

**WHO Technical Consultation
on the Implementation and
Evaluation of Annex 2 of the
INTERNATIONAL HEALTH
REGULATIONS (2005)**

Geneva, Switzerland
20 to 22 October 2008

Summary report



International Health Regulations
Coordination



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1 Introduction

World Health Assembly (WHA) resolutions WHA58.3 and WHA61.2 requested the Director-General of WHO to (i) prepare guidelines for the implementation of the decision instrument and; (ii) conduct studies to review and evaluate the functioning of Annex 2 of the International Health Regulations (2005) (hereinafter "IHR" or "the Regulations"). The 61st WHA further decided that the first review and evaluation of the functioning of Annex 2 shall be submitted to the 62nd Sixty-second Health Assembly in May 2009. In response to these resolutions, the IHR Coordination Department convened a "Technical Consultation on the Implementation and Evaluation of Annex 2 of the IHR (2005)". The Technical Consultation was held in Geneva from 20 to 22 October 2008 and was attended by experts from 13 States Parties and all WHO Regional Offices.

Dr David L. Heymann, Assistant Director-General, Health Security and Environment Cluster, WHO, opened the meeting by welcoming the participants on behalf of the Director-General and gave a brief account of the history and importance of notification under the IHR. Dr Max Hardiman, Coordinator in the IHR Coordination Programme, then outlined the objectives of the consultation:

1. To finalize the guidance on the use of Annex 2 of the IHR prepared by the WHO Secretariat;
2. To identify appropriate methodologies for the studies to review and evaluate the functioning of Annex 2.

The meeting participants appointed Dr Preben Aavitsland as Chairperson and Mr Andrew Forsyth as Rapporteur for the Technical Consultation.

This report summarizes the presentations, discussions and conclusions from the consultation. On the first day of the consultation, the development process and content of the interim guidance document was outlined and discussed. In addition, the WHO training module for the use of Annex 2 was introduced. The "WHO Interim guidance on the use of Annex 2 of the IHR (2005)" was sent to participants in advance of the consultation. On the second day, a draft set of study questions to evaluate the functioning of Annex 2 and corresponding methods were presented and the floor was opened for discussion. After having agreed upon a set of study questions, the results of the deliberations of four breakout groups on appropriate study methodologies were presented and discussed. On the third day, the case scenarios included in the interim guidance document on Annex 2 were discussed and recommendations were made by the experts. Finally, the Chairperson summarized the major findings and recommendations of the consultation.

2 WHO interim guidance on the use of Annex 2

2.1 Background

The origins and concept of Annex 2 of the IHR

Annex 2 was developed and tested over a number of years beginning in 2000 by technical experts working with WHO. The final content and format was negotiated and agreed to by an Inter-governmental Working Group in 2004-2005 charged with revising the IHR.¹ Under the IHR, States Parties are required to carry out an assessment of public health events arising in their territories utilizing the decision instrument contained in Annex 2 of the Regulations, and then to notify WHO of all qualifying events within 24 hours of such an assessment.

Guidance for the utilization of Annex 2

The guidance document main target audiences are National IHR Focal Points (NFP) and others responsible for assessing the need to notify WHO of events under the IHR. The document itself was designed to support States Parties to the IHR for the use of Annex 2. In the absence of scientific analysis upon which to base such guidance the approach taken was to explain the role and function of the decision instrument and to describe when and how to use it. Importantly, a number of case scenarios were developed to illustrate the four assessment criteria. Through these scenarios, the four criteria set out in the decision instrument are tested against fictional events, while applying established epidemiological and public health principles. The guidance document also includes case definitions for the four notifiable diseases.

Development of the interim guidance document

The interim guidance was prepared by the WHO Secretariat and extensively refined through input from all WHO Regional Offices in advance of the consultation. In addition, experts from all WHO Regions who had contributed to the development of Annex 2 during the IHR revision process were invited to review the document, including the case scenarios. Based on their comments, and with further revisions, a consolidated version of the Guidance document was published on the IHR website in September 2008. From 20-22 October 2008, this working document was reviewed by a group of experts from 13 countries as well as staff members from WHO Regional Offices and WHO Headquarters during the Technical Consultation summarized in this report. A further updated version of the Guidance document is scheduled for publication in 2009.

