Report (Draft)

“Interagency Emergency Health Kit (IEHK)
Update 2010

Inaugural meeting of the IEHK Review Committee

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Background:

UN agencies and international and nongovernmental organizations are increasingly called upon to respond to large-scale emergencies to prevent and manage serious threats to the survival and health of the affected populations. Medicines and medical devices (renewable and equipment) have been supplied by relief agencies for decades. In 1980s, WHO facilitated a process to encourage the standardization of medicines and medical supplies needed in emergencies to allow efficient and effective responses to the need for medicines and medical devices. This initial work lead to the supply of standard, pre-packed kits that could be kept in readiness to meet priority health needs in emergencies.

The first “WHO Emergency Health Kit” was launched in 1990. After revision and further harmonization, the contents of the second kit, “The New Emergency Health Kit 98” was endorsed by WHO in collaboration with a large number of international and nongovernmental agencies. The current kit, the “Interagency Emergency Health Kit 2006” (IEHK 2006), accommodates emergency prophylaxis to prevent HIV infection after sexual violence, the increasing antimicrobial resistance to commonly available antimalarials and antibiotics, injection safety policy, and the experience of agencies using the emergency health kit in the field.

Over the years, the number of partners included has risen from two in the early 1980s to more than 10 partners and suppliers in 2006. It was essential that there was consensus on the content. The 2006 process was complex and there were some difficulties and delays in obtaining consensus. As a result, the Secretariat has proposed a process to formalize future revisions, including oversight by the Expert Committee after appropriate consultation. This procedure has been published in the Report of the 2007 Meeting of the WHO Expert Committee on Selection and Use of Essential Medicines.

The WHO Secretariat hosted this first planning meeting to initiate processes that will facilitate the timely delivery of the next version of the IEHK, which is due in 2010.

Specific Objectives of the meeting

The specific objectives this meeting were:

- To confirm the membership of the IEHK Review committee and identify relevant WHO staff to act as technical advisers in the revision process.
- To operationalize the procedures for the managing and review of applications for additions, deletions and other changes to the kit, and agree on a how to share information on decisions.
- To identify priority medicines that may need to be included in the kit, but not in the current WHO Model List of Essential Medicines. (These medicines will require submissions to the expert committee by October 2008 for consideration in the meeting in March 2009.)
- To identify priority actions to be taken between now and the first review meeting of the IEHK Review Committee
- To develop a work plan and timeline for updating the IEHK by 2010.

The agenda is attached as Annex 1

1 WHO Technical Report Series 946
www.who.int/entity/medicines/publications/essentialmeds_committeereports/TRS946_EMedLib.pdf
Overview of the proceedings:

The meeting was opened by Dr Clive Ondari, who welcomed all participants to the meeting. The meeting started with a reflection on past experiences, not only with updating the kit, but also on the use of the kit. The delays experienced in updating the kit were reviewed, and it was agreed that all effort will be employed to ensure an efficient process for the 2010 update.

The process and procedures published in the report of the Expert Committee on Selection and Use of Essential Medicines WHO TRS 941, was used as the basis of the discussion of the main agenda points. The recommended updates to the sections are attached in the revised procedure in Annex 2. The terms of reference of the Secretariat and Review committee were reviewed and are included in the updated procedure in Annex 2, Section 2.

The discussion on experiences with the use of the kit was deferred to the last session of the meeting. The meeting focussed on the procedures and processes for review, and did not discuss any changes in the content during this meeting. However, some potential areas that may need special review were identified and listed for follow up in the first meeting of the review committee.

Summary of Introductory Discussions

During the introductory discussions, six core observations were raised:

- There are various requests for expanding the contents and/or increasing the quantities of products in the kit, not all of them in line with the underlying philosophy that the IEHK is sent blindly as a first response to an emergency. Anecdotal reports of the use of the kit for other purposes exist, but the appropriateness of such use is the responsibility of the supplier/provider and will not be considered in the next review. While it was agreed to focus on the purpose of the kit in discussion on contents, some key questions were raised as issues for follow up:
  - What to do after the first round of kits had been supplied? It is wasteful to supply the IEHK after an emergency. What policies exist to ensure a sustainable supply of medicines, medical devices and others related supplies after the initial phase of an emergency?

