



**World Health
Organization**

Development of Stockpiles for Radiation Emergencies

Report of the Radio-Nuclear Working Group

**WHO consultation meeting on Development of Stockpiles
for Radiation and Chemical Emergencies**

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Radio-nuclear Working Group (RNWG)

On the photo left to right: Makoto Akashi, Wendla Paile, Steven Bice , Zhanat Carr, Sigfrid Joussineau, Richard Hatchett, Volker List, Maria del Rosario Pérez, Valery Krasnyuk, Ying Liu, Charles Miller, Nicholas Dainiak, Albert Wiley, Michael Hopmeier, Nelson Valverde.
(absent from the photograph: John Croft, Harald Dieter Dör, Viktor Meineke and Hilary Walker)

SUMMARY

The exposure of an unwitting population to radioactive material in an uncontrolled manner, whether intentionally or by accident, is an ever increasing possibility in the current world situation. It is thus vital that the WHO maintain the resources and wherewithal to respond to and assist Member States (MS) in such events.

In this context, a Consultation Meeting on the Development of Stockpiles for Radiation and Chemical Emergencies was convened by the WHO at its headquarters (HQ) in Geneva, between 14th and 16th February 2007. The purpose of this WHO consultancy meeting was to draft technical concepts for radiological and chemical stockpiles. The Working Groups (WG) began the process of defining the needs (composition, criteria for use, formulary, training, etc) of a stockpile for radio-nuclear and chemical emergencies to be maintained and operated by WHO and its subordinate organizations. The meeting brought together experts from WHO MS.

Specific issues were discussed in parallel working sessions by the radiological and chemical countermeasures groups. These two separate expert groups reported their outputs during a final Plenary Session during which general conclusions and recommendations were agreed by the participants. This report summarizes the meeting discussions, conclusions and recommendations for the next steps WHO might take concerning stockpiling for radio-nuclear emergencies.

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1. OPENING PLENARY SESSION

The meeting began with a Plenary Session opened by Dr Susanne Weber-Mosdorf, Assistant Director-General, Sustainable Development and Healthy Environments and Dr Ala Alwan, Assistant Director-General, Health Action in Crises, who welcomed all the participants.

Dr. Weber-Mosdorf noted that the environment has an increasing effect on human health and that promotion of a healthy environment is an important objective for WHO. She also noted that preparedness and response to environmental emergencies is part of this objective and that the revised International Health Regulations (IHR) would provide a global framework to address these needs through the prevention, detection, and timely response to any public health emergency of international concern.

She mentioned that emerging threats underline a growing need for a multiple hazard approach including biological, chemical and radio-nuclear risks and that this meeting would be a milestone in developing a stockpile to be rapidly available for countries.

Dr Alwan mentioned that, based on experience from past crises and the increasing number of disasters worldwide, WHO had launched an initiative to scale up health action in emergency preparedness, response and recovery. He stressed the need for building MS capacities to address emergencies and crises through an "all hazard" approach and highlighted the role of WHO as the lead organization of the health sector. He reiterated that one of the key areas in emergency preparedness and risk management is environmental health and that the WHO Department of Public Health and Environment has a leading role in this field. He described the importance of the meeting and stressed the need for a secure stockpile ready to use in chemical and radio-nuclear emergencies.

After expressing her great pleasure and satisfaction for hosting the meeting and thanking all the participants for their engagement in this event, Dr. Maria Neira, Director of the Department of Public Health and Environment (PHE), gave a lecture on Preparedness and Response to Environmental Threats.

Dr. Neira referred to the influence of environmental risk factors on human health, noting that 24% of global disease burden and 23% of deaths are attributable to environmental factors¹. In children, environmental factors can account for more than one-third of the disease burden. These findings have important policy implications, because the environmental risk factors can be modified by established, cost-effective interventions.

She spoke about the new challenges of global environment e.g. urbanization, proliferation of chemical and radio-nuclear technologies, deliberate threats and hazardous waste. She mentioned the conference "Citizens of the Earth" held in Paris on 2-3 February 2007, during which an international call for global ecological governance had been launched.