¹ For more information see <http://www.who.int/gb/ghs>

2.2 Discussion

Each section of the interim guidance document was discussed during the consultation. The main points raised by the participants are summarized under the section titles below.

2.2.1 General comments

- The group considered the interim guidance document to be important as there is currently limited information or educational material on the process of risk assessment for the purpose of notification under the IHR.
- A number of participants mentioned the fact that countries sometimes perceive notification as a significant or formal process or as a determination involving extensive internal procedures. It was considered that this may delay or act as a disincentive for timely notifications. The potential relevance of consultation (under Article 8 of the IHR) as an additional way of informing WHO of events and seeking support from WHO was noted.
- The group highlighted the fact that surveillance/notification should be sensitive. The attention of participants was drawn to the fact that during the first year after entry into force only about 12% of events considered by WHO came from notifications.
- The fact that, in addition to receiving notifications, WHO may consider public health information from informal sources (subject to IHR requirements) was considered a key aspect of the IHR. However, this does not diminish the important obligations of States Parties with respect to notification and other official reporting. The group stressed the reciprocal nature of the role of WHO and States Parties in implementing the IHR.
- Experts suggested including a new section on the outcomes or public health benefits of notification to and consultation with WHO. They further discussed adding a clarification about the links to WHO's IHR Event Information Site and an explanation of the PHEIC (public health emergency of international concern) determination process. With regard to this section, there was also a proposal to address the concerns of States Parties who may be reluctant to notify events to WHO due to the perception that a notified event will automatically be determined as a PHEIC or posted on the IHR Event Information Site, which may stigmatize their country.
- The expert group discussed the need for the guidance document to indicate that the decision instrument reflects a shift in thinking and a new paradigm, i.e. towards event-based notification and a more prominent and broad approach to risk assessment.
- A number of experts suggested that WHO seek and take into account comments from NFPs/States Parties when finalizing the guidance document and in any subsequent revisions.

- Various participants raised the possibility of making minor regional adaptations to the Guidance document (e.g. for the case scenarios).
- Confusion was expressed by participants regarding aspects of the role of NFPs in the assessment of events.
- The possibility of developing a template for notification to WHO was raised in the discussions.
- The group felt that the guidance document would benefit from more case scenarios.

2.2.2 Section 1 - Objectives of this guidance

- In addition to the brief description of the aim and purpose of the guidance document, the consultation sought clarification of the following:
 - When does a communication between a State Party and WHO need to go through the NFP?
 - What is considered a notification by WHO?

Irrespective of the label given to a particular communication, the group stressed the importance of timely information sharing

- In addition to the NFP, participants discussed the benefits of including senior officials involved in the notification assessment process in the guidance document's target audience (as well as representatives of the different sectors involved in IHR implementation at the national level). It was felt that their increased knowledge and understanding of the assessment and notification requirements might empower NFPs in carrying out the notification obligations.
- The guidance document should seek to standardize the processes used by States Parties for event communications in support of WHO global surveillance functions. The guidance document should also emphasize the use of Annex 2 on a routine basis as part of a risk assessment approach to notification.

2.2.3 Section 2 - Scope for notification under the IHR

- Group members indicated that the guidance document would benefit from further clarification as to the extent to which vaccine/pharmaceutical related events may fall within the scope of the notification assessment under the IHR.
- Participants mentioned that one example provided in the interim guidance concerning the scope of Annex 2 ("events outside established patterns of occurrence") does not explain the broad scope but reflects the second criterion of whether an event is considered "unusual".

- The group felt that it would be desirable to replace the table on the differences between IHR (1969) and IHR (2005) with a paragraph listing the public health benefits of notification and consultation under the IHR.
- Once again, the Technical Consultation was supportive of encouraging and emphasizing early consultation of WHO by States Parties (under Article 8) in the guidance document.