- The selection and validation of the medical devices in the kit were recognized as being challenging, and the inputs from MSF and UNICEF were highly appreciated. MSF and UNICEF have offered to review the medical devices. It is not clear which department in WHO is best suited to provide assistance in this regard.

- The malaria module in particular will need a review. Some areas of concern raised were:
  - Currently it is the cost driver in the kit, and agencies have different approaches - some agencies will supply unless the malaria module is denied, others will supply only if the malaria module is requested. In most cases these options are applied after dialogue with the recipients.
  - Little is known about the relevance of quantities
  - There is uncertainty how the inclusion of Co-artem® is interpreted in countries where the malaria policy recommends different products.
  - There are short shelf life products included, which complicated the supply management of the kit.
• Common problems with supply logistics are experienced the kit, such as
  o The kit has become bigger and more costly over time, especially since the last update of
    the malaria module which has trebled the cost of the kit.
  o Importation and clearance problems, with kits getting blocked on route
  o Logistic problems, especially now that the complete kit weighs more than a metric ton
    and a truck is needed for its distribution
  o Packaging for countries such as Yemen and the Middle East.
  o Quality assurance procedures of basic pharmaceutical products of suppliers of the kits
    are not harmonized, and it is not always possible to obtain appropriate document from
    suppliers of the kit to establish whether quality specifications comply with
    organizational standards. It was noted that these medicines are not included in the
    WHO prequalification process, and that a similar harmonized approach could assist
    greatly with ensuring the quality of products.

• The availability of the document in English, French and Spanish is critical to the changeover in
  contents between old version and new version of the kit. Effort should be made to ensure
  timely availability of the actual publication

• To date, the feedback received using the feedback form in the manual has not been useful to
  inform the decisions on the contents of the kit. From the discussions it was clear that those
  agencies with local teams supporting countries in emergencies are in a better position to obtain
  information on the usefulness of the kit than suppliers.

Membership and participation
It was agreed that membership in the review committee will be limited to those agencies that are using
the kit for its intended purpose at country level. Other stakeholders will be consulted as part of the
broader review process, as outlined in the formalized procedure. A clear distinction was made between
agencies that supply kits, either commercially or for humanitarian reasons, without having staff in the
field (referred to as suppliers of kits), and agencies engaged in humanitarian response in the acute
phase of emergencies (referred to as users of the kit).

According to the procedure, participation in the review committee is conditional to a commitment to
ensure continuity, i.e., nominated members should be available at least for 2 years. The meeting debated
the feasibility of this requirement, as most of the staff members of relief agencies using the kit are
employed on short term contracts, and may not be available for a 2 year cycle. It was agreed not to
compromise the recommended period of commitment. However, the timelines for updating the kit
will be coordinated in such a manner that the review can be completed in one calendar year. See
timeline for updating the kit by 2010.
Review of experiences with the kit

Ideally, a review of experiences should be included in the review of the contents of the kit. However, agencies do not get feedback on the value and appropriateness of the kit via the questionnaire included in the document Interagency Emergency Health Kit guideline (delivered as part of the IEHK basic unit content). While feedback on the use of the kit would be useful, it was agreed that a pro-active review of experiences with the kit should not delay the update of the kit. An initial review will be undertaken to identify users and suppliers (as defined in the section on membership), not known to the review committee, to try to compile supply data of the 2006 edition since its use.

**Suppliers:** Agencies that supply kits, either commercially or for humanitarian reasons, without having staff in the field using kits during the acute phase of an emergency.

**Users:** Agencies engaged in humanitarian response in the acute phase of emergencies. Note that users may be suppliers as well.