Then she described WHO's environmental health activities undertaken by PHE, reminding that environmental health comprises those aspects of human health determined by physical, chemical, biological, social, and psychosocial factors in the environment. She also explained that the assessment, correction, control and prevention of those factors in the environment that can

¹Preventing disease through healthy environments: towards an estimate of the environmental burden of disease (WHO-2006) in: http://www.who.int/quantifying_ehimpacts/publications/preventingdisease.pdf

potentially affect adversely the health of present or future generations are part of environmental health actions such as:

To attain safe, sustainable and health-enhancing human environments, protected from biological, chemical and physical hazards, and secure from the adverse effects of global and local environmental threats;

To facilitate incorporation of effective health dimensions into regional and global policies affecting health and environment, and into national development policies and action plans for environment and health, including legal and regulatory frameworks governing management of the human environment.

To achieve these goals, PHE Department has established several strategic directions to:

- *Provide health leadership on international environment policy:*
provision of norms, standards, guidelines; evidence and global monitoring.
- *Reinvigorate WHO leadership in risk assessment and management:*
focus attention on priority chemical, microbiological, and radiological hazards.
- *Provide a "preventive health" perspective within WHO:*
new health sector emphasis on "preventive actions" addressing environmental risks to health.
- *Prepare for, and respond to, environmental emergencies and disasters*².
e.g. REMPAN³ and the chemical arm of WHO alert and response.
- *Identify and respond to emerging threats.*
e.g. energy and health; radiation and EMF.
- *Focus action through integrated healthy settings approaches:*
mobilize local awareness and support through action in communities, homes, markets, workplaces and schools.

Dr. Neira explained that all countries should have in place well established, tested and effective environmental health (EHE) management systems including prevention, preparedness, alert, response and recovery. She stressed the importance of this meeting to extending further the existing WHO stockpiles for radiation and chemical emergencies, to be better prepared and to respond better to a country's needs if a disaster should occur.

She noted that this consultation meeting would focus on medical and other supplies to be stockpiled, so that they can be made rapidly available when needed. She added that complementary efforts would be made to develop and maintain a roster of environmental health experts available for rapid deployment to assist countries in emergency response. She also noted that the nature of this work on incidents or emergencies, whether natural, intentional or accidental, requires a high level of coordination with a variety of partners, not only within WHO but also through the wider UN system as well as with external partners.

She summarized the questions to be discussed during this consultation meeting such as:

- for whom is the stockpile intended?
- what are the scenarios and circumstances for which the stockpile will be deployed?
- how can the stockpile be established?

² For more information see WHO Guide on Environmental Health in emergencies and disasters
http://www.who.int/water_sanitation_health/emergencies/emergencies2002/en/index.html

³ Radiation Emergency Medical Preparedness and Assistance Network

- how large should the stockpile be?
- what training is required?

The consultation would agree on emergency scenarios and a generic list of supplies and equipment that should be made available internationally. Discussion would include the logistics of supplies pre-positioned at UN warehouses for dispatch to MS requiring assistance. In addition a set of ground requirements needed developing for education, training and exercise to make use of the WHO stockpile.

Next, the participants briefly introduced themselves, their organizations and professional profiles, and formally adopted the proposed agenda.

An overview of international health response to emergencies was then presented, which included the following issues:

International Health Regulations (Dr Max Hardiman);

WHO Epidemic and Pandemic Alert and Response (Dr Michael Ryan);

WHO Health Action in Crisis Situations (Dr Jules Pieters); and

WHO Environmental Health Emergency Response (Dr Kersten Gutschmidt and Dr Zhanat Carr).

Dr M. Hardiman explained that one of the main challenges from the new horizon of public health is achieving international public health security and that the enactment of the revised International Health Regulations (IHR) provides a legally binding global agreement to protect public health by preventing, detecting, assessing and responding to public health emergencies that have potential for international spread.

IHR revision resulted in a completely different approach to Epidemic Alert and Response (EPR), with a broader scope which now includes every public health event with potential for becoming of international concern, whatever the causal agent and/or irrespective of its origin. Because of this broader scope, certain chemicals and radio-nuclear emergencies may now fall within the scope of IHR.