2.2.4 Section 3 - Overview: Role and function of the decision instrument

- Participants discussed the need for clarification of the timeframes required by States Parties for event assessment and notification under the IHR (i.e. initial 48-hour assessment period, then 24 hours to notify if the event fulfils two of the four decision instrument criteria of Annex 2). Where an initial assessment of an event is negative but a subsequent assessment meets the notification requirement, then it has to be notified to WHO within 24 hours following this positive re-assessment. The explanation of the "timeframes" could include a statement on the need for regular and routine assessment of events at the national level.
- The group felt that there were advantages and disadvantages to the emphasis on the notification requirement based on the fulfilment of two decision instrument criteria. In order to promote the sensitivity of the decision instrument, the focus of early risk assessment with WHO support concerning significant events should be stressed. Participants indicated that the guidance document would benefit from adopting a precautionary approach towards early event reporting by States Parties to WHO, i.e. even if an event is not notifiable using Annex 2, States Parties may nonetheless communicate/consult with WHO.

2.2.5 Section 4 - Assessment of events according to the decision instrument

- It was suggested to provide definitions of the terms "criteria", "questions" and "examples" in a separate box.
- The question of whether a single factor associated with an event should be considered under only one of the decision instrument criteria was raised. For example, the identification of a large number of related cases indicates that the event has, first, a serious public health impact (criterion one) and, second, it may be unusual or unexpected (criteria two).
- Participants raised their concern that the WHO case definitions for the four diseases requiring immediate notification to WHO call for laboratory analysis which may delay notification. It was further observed that the interim guidance document already indicates that the decision instrument criteria must also be used to evaluate events involving suspected cases of the four notifiable diseases, e.g. a single suspected case of smallpox. However, it should be further highlighted that a State Party must notify such an event to WHO if two of the decision instrument criteria are met even if laboratory confirmation is

not yet available. The group felt that this should be clearly stated in the guidance document and could be illustrated by a new case scenario using "a considered or suspected case of smallpox" to show that a clinically suspected case without laboratory confirmation may still be communicated to WHO.

2.2.6 Section 5 - Important considerations in the context of assessment and notification

- The group discussed the need to re-organize paragraphs three and four of this section. More specifically, the group felt that the points a) to d) below, which outline the key actions that WHO will or may take following notification (i.e. consequences and benefits of notification and other types of event reporting to WHO) should be taken into consideration for the revised guidance document:
 - a. Joint risk assessment with the notifying State Party.
 - b. Offer of assistance by WHO to the notifying State Party.
 - c. Provision of information by WHO to all States either using the public website and/or the restricted access IHR Event Information Site which facilitates secure communications under the IHR.
 - d. Determination of a PHEIC, e.g. description of the WHO decision-making process and standing operating procedures on when and how a PHEIC is determined and on the timeline for such a determination.
- Participants indicated that a notifying State Party must provide the outcome of its risk assessment to WHO, i.e. explaining how it came to the decision to notify, which decision instrument criteria were met, overall risk assessment, etc.
- The Technical Consultation discussed the added-value of moving the subsection on "other types of reporting to WHO" to the Introduction.
- Experts discussed and agreed to delete the summary at the end of the section.

2.2.7 2.2.7 Section 6 - Illustrations of the use of the decision instrument in a number of case scenarios

- The case scenarios were seen by the group as an essential part of the guidance document.
- It was felt that the revised guidance document would benefit from additional case scenarios to illustrate the broad scope of the IHR, including a scenario which involves one of the four disease entities requiring automatic notification to WHO.
- The group was very supportive of the scenarios, but also felt that they provided very "clear-cut" decisions, whereas in reality the assessment of public health events is usually

wrought with several "grey areas" and uncertainty. This aspect of the guidance document would benefit from further explanation in the Introduction.

2.3 Conclusions

The following conclusions were presented by the Chairperson and were the consensus of the participants.