As a second step, questionnaires will be prepared to obtain further information on experiences with the kit since the 2006 version of the kit come into operation. Key questions could include:

<table>
<thead>
<tr>
<th>SUPPLIERS</th>
<th>USERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since the 2006 kit come into operation, the number of full kits (all modules) dispatched ?</td>
<td>Since the 2006 kit come into operation, the number of full kits (all modules) received ?</td>
</tr>
<tr>
<td>When (dates) were the kits sent</td>
<td>When (dates) were the kits received ?</td>
</tr>
<tr>
<td>To which countries, destinations ?</td>
<td>In which countries, areas ?</td>
</tr>
<tr>
<td>Which modules, how many were sent ?</td>
<td>Which modules, how many were received ?</td>
</tr>
<tr>
<td>Is the intended use known (don’t know, sent blindly/immediate response in acute phase, after needs assessment) ?</td>
<td>What was the intended use (don’t know, sent blindly/immediate response in acute phase, after needs assessment) ?</td>
</tr>
<tr>
<td>When was it sent (prepositioned, within 0-4 weeks, 8 - 12 weeks of the emergency occurring, other) ?</td>
<td>When was it used (prepositioned, within 0-4 weeks, 8 - 12 weeks of the emergency occurring, other) ?</td>
</tr>
<tr>
<td>Any comments/suggestions on the contents of the kit, product and quantities ?</td>
<td>Any comments/suggestions on the contents of the kit, product and quantities ?</td>
</tr>
</tbody>
</table>

**MALARIA MODULE**

<table>
<thead>
<tr>
<th>SUPPLIERS</th>
<th>USERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since the 2006 kit come into operation, the number of MALARIA modules dispatched ?</td>
<td>Since the 2006 kit come into operation, the number of MALARIA modules received ?</td>
</tr>
<tr>
<td>How is the Malaria module sent ?</td>
<td>How did you order the Malaria module ?</td>
</tr>
<tr>
<td>With the IEHK, as an automatic inclusion in a request for the IEHK ?</td>
<td>With the IEHK, as an automatic inclusion in a request for the IEHK</td>
</tr>
<tr>
<td>With the IEHK, but on request/after confirmation by users that they need the Malaria module ?</td>
<td>With the IEHK, but on request/after confirming the need for the Malaria module</td>
</tr>
<tr>
<td>As a stand-alone module ? Other, describe</td>
<td>During the emergency as a stand-alone module Other, describe</td>
</tr>
<tr>
<td>When were they sent (dates), to which countries</td>
<td>When were they used (dates), in which countries</td>
</tr>
<tr>
<td>Any comments/suggestions on the contents of the malaria kit, product and quantities ?</td>
<td>Any comments/suggestions on the contents of the malaria kit, product and quantities ?</td>
</tr>
</tbody>
</table>
Issues for consideration at 1st Review meeting

The following list is of issues that were discussed during the review of the procedures, and as such have no actual place in the revised procedures in section 1.

1. Other kits developed by individual agencies for specific health conditions, such as cholera, malnutrition, reproductive health, and emergency surgical interventions, may be considered as possible complementary kits to the IEHK will have to be ordered separately after an assessment of the needs.

2. The emerging need to develop responses for HIV and AIDS, tuberculosis and other chronic conditions, such as diabetes, asthma, cardiovascular diseases etc. can no longer be ignored in emergencies. People on long-term treatment cannot be excluded in the acute phase of emergencies. To respond to supply gaps for HIV, AIDS, tuberculosis, chronic conditions, an emergency surgical interventions in disasters, it was suggested that quantified lists should be developed rather than specific kits to respond to acute needs.

3. The inclusion of formulations for children for priority diseases also needs to be considered. It is expected that there will be a number of children's formulations (from the EML 2009) that will be suitable for inclusion in the updated IEHK, and these should be considered in the review of the current version of the IEHK.

4. All members of the committee will undertake a survey within their respective organisations on the use of IEHK, either in pre-positioning, during emergencies as well as in protracted settings. In addition, the most often encountered problems will be reported, such as whether products are missing from the IEHK, the quantities included are not optimal etc.