He explained that IHR implementation is an obligation for States party to these regulations and also for WHO. Under IHR there is a requirement for States to establish national core capacities for detection and response. IHR also place an obligation on WHO to support MS in responding to public health risks. In this context, stockpiling is a relevant aspect of preparedness and response closely related to national core capacity as well as to international assistance. IHR also imply obligations for notification and verification of the event. Finally, Dr. Hardiman stressed that the potential for international spread of public health emergencies can be avoided by early preparedness at both national and international levels.

Dr M. Ryan referred to global public health security epidemic and pandemic alert and response (EPR) based on strengthening national response and effective international assistance. He noted that in those situations, immediate access to the appropriate expertise and resources is needed and no single institution has all the capacity for responding. As an example he mentioned the Global Outbreak Alert and Response Network (GOARN) which is a partnership coordinated by WHO. Under GOARN around 500 international experts from 60 countries aimed to provide the framework to mobilize and connect resources for the control of known and emerging disease outbreaks which have threatened national and global health security.

He presented a broader concept of risk management including disease risk identification and characterization; disease risk reduction; disease-specific preparedness; event detection/

investigation and risk assessment; event response, evaluation and audit of response and future risks. He noted that development of national core capacities is among the major priorities for EPR/ IHR and therefore establishment of stockpiles is a relevant issue.

Dr. J. Pieters said the WHO is the leading agency in health crises and referred to Health Action in Crises (HAC) as the cluster which coordinates emergency and crisis preparedness, response and recovery. He explained that crises (overwhelmed local and national systems) may be triggered by sudden, catastrophic events as well as by complex continuing emergencies and slow onset disasters, in many diverse scenarios e.g. natural disasters, technological disasters and deliberate events. He spoke about HAC activities including health assessment and tracking; co-ordinating health actions; identifying and filling the gaps in the response; building/strengthening local capacities; developing an operational platform concerning staff, transport, communication, equipment and supplies. He mentioned public health pre-deployment training activities and their importance for the establishment of an emergency roster (potential need for rapid deployment of a team, under the leadership of environmental health specialists).

Concerning the development of stockpiles he stressed the need of health-related supplies pre-positioned at the 5 regional hubs for rapid deployment: Panama, Brindisi, Accra, Dubai and Subang. He mentioned several factors to be taken into account for stockpile development such as personal protection equipment (PPE), vehicles, survival kits, information technology and communications, the means for transport and rapid deployment.

He noted that chemical and radio-nuclear emergencies have collateral implications such as the need for a wide network of health partners, interagency coordination, safety and security issues, mass evacuation and population displacement.

Dr. Gutschmidt and Dr. Carr gave a joint presentation on WHO Environmental Health Emergency Response. They explained that chemical and radio-nuclear threats have significantly increased. They noted that world chemical industry outputs have risen from less than 200 billion dollars in the 1970's to more than 1500 billion dollars at the end of the 1990's⁴. In addition a 34-86% increase in nuclear electricity generation by nuclear power plants is projected by 2030⁵. They also mentioned the additional threats posed by the deliberate and malevolent use of biological agents, chemical substances or radioactive sources. They drew parallels between the "traditional" vs. the "new" challenges concerning environmental health in natural and complex disasters i.e. unsafe water, poor sanitation and lack of hygiene vs. release of hazardous agents/material and waste management.

They explained that technological disasters are almost as frequent as natural disasters, although their consequences may be quite different. As an example of this, they presented statistical data concerning 5989 global disasters that occurred between 1995 and 2004⁶ showing that 3199 (54%) were due to natural processes and 2780 (46%) were technological disasters. However, around 90% of deaths and more than 99 % of people affected were due to natural disasters.

⁴ Source: OECD Environmental Outlook for the Chemicals Industry (2001) OECD, Paris.

⁵ Source: Nuclear Technology Review – Update 2005, IAEA.

⁶ Source: World Disasters Report 2005, International Federation of Red Cross and Red Crescent Societies; and EM-DAT: The OFDA/CRED International Disaster Database - Université Catholique de Louvain - Brussels - Belgium.

They noted that the framework for EHE actions includes the revised IHR as well as the international humanitarian assistance⁷ upon request from MS.

They stated that WHO is a recognized and authoritative voice in the international policy agenda for EHE, based on two pillars: all countries should have in place well established, tested and effective environmental health systems to reduce disease burden from emergencies ("national capacity building"); and all countries should have access to a WHO system for international environmental health assistance in emergencies ("international alert and response").