2.3.1 General conclusions on the interim guidance document

A new, more elaborated introductory section should:

- include a short historical background on Annex 2
- emphasize the public health benefits of early communication, i.e. to motivate informed use of Annex 2
- describe WHO event management
- mention the fact that the guidance document is not legally binding

2.3.2 Specific conclusions on the interim guidance document

Section 1 - Objectives

The need to:

- include senior decision makers and other sectors involved in IHR implementation at national level as part of the target audience of the revised guidance document.
- encourage and standardize event communications in support of WHO's global surveillance functions
- promote a risk assessment approach to notification

Section 2 - Scope for notification

The need to:

- include the word “pharmaceutical” after "food" at the top of page 5
- move contents of the last paragraph to the Introduction
- replace the table with a paragraph listing the benefits of notification to WHO
- make a reference to early consultation to WHO under the IHR (Article 8)

Section 3 - Role and function of the decision instrument

The need to:

- remove "cases and" from the heading at the bottom of page 6
- switch a) and b)
- include the regular and routine assessment of national events under "Timing".
- encourage early consultation to WHO (Article 8)
- clarify the timing (i.e initial 48-hour assessment period, then 24 hours to notify (if positive, i.e. two criteria are fulfilled) and, if the initial assessment is negative, 24 hours to notify after any subsequent positive re-assessment)

Section 4 - Assessment of events according to the decision instrument

The need to:

- remove "Notifiable cases/diseases and" from the heading on page 8
- move the second paragraph after the fourth paragraph
- illustrate the definitions of the terms "criteria", "questions" and "examples" in a separate terminology box as follows:
 - a. Criteria = 4 decisions in the algorithm
 - b. Questions = 11 numbered questions supporting the assessment of each criterion
 - c. Examples = illustrations to inform the assessment

Section 5 - Important considerations in the context of assessment and notification

The need to:

- delete b) at end of paragraph 1 of considerations for notification
- include "population at risk" and “reasons for notification” as part of the information in the second paragraph

- reformat paragraphs three and four of this section under the following headings describing the key WHO actions following notification:
 - 1) Risk assessment with the notifying State
 - 2) Provision of information (more description is needed)
 - 3) Offer of support
 - 4) Determination of PHEIC (more description is needed)
- move "other types of reporting" to the Introduction
- delete the summary

Section 6 - Case scenarios illustrating the use of Annex 2

The need to:

- add the following scenarios: (1) one on toxic/pharmaceutical, radio-nuclear event; (2) one on a "notifiable disease"; and (3) one that is much less clear cut ("grey scenario") where consultation under Article 8 is important.
- describe in each learning point box the public health benefits and WHO actions (e.g. offer of assistance, assessment)
- use the same scenarios in the on-line training tool, giving information in a stepwise manner
- add and emphasize the following in the Introduction:
 - a decision as to which criteria are fulfilled may depend on the capacity to respond of a given country
 - NFPs may consult with WHO under Article 8
 - the assessment of public health events is a continuous process that must start early and be repeated when new information becomes available
 - scenarios are intentionally made more clear-cut than in the real world where assessment is often more difficult than a clear yes/no
 - users of the guidance document may arrive at different conclusions regarding the decision instrument criteria, based on their experience

3 Review and evaluation of the functioning of Annex 2

3.1 Background

To provide a context for the evaluation of the functioning of Annex 2, the Chairperson explained that event-based notification represented an important shift in paradigm from the IHR (1969). During the process of revising the Regulations, a number of countries expressed the concern that the new approach would not result in sufficiently rapid notification of relevant events to WHO. Consequently, WHO Member States decided that an assessment of the functioning of Annex 2 would be needed following the entry into force of the IHR. Specific study questions or methods, however, were not proposed. The topic was therefore included in this Technical Consultation to identify appropriate evaluation methods. The results of any studies carried out are to be submitted to the World Health Assembly for its consideration.