5. The availability of IEHK's during the initial phase of emergencies, i.e. for intended use, should be studied.

6. The general availability of products as included in the IEHK should be considered, also for newly proposed products.

7. Generic technical specifications for all medical devices included in the IEHK are available from UNICEF web catalogue (as part of UNICEF standard products range). This is currently the only on-line source of this information. There are gaps in quality assurance of medical devices, and the maintenance and issuance of specifications for medical devices are not coordinated within WHO. Linkages between the Review Committee and the relevant persons in WHO need to be explored.

8. A survey into the possible problems related to the fact that ketamine and other controlled substances might pose importation problems should be considered.

9. In future versions of the IEHK, all medicines nomenclature and formulations should be in concordance with the most current version of the EML.

10. The number of RDT for malaria in current version of IEHK should be re-quantified based on input from a number of end-users.

11. There should be an active process within WHO to identify ongoing guidelines development and other relevant issues (PHC manuals, integrated approaches).

12. The issue of addressing mental health within the context of the IEHK setting in general should be studied and defined.

13. Preparation of a report on the intended use of IEHK, in order to verify the basic assumption of the IEHK is still correct: for first response, to be sent blindly. The survey, over the current version i.e. the years 2007 and 2008, should ideally include all or most of the following information: how many IEHK are used by which organizations, in which circumstances, i.e. at what stage of emergency, by which level of skill of the staff using the units, when was the order placed, when were IEHK delivered, what was sent (basic units, complete IEHK, malaria modules) throughout the responding agencies to include the present IEHK Review Committee members, as well as Merlin, UNHCR, IOM. The intended use could be derived from the date the order was placed in relation to actual events (i.e. directly thereafter is first response, months later is resupplying).
14. While it was agreed that the purpose of the kit was to provide a response to the acute phase of an emergency, key questions such as what to do after the first round of kits had been supplied were raised. There is need for policy guidance to relevant actors to prepare/reconstruct and reduce need for IEHK by assessing health needs and restoring/setting up a procurement system.

Timeline for 2010 Update
(For more information on the procedure and process for updating the kit, refer to Annex 2)

October 2
- Call for submission of applications *
  - verification screening of documents* by secretariat
  - verified dossiers* then posted on website for one month prior to meeting for comments

  (call open for approx. 5 months, closing date at least 6 weeks before the 1st review meeting, posting of verified applications* at least one month before 1st review meeting)

March 3
- 1st meeting of review committee
  - division of tasks
  - identification of consultations needed

  Consultation round:
  electronic consultation of completed dossiers* by members
  accessible for interested parties
  consultation on specific technical issues
  with relevant technical experts

  (one month prior to 2nd review meeting finalized dossiers* will be circulated to all committee members)

(late)June 6
- 2nd meeting of review committee

End of year 6
- Release of consensus document
  Translations Spanish, French, with logos of endorsing agencies.

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2 2008 and every 4th year thereafter
3 2009 and every 4th year thereafter
4 'version 2010' and every 4th year thereafter. Release at beginning of year will enable agencies to adapt procurement accordingly.
Annex 1: Agenda

“Interagency Emergency Health Kit (IEHK) Update 2010

Inaugural meeting of the IEHK Review Committee

23 - 24 July 2008

23 July 2008:

<table>
<thead>
<tr>
<th>9.00-9.30</th>
<th>Opening and Welcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.30-10.30</td>
<td>Introduction: Revised procedure for updating the content of the IEHK</td>
</tr>
<tr>
<td></td>
<td>• Terms of Reference of Secretariat</td>
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<td>• Terms of Reference of Review Committee</td>
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<tr>
<td></td>
<td>• Membership and participation</td>
</tr>
<tr>
<td>10.30-11.00</td>
<td>Coffee-break</td>
</tr>
<tr>
<td>11.00-12.00</td>
<td>Qualitative and Quantitative Monitoring of the appropriateness of the contents of the kit</td>
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<tr>
<td></td>
<td>• ? Questionnaires</td>
</tr>
<tr>
<td>12.00-13.00</td>
<td>Lunch</td>
</tr>
<tr>
<td>13.00-15.00</td>
<td>Applications for inclusions, deletions and changes to the kit</td>
</tr>
<tr>
<td></td>
<td>• Information to be included for medicines</td>
</tr>
<tr>
<td></td>
<td>• Information to be included for medical devices</td>
</tr>
<tr>
<td></td>
<td>• Procedures for the review of applications</td>
</tr>
<tr>
<td>15.00-15.30</td>
<td>Coffee-break</td>
</tr>
<tr>
<td>15.30-16.45</td>
<td>Information exchange</td>
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<tr>
<td></td>
<td>• Information in the public domain</td>
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<tr>
<td></td>
<td>• Information exchange among reviewers</td>
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<tr>
<td></td>
<td>• Information exchange among committee members</td>
</tr>
<tr>
<td>16.45-17.00</td>
<td>Discussion, summary of outcomes.</td>
</tr>
</tbody>
</table>