They highlighted the WHO endeavors to achieve these goals. These included advocating for strengthening environmental health management in emergencies at individual country level by providing technical support such as guidelines, tools, and training; and establishing critical mass capacity to supplement countries in dealing with EHE that overwhelm their national response abilities. These objectives should address all stages of the EHE cycle, namely prevention, preparedness, alert, response and recovery. EHE planning should cover uncontrolled and unexpected releases of chemicals and radio-nuclear material, environmental risk factors in outbreaks of infectious and non-infectious disease and disruption of environmental health services in emergencies (e.g. water and sanitation).

Concerning international response to EHE, they firstly stressed the need for developing a roster of experts to be deployed (i.e. qualification criteria, profiles, identification, training, pre-deployment preparedness, maintenance of roster). They then stressed the need for establishing strategic stockpiles for rapid release (i.e. criteria, lists, pre-positioning strategies, standard operation procedures, financing, maintenance and dispatching, etc). Finally they noted the requirement for other types of assistance in EHE, such as providing information "off the shelf" and use of existing infrastructures (e.g. laboratories).

2. RADIO-NUCLEAR WORKING GROUP

The Radio-Nuclear Working Group (RNWG) included 18 external experts from 10 MS and WHO staff members from various departments (see Appendix 2: RNWG participants list). The group addressed the conceptual and practical definition of a stockpile of medical countermeasures for application to nuclear and radiological emergencies. Working Sessions were managed by Dr Zhanat Carr, and were co-chaired by Dr Steven D. Bice and Dr Michael Hopmeier. Dr Maria del Rosario Pérez was rapporteur.

After considerable discussion the expert group agreed on the need for a stockpile of medical countermeasures to be managed by WHO and they recommended next steps for achieving this goal and made recommendations to WHO and MS (please see Para 20 RNWG Recommendations).

⁷ The Inter-Agency Standing Committee (IASC) is a forum for inter-agency coordination of humanitarian assistance, involving the key UN and non-UN humanitarian partners. For more information see <http://www.humanitarianinfo.org/iasc/content/about/default.asp>

3. WHY A WHO STOCKPILE FOR RADIO-NUCLEAR EMERGENCIES?

The RNWG believed it necessary to first debate and agree whether WHO should in fact maintain and manage a medical countermeasures stockpile for radio-nuclear emergencies. After considerable discussion, the following points were agreed by the group:

- Today's world faces a changing and evolving environment wherein global safety and security are key issues
- RN emergencies may have a low probability of happening, but they could result in very high impact-events
- WHO is the leading international organization in public health and has both the authority and responsibility to assist in radio-nuclear (RN) emergencies.

Medical research and development continues to offer the world new applications of ionizing radiation in diagnostic and interventional radiology, radiotherapy and nuclear medicine. Moreover, the world-wide use of radioactive sources in research and industry has increased during recent years. Approximately, 435 nuclear power reactors are operational today, and forecasters predict that the nuclear industry will grow quite rapidly.⁸ Despite the fact that accidents involving radiation sources can usually be prevented by application of radiation safety standards and regulatory controls, they (accidents and/or sabotage) may occur and we must be prepared to deal with the consequences. Radiological accidents⁹ are significantly more frequent than nuclear accidents¹⁰ and, depending on the scenario, their consequences may be very severe. The proliferation of nuclear material and technology has increased the risk of radiological and nuclear accidents as well as the risk of acquisition and malicious use of radioactive material. Indeed, there exists an increasing international concern about the probability of unforeseen or illicit activities involving radioactive sources. The political instability of some nations and current regional conflicts contribute to the possibility of terrorist attacks that may use radiological dispersal devices or small nuclear weapons. As a consequence, the probability of a mass casualty event with significant environmental impact is higher now than ever before. A stockpile which contains medical countermeasures may save hundreds of lives and mitigate against suffering for thousands. Medical supplies are an essential aspect of radiation emergency planning and response, since ultimately the main goal of any emergency response must be to save lives and to minimize health consequences. This philosophical statement indicates a clear need for improving preparedness and response to nuclear and radiological emergencies.