3.2 Discussion

3.2.1 General comments on Annex 2 studies

Experience on the evaluation of Annex 2

Several States Parties to the IHR, such as Brazil, began conducting studies on Annex 2 prior to entry into force. This evaluation of the functioning of Annex 2 involved national experts who applied the decision instrument criteria to a number of fictional events. The results of this study were validated by a panel of experts (who acted as the “gold standard”) and presented their results at a workshop in Brazil in 2006. In this study, the sensitivity of Annex 2 was shown to be 100% and the specificity 55% while the study revealed 66% concordance and 34% non-concordance. Although most participants of the Technical Consultation considered the study presented by the colleague from Brazil as a good approach for evaluating certain aspects of the functioning of Annex 2 (e.g. allowing conclusions to be drawn on the reliability of Annex 2), it was mentioned that it can provide only limited information on its validity. For instance, it was remarked that a low level of reliability revealed by a concordance study would indicate that the validity is also low, but high degrees of concordance would not necessarily indicate that validity was also high. In addition to the studies from Brazil, the Chairperson reported that Annex 2 was tested during a training course involving Nordic, Baltic countries and Russia. This training involved 10 case scenarios that looked at concordance for each of the four decision instrument criteria, with favourable results.

Methodological Challenges

The self referential nature of Annex 2 and the text of the IHR mean that there is no external "gold standard" against which to compare the functioning of the decision instrument. In addition, it might be methodologically difficult to distinguish the question of whether the tool is used appropriately by States Parties from whether it is a good instrument, i.e. helping States Parties to notify important events to WHO.

Prioritization of evaluation studies

Because the implementation of Annex 2 is at an early stage, the first focus of the review studies should be on the usage of the tool by countries and the problems encountered when working with the tool, as well as the identification of the variability in use and understanding of the objectives of the Annex between countries. It is too soon to evaluate the full impact of the tool on international notification. A study plan should be presented to the 62nd WHA to show that an appropriate process of evaluation is being initiated. A later stage of the evaluation should then address the functioning of the international surveillance tool itself.

3.2.2 Discussion on study objectives for evaluating Annex 2

Utilization of the tool

The group indicated that an evaluation of Annex 2 should look at how (well) it is being used, who is using it and barriers to its use, i.e. the actual **utilization of the tool** by States Parties at the national level. The study should also identify the reasons for variation in levels of awareness and utilization by countries. The recognition of challenges to the effective use of Annex 2 will help to identify appropriate interventions to improve utilization (e.g. regular support by the WHO Country Office). It was felt that carrying out a qualitative study involving a limited number of States Parties would be the best way to obtain meaningful results for such an evaluation.

Effectiveness of the tool

Participants discussed the need for studies to address the **effectiveness of the tool** itself; i.e. does it achieve what it meant to achieve; is it a useful tool for the identification of relevant events? Despite some uncertainty regarding the feasibility of measuring the sensitivity and specificity of Annex 2 in a quantitative way, it was thought useful to measure how some representative NFPs would judge certain fictitious or real life events for a given situation, as provided in the teaching module or guidance document on Annex 2. In order to elucidate this question, an in-depth interview alone would not suffice. However, the difficulty of measuring the political considerations on whether an incident has a positive or negative outcome regarding notification was recognized.

Impact of use

The concern was raised that the review and evaluation of the **impact of use** could overburden the expectations regarding the Annex. It would be unrealistic to expect that this notification tool could solve all the organizational problems of national or international public health risks and emergencies, e.g. rate and timeliness of notifications or results of public health response following notification. Therefore, it was felt that the evaluation of the Annex should be limited to its actual purpose: to provide a sensitive case definition for the assessment and notification of public health events. However, a number of participants stressed the importance of assessing the effects of the use of Annex 2. In particular, the impact of Annex 2 on the timeliness of notification was seen as an issue. Questions addressing broader public health benefits flowing from the use of Annex 2 were found to be relevant, but they need not be asked of every State Party. These broader questions include the impact on overall event-related communications between countries and WHO, the effect on public health responses and the influence on both national surveillance systems and decision-making processes with respect to notification.