13 August 2008:

| 09:00-10:30 | Group work |
|            | • Workplan and priority actions |
|            | • Membership and Participation |
|            | • Operationalising the procedures for updating the IEHK |
| 10.30-11.00 | Coffee-break |
| 11.00-12.00 | Feedback from Group 1: Workplan and Priority Actions |
| 12.20-13.00 | Lunch |
| 13.00-14.00 | Feedback from Group 2: Membership and Participation |
| 14.00-15.00 | Feedback from Group 3: Procedures for updating the IEHK |
| 15.00-15.30 | Coffee-break |
| 15:30-16:00 | Conclusions and priority actions summary |
| 16:00-16.30 | Closure |
Annex 2: Revised procedure for updating the IEHK

1. The Interagency Emergency Health Kit

1.1 Background

The agencies of the United Nations system and international and nongovernmental organizations are called upon to respond to an increasing number of large scale emergencies many of which pose a serious threat to health. Much of the assistance provided in such situations is in the form of medicines and medical devices (renewable and equipment).

During the 1980s, the World Health Organization (WHO) took up the question of how emergency response could be facilitated through effective emergency preparedness measures. The aim was to encourage the standardization of medicines and medical supplies needed in emergencies to permit a swift and effective response with medicines and medical devices using standard, pre-packed kits that could be kept in readiness to meet priority health needs in emergencies.

The first “WHO Emergency Health Kit” was launched in 1990. After revision and further harmonization, the contents of the second kit, “The New Emergency Health Kit 98” was endorsed by WHO in collaboration with a large number of international and nongovernmental agencies. The current kit, the “Interagency Emergency Health Kit 2006” (IEHK 2006), accommodates emergency prophylaxis to prevent HIV infection after sexual violence, the increasing antimicrobial resistance to commonly available antimalarials and antibiotics, injection safety policy, and the experience of agencies using the emergency health kit in the field.

Over the years, the number of partners included has risen from two in the early 1980s to more than ten in 2006. The 2006 process for updating the kit was complex and there were some difficulties and delays in obtaining consensus. As a result, the Secretariat has proposed a process to formalize future revisions, including oversight by the Expert Committee after appropriate consultation. The proposed procedure was published in the Report of the 2007 Meeting of the WHO Expert Committee on Selection and Use of Essential Medicines, and was further expanded upon in this first meeting of the review committee of the IEHK, July 2008.

1.2 Guiding principles for the revision of the IEHK

The new procedure for updating the IEHK will be based on major features of the revision procedure of the WHO Model List of Essential Medicines, such as:

- The updated WHO Model List of Essential Medicines and WHO standard treatment guidelines will be the baseline references for considering a proposed revision of the content of the IEHK. The term “essential medicines” will be used instead of “essential drugs”, reflecting the common use of the term “medicines” to describe pharmaceutical preparations in clinical health care practice.
- A transparent process will be adopted for selecting and estimating medicines and medical devices to be included in the kit, including systematic analysis of effects and appropriateness of medicines and medical devices proposed for use in emergency care for different health conditions.
- A systematic approach will be adopted to manage proposals for the deletion, change to or inclusion of medicines and medical devices in the current IEHK.

