepatitis Global Policy Report for World Hepatitis Day 2013 via a webinar on Wednesday 24th July.

The time will be:

Geneva: Wednesday, 24 July 2013 at 12:30 PM

Karachi: Wednesday, 24 July 2013 at 3:30 PM

Mumbai: Wednesday, 24 July 2013 at 4:00 PM

Bangkok: Wednesday, 24 July 2013 at 5:30 PM

Kuala Lumpur: Wednesday, 24 July 2013 at 6:30 PM

Singapore: Wednesday, 24 July 2013 at 6:30 PM

Hong Kong: Wednesday, 24 July 2013 at 6:30 PM

Beijing: Wednesday, 24 July 2013 at 6:30 PM

Taipei: Wednesday, 24 July 2013 at 6:30 PM

Seoul: Wednesday, 24 July 2013 at 7:30 PM ←

Melbourne: Wednesday, 24 July 2013 at 8:30 PM

We are only 5 days to World Hepatitis Day 2013. All the best with your World Hepatitis Day campaigns and we look forward to sharing your successes with CEVHAP's membership in due course.

Best regards,

CEVHAP Secretariat



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