3.2.3 Discussion on study questions

Based on a presentation and the foregoing discussion on the evaluation of the functioning of Annex 2, the participants proposed the following study questions:

- Study questions related to the evaluation of the use of Annex 2:
 - a) Are States Parties aware of Annex 2?
 - b) Do States Parties understand the purpose and contents of Annex 2?
 - c) Are States Parties actually using Annex 2?
 - d) Do States Parties consider Annex 2 to be user-friendly?
 - e) Do States Parties consider Annex 2 to be useful? What are the positive effects?
 - f) What are the practical experiences of States Parties in using Annex 2 and what difficulties/challenges have been faced (who, how, when, why)?
 - g) What activities have been undertaken to implement Annex 2 (training on Annex 2, strengthening infrastructure for surveillance and risk assessment)?

- Study questions to assess the reliability/concordance of Annex 2:
 - h) Are NFPs concordant in the judgment of certain described events using Annex 2?

These study questions were then addressed by four breakout groups to come up with appropriate study methodologies.

3.3 Conclusions

3.3.1 Conclusions on study methodologies

Regarding the identification of appropriate study methodologies for the review and evaluation of Annex 2, the Chairperson summarized the conclusions.

Methodologies

1. Qualitative study (to be implemented by an independent entity): Pilot before 03/09?
2. Survey (to be implemented by: WHO or an independent entity): Pilot before 03/09?
3. Study of concordance (to be implemented by WHO or an independent entity): Pilot before 03/09?
4. WHO HQ/RO databases study (to be implemented by WHO): Before 03/09; results to be submitted to 62nd WHA

Design of the qualitative study

- To address study questions: a) to g)
- Contact through: NFP as the entry point to the selected States Parties, but to include other relevant country stakeholders
- Informants: Risk assessors at the national level (and other sectors)
- Data collection: telephone interviews or focus groups in a representative sample of States Parties
- Data collection instrument: Interview guide with open questions
- Sample: Approximately 20 countries, fairly representative concerning size, region, developmental level, progress on IHR implementation and other factors
- Anonymity: Anonymous report

Design of the survey

- To address study questions a) to g)
- Contact through: NFP as the entry point to the selected States Parties, but to include other relevant country stakeholders
- Informants: risk assessors at national level
- Data collection: E-mail survey possibly linked to other WHO progress reporting for IHR

- Data collection instrument: questionnaire with closed and open questions in the six official languages (web-based)
- Sample: All States Parties (manage duplication)
- Anonymity: Anonymous report (optional: States Parties send copy of questionnaire to WHO Regional Offices)

Design of the concordance study

- To address study question: h)
- Contact through: NFP as the entry point to the selected States Parties, but to include other relevant country stakeholders
- Informants: risk assessors at national level
- Data collection: Mail survey (and/or WHO intercountry/regional IHR meetings)
- Data collection instrument: (Web-) Questionnaire with a number of case scenarios (fictitious or real-life) to assess reliability (consistency/reproducibility of notification assessment)
- Sample: All States Parties
- Anonymity: Anonymous report
- Feedback: Comments on report (possibly by expert panel) with information on global distribution of responses plus some information on what WHO would do with the event (assessment, offer of support, information sharing, PHEIC determination etc.)

Design of the WHO databases study

- Study question: Experience of event surveillance since 15 June 2007, including the relationship between notified events and other events recorded by WHO and events that States Parties have enquired WHO about as these events occurred elsewhere (indicator of "sensitivity").
- Method: Review of WHO Event Management System and other relevant WHO databases at HQ and in WHO Regional Offices.
- Informants: WHO staff, HQ and WHO Regional Offices

4 Agenda



WORLD HEALTH ORGANIZATION

WHO Technical Consultation on the Implementation and Evaluation of Annex 2 of the International Health Regulations (2005)