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Applications and draft recommendations will be available on the WHO web site. The link to the website will be made available to the committee as soon as it is functioning.

The list of items and the quantities thereof in the IEHK is harmonized, specified list to which all agencies should adhere.

Product availability is one of the criteria for inclusion of a medicine on the Model List and any comment on availability made by the Expert Committee will be taken into account.

The absolute cost of the treatment will not constitute a reason to exclude a medicine and/or a device from the IEHK that otherwise meets the stated selection criteria.

The patent status of a medicine is not considered in selecting medicines for the IEHK.

Full involvement of different WHO departments and other partner UN agencies and international organizations operating in emergencies will be pursued, especially during the application and review process, linking the process to clinical guidelines and essential emergency supply lists disseminated by WHO, medical devices specifications from UNICEF, and best practices in emergencies pursued by all WHO departments and partners.

Opportunities to react for interested parties, including WHO’s regional and country offices, relevant UN agencies, international organizations and nongovernmental organizations, will be offered with regard to both applications and draft recommendations prior to the meeting of the IEHK Review Committee.

The Secretariat of the IEHK Review Committee is the Medicine Supply Unit in WHO Department of Essential Medicines Policy and Standards (WHO / EMP / MSU).

The IEHK Review Committee is composed of representatives of UN agencies, and international organizations and nongovernmental organizations operating in emergencies, who endorse the IEHK and participate actively in the process of revision of the kit. Relevant WHO staff members and stakeholders will be invited to attend the IEHK Review Committee meeting or to contribute to the consultation process as technical advisers.

IEHK Review Committee members will represent their organizations for at least 2 years to guarantee continuity.

1.3 The Revision procedure

A similar procedure to updating the Model List of Essential Medicines is envisaged, which will allow for wider consultation and an evidence-based more efficient process. Future versions will be developed in accordance with agreed criteria and procedures, and will be endorsed by the review committee and they agencies they represent. This endorsement will be expressed by granted permission to use the logo of the respective agencies on the interagency publication on The Interagency Emergency Health Kit, currently in its 2006 version.

The review process will be initiated by a public call for applications for changes: inclusions or deletions to the content of the IEHK, issued by the Secretariat. Notification of the call for input will follow as a courtesy to departments of WHO, UN agencies, international organizations and NGOs operating in emergencies. Upon receipt, the Secretariat will screen the applications for completeness, and will verify that applications are relevant and in line with the principles underpinning the inclusion changes of products in the kit. Submissions will be posted on the website for comment one month before the first scheduled meeting of the IEHK Review Committee.

All relevant applications will be considered during the first review meeting, and the need for further consultation, if any, will be identified. Further consultation may vary from actual expert meetings to literature and/or field experience research by collaborating agencies or invited experts. Collated inputs will be published on the website for further consultation. One month before the final meeting of the review committee, full dossiers will be circulated to the members of the review committee. These dossiers will include recommendations on the received applications and comments received after the verified applications were posted on the website. The committee will review the efficacy, safety and suitability and relevance of products, and how decisions will impact on the structure of the IEHK.
Final decisions will be taken in the second meeting. Decisions will be consensus-based. In case consensus cannot be reached on an issue, there will be no change to the IEHK, and the issue will be put on the agenda of the next Review Committee meeting, i.e. at the start of the next review process. The decisions supporting each recommendation will be summarized explicitly in meeting reports, and agreed changes and the full meeting report will be posted on the WHO website for future reference.

2. Terms of reference of the IEHK Secretariat and Review Committee

2.1 Terms of Reference for the IEHK Secretariat

The IEHK Secretariat is the Medicine Supply Unit in WHO Department of Essential Medicines Policy and Standards (WHO / EMP / MSU). It is responsible for initiating reviews of the IEHK structure and content, developing and maintaining a specific web site, organizing meetings of the IEHK Review Committee, and collecting collating and sharing relevant information with IEHK partners and suppliers. The Secretariat will be responsible for receiving submissions for changes to the IEHK, verifying them, organizing the various meetings, and publishing the updated IEHK booklet in print and electronic versions simultaneously in 3 languages: English, French and Spanish.