WHO Headquarters, Geneva, Switzerland

20 to 22 October 2008

Day 1: 20 October 2008

Room M605, M Building

08:00 - **Registration**
09:00

09:00 - **Opening**
09:40

Welcome and opening notes	David Heymann, ADG/HSE
Objectives and overview of the meeting, and administrative matters	Max Hardiman, Coordinator
Endorsement of the meeting Chair and Rapporteur	Max Hardiman
Adoption of the agenda	Chair
09:40 - Session 1: Guiding use of Annex 2 - work to date and the following process 10:30	Chair
Overview of the WHO interim guidance and the development process (20')	Helge Hollmeyer
WHO training module on the use of Annex 2 (10')	Pierre Nabeth
Questions and comments on the process and general content of the interim	Max Hardiman

	guidance (20')	
10:30 - 11:00	Refreshment Break (30')	
11:00 - 12:00	Session 2: Review of the interim guidance for the use of Annex 2	Chair
	Discussion (60') on explanations in the interim guidance concerning: <ul style="list-style-type: none"> ▪ Objectives of the guidance document (Section 1) ▪ Scope for notification under IHR (2005) (Section 2) ▪ Role and function of the decision instrument (DI) (Section 3) 	Bruce Plotkin
12:00 - 13:30	Lunch Break	
13:30 - 14:30	Session 3: Review of the interim guidance for the use of Annex 2	Chair
	Continued discussion (30') on <ul style="list-style-type: none"> ▪ Assessment of events according to the DI (Section 4) ▪ Further considerations for assessment and notification (Section 5) 	Max Hardiman
	Finalizing views, and discussion on any other important issues regarding the first part of the interim guidance (30')	Max Hardiman
14:30 - 15:30	Session 4: Case scenarios illustrating use of the Decision Instrument	Chair
	Discussion on the case scenarios of the guidance (60') (Section 6)	Helge Hollmeyer
15:30 - 16:00	Refreshment Break (30')	
16:00 - 17:00	Session 5: Review and evaluation of the functioning of Annex 2	Chair
	Introduction to potential study questions and methods to answer these questions (20')	Helge Hollmeyer
	Questions and comments on the proposed study questions and corresponding methods (40')	
17:00 - 17:15	Wrap up of Day 1 (15')	Chair

Day 2: 21 October 2008

Room M605, M Building

09:00 - 09:15	Opening: summary of Day 1, overview of Day 2 (15')	Chair
09:15 - 10:30	Session 6: Identification of study questions to review and evaluate the functioning of Annex 2 - What should be evaluated? Finalizing views on appropriate study questions (75')	Chair
10:30 - 11:00	Refreshment Break (30')	
11:00 - 12:00	Session 7: Breakout sessions on the Annex 2 study methodologies - How to evaluate? Four breakout sessions in parallel on the appropriate methods to address the identified study questions - Rooms M205, M405, M505, M605 (60')	Chair
12:00- 13:30	Lunch Break	
13:30 - 15:00	Session 8: Identification of the appropriate study methodologies Presentation from each group on appropriate methodologies to answer specific study questions (40') Discussion on the appropriate study design (50')	Chair
15:00 - 15:30	Refreshment Break (30')	
15:30 - 16:00	Session 9: Implementation of evaluation study - Who should conduct the evaluation? Discussion on appropriate partners for study implementation (30')	Chair
16:00 - 16:45	Session 10: Other activities to make the implementation of Annex 2 more useful Discussion on additional activities to support application of Annex 2 (60')	Chair
16:45 - 17:00	Wrap up of Day 2 (15')	Chair

Day 3: 22 October 2008

Room M105, M Building

09:00 - 9:15	Summary of Day 2, overview of Day 3 (15')	Chair
09:15 - 10:15	Session 11: Conclusion and recommendations on WHO guidance for Annex 2 (60')	
10:15 - 11:30	Session 12: Conclusion and recommendations on the study to evaluate the functioning of Annex 2 (75')	
11:30 - 11:45	Chair's summary (15')	Chair
11:45 - 12:00	Closing remarks (15')	Max Hardiman

5 List of participants

WHO Technical Consultation on the Implementation and Evaluation of Annex 2 of the International Health Regulations (2005)

WHO Headquarters, Geneva, Switzerland

20 to 22 October 2008

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