2.2 Terms of Reference for the IEHK Review Committee

The IEHK Review Committee is composed of representatives of UN agencies, and representatives of international organizations and NGOs involved in relief work during emergencies that are actually using the IEHK. The members of the IEHK Review Committee will provide technical contributions on medical, pharmaceutical or supply issues during the consultation phase of the review process or invite selected technical advisers to assist in the review process. Relevant WHO staff members will be invited as technical advisers to attend the IEHK Review Committee meeting or to contribute to the consultation process.

The Committee is responsible for the regular updates of the content of the IEHK according to the guiding principles and procedure for IEHK revision.

2.3 Commitment

WHO/EMP/MSU is committed to being the Secretariat of the IEHK Review Committee.

IEHK Review Committee members will represent their organization in the IEHK Review Committee for at least two years to guarantee continuation. Individual Committee members will be involved in the review of applications and will draft recommendations.

In principle, members of the Committee that are not able to attend any of the IEHK Review Committee meetings agree with the decisions taken during the consensus round of the meeting. Members not able to attend meeting shall state their arguments in writing for consideration during the meeting. However this text must be circulated to all other members in due time, with a minimum of one week before the meeting.

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7 Agenda, points of discussion and applications with recommendations will be circulated to all IEHK Review Committee members one month prior to the consensus meeting. Written contributions to the discussion by absent members must be circulated (by the absent member) one week prior to the consensus meeting.
2.4 Funding

The Secretariat will guarantee sufficient funding for its tasks, including the publication of the IEHK booklet simultaneously in 3 languages: English, French and Spanish. The individual members of the IEHK Review Committee will fund themselves for attendance at meetings and will allocate official time to review applications as requested.

3. Principles for Selecting medicines and medical devices for the IEHK

The content of an Interagency Emergency Health Kit (IEHK) is intended to enable an immediate response to the basic health needs of a population of 10,000 people for a period of three months in the acute phase of an emergency.

As soon as it is feasible, the actual requirements for further supplies should be assessed and medicines and medical devices should be ordered through the national supply system or its temporary replacement.

Assumptions guiding the use of the IEHK are:

1) the IEHK was developed to save lives in a 'worst-case scenario' where the health care system is no longer functioning, and assumes a higher than normal morbidity and mortality pattern;

2) the IEHK is sent 'blindly' as soon as an emergency occurs, to allow for immediate response;

3) the IEHK is intended to enable basic service delivery; the medicines and medical devices are selected on the basis of 'keep it simple and avoid confusion' to ensure that the staff at the receiving end are able to use the medicines and medical devices appropriately; (e.g.: no injections are available in the basic unit and contents can be used by emergency staff with limited training);

4) the complete IEHK consists of 10 basic units and one supplementary unit for more skilled medical staff, it is intended to serve a population of 10,000 people for 3 months. The supplementary unit, used for referral, needs to be used with at least one basic unit.

3.1 Criteria for selection of essential medicines and medical devices

The selection of essential medicines and medical devices in emergencies are guided by several sources of information, including:

- epidemiological data;
- population profiles;
- disease patterns; and
- practical experience gained by UN agencies and international organizations in emergency situations.

Factors that influence the selection of medicines and devices are:

- The most peripheral level of health care may be staffed by health care workers with limited medical training, who treat symptoms rather than diagnosed diseases. They will use the basic units of the kit, and refer patients who need more specialized treatment to the next level of care;

- The first referral level of health care is staffed by general medical doctors, experienced nurses, midwives, or medical assistants, with no or limited facilities for inpatient care. They will use the supplementary unit in conjunction with one or more basic units;
The proportion of patients presenting with the more common symptoms or diseases can be predicted.

Criteria for the selection of essential medicines and medical devices for the IEHK are:

- WHO standard treatment guidelines and the WHO Model List of Essential Medicines are references for the selection of medicines included in the IEHK, to provide sound and adequate data on the efficacy, safety and suitability of selected treatment regimens for consideration in the context of emergencies;
- Stability of the product, the need for special diagnostic or treatment facilities are considered if relevant;
- Stability of the product under various conditions, the need for special diagnostic or treatment facilities and pharmacokinetic properties are also considered if appropriate;
- Fixed-dose combination products are selected only if the combination has a proven advantages in therapeutic effect, safety or compliance, more so for emergency settings.

The cost of the contents of the IEHK is not a criterion and the patent status of a medicines is not considered in selecting medicines for the IEHK.

3.2 Estimating quantities of medicines and medical devices

Estimation of quantities of a medicine and/or a medical device in the IEHK is based on:

- average morbidity patterns among affected populations
- use of standard treatment guidelines
- figures and data provided by agencies with field experience

The following assumptions were adopted for guiding the forecast of supply needs

- During emergencies, the estimated average number of visits for advice or treatment by every individual to facilities is four times per year;
- Half of the population who will need assistance is under 15 years of age;
- The estimated rate of referral from the most peripheral to the next level of health care is 10%;
- Based on attendance estimates, the supplies included in one IEHK (10 basic units and 1 supplementary unit) should serve the need of a population of 10,000 people for a period of approximately 3 months;
- Each of the 10 identical basic units contains medicines and medical devices (renewable and equipment), for a population of 1,000 people for 3 months. The supplementary unit contains medicines and medical devices (renewable and equipment) to be used at the first referral level for a population of 10,000 people for 3 months. The supplementary unit should be used with at least one or more basic units;
- Needs estimation of some medical devices need will be complementary to medicines estimation: e.g.: estimation of syringes needs is based on the number of injectable medicines included in the supplementary unit, which are to be used in accordance with the treatment guidelines provided.

4. Submissions for changes to the IEHK

The following information should be included with an application for inclusion or change of a medicine or medical device to the content of the IEHK.

1. Summary statement of the proposal for inclusion or change, in the context of an emergency situation;
2. Name of the responsible person and organization submitting the application;
3. Profile of submitting organizations (use of IEHKs, working in emergency settings, phases of emergency)
4. Consequences for other items present in the IEHK (e.g. number of syringes for injectables);
5. Information affecting applications for inclusion of medicines:
   - International Nonproprietary Name (INN, generic name) of the medicine;
   - Dosage form or strength proposed
   - Additional information on suitability for use in emergencies besides clinical information provided by the WHO Expert Committee for the selection and use of essential medicines;
   - Information supporting the health emergency or public health relevance, including epidemiological information on disease burden, assessment of current use;
   - Treatment details, including dosage regimen, duration; reference to existing WHO or other clinical guidelines; or treatment facilities;
   - Quantities suggested, including information about the method used, if this is an application for change to or inclusion of a new product;
   - Availability of suppliers, with summary of information on the regulatory status of the product. Quality assurance information on the medicine should be available on request.

6. Information affecting applications for inclusion of medical devices:
   - Device name and short description from UNICEF or other;
     - for newly proposed devices, provide device name and full specifications;
   - Information supporting the health emergency or public health relevance, including epidemiological information on disease burden, assessment of current use;
   - Description of current use, including need for medical devices, special diagnostic or treatment facilities;
   - Quantities suggested, including information about the method used, if this is an application for changes or inclusion;
   - Consequences on other items present in the IEHK (e.g. number of syringes for injections);
   - Availability of supplier(s), information on regulatory status (where applicable) and quality information on the medical device should be available on request.

The following information should be included with an application for deletion of a medicine or medical device from the content of the IEHK

1. Summary statement of the proposal for deletion;
2. Name of the responsible person and organization submitting the application;
3. Profile of submitting organizations (use of IEHKs, working in emergency settings, phases of emergency)
4. Consequences on other items present in the IEHK;
5. a) Information requested for medicines:
   - International Nonproprietary Name (INN, generic name) of the medicine;
   - Justification supporting the request for deletion;

5. b) Information requested for medical devices:
   - Device name and short description from UNICEF, or other;
   - Justification supporting the request for deletion.
Annex 3: List of participants
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