The success for enhancing international medical assistance in nuclear and radiological emergencies depends, among other things, on local health care capabilities worldwide and on the ability to respond effectively to such events with the necessary pharmaceutical and medical supplies and equipment. Depending on the magnitude of the event, regional resources may not be sufficient. Thus, the creation of a WHO stockpile for radiation emergencies would serve as an

⁸ Data up-dated in January 2007 by World Nuclear Association: 435 operational nuclear power reactors (NPR) ; 28 NPR under construction; 64 planned NPR and 158 proposed NPR.

⁹ Accidents involving radioactive sources are commonly referred as "radiological accidents"

¹⁰ Accidents involving nuclear fission, more often related to nuclear reactors, are commonly referred as to "nuclear accidents".

important strategic resource for efficient response in the case of emergencies involving ionizing radiation.

A WHO stockpile for radiation emergencies (or SP) would be set up and run by WHO. Such a stockpile must be complimentary to and integrate with existing national stockpile programmes in countries around the world. While many of these stockpiles were initially designed for biological and chemical agent response and environmental hazards assistance ("all-hazards approach"), several now also include radio-nuclear medical countermeasures. The RNWG was made aware of existing WHO facilities and the group strongly suggests that where feasible they should be expanded to include a RN medical stockpile whilst ensuring that this does not lessen their capacities to respond to any form of emergency.

Finally, the RNWG agreed that the stockpile is a tool to achieve the goal of medically protecting and/or treating victims of accidents or incidents and not an end unto itself. The WHO SP is intended to assist MS upon their request should local biomedical supplies be depleted or are unavailable.

4. ROLE OF WHO

The World Health Organization (WHO) is the United Nations' specialized agency for public health and medical issues. It was established on 7 April 1948. WHO is governed by the World Health Assembly, which is composed of representatives from the 193 WHO's MS.

WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The role and responsibilities of WHO with respect to health emergencies has been set out clearly by the United Nations (UN) Inter-Agency Standing Committee for humanitarian purpose (IASC). Within the system, WHO is the focal point for all health matters related to emergency preparedness, emergency response and disaster reduction/mitigation. Moreover, the entry into force of the IHR on 15th June 2007, provides a new legal framework in which to deal with potential public health emergencies of international concern. As a result of the IHR, WHO now has a much stronger position than it previously held and is indeed a key decision-making partner for international public health. This was achieved thanks to the following elements:

WHO voiced a clear commitment based on the UN mandate and the role of the organization as the leader in international health.

WHO based its strengths on the technical excellence available within WHO at large and the extended field presence and networks we benefit from.

WHO has adopted a seven-point global health agenda, with human health security being a key aspect.

WHO has enhanced operational and financial capacity.

To support the response to radiation disasters, the WHO created the Radiation Emergency Medical Preparedness and Assistance Network (REMPAN). REMPAN is a network of collaborating centers and liaison institutions for the promotion of radiation emergency medical preparedness and for practical assistance and advice to countries in the case of overexposure from any source of radiation. The primary objectives of REMPAN are to promote medical

preparedness for radiation accidents and radio-nuclear threats among WHO MS; to provide medical and public health advice, assistance and coordination of medical management at international and regional levels in the case of a nuclear accident or radiological emergency; and to assist in follow-up studies and rehabilitation. REMPAN places WHO in a legal position to undertake the role of managing public health issues arising from a radiological event, to analyze and counter impacts upon and offer medical mitigation to affected populations. A stockpile is one tool which may be required to assist the WHO in achieving these objectives.

5. ROLES OF OTHER ORGANIZATIONS

IAEA is the leading agency for response in nuclear and radiological emergencies. Upon request, IAEA could deploy an expert team to provide consultation and/or assistance. In this context, the Convention on Early Notification of a Nuclear Accident and the Convention of Assistance in the Case of a Nuclear Accidents or Radiological Emergency, set out an international framework for international co-operation in the event of nuclear accidents or radiological emergencies. WHO has endorsed these conventions along with other international organizations.

Pursuant to the obligations placed by these conventions, the IAEA regularly convenes the Inter-Agency Committee on Response to Nuclear Accidents (IACRNA), which is the coordination mechanism for international arrangements for preparedness and response to radiation emergencies. WHO is a key partner of the IACRNA and has also co-sponsored the Joint Radiation Emergency Management Plan of the International Organizations¹¹ ("Joint Plan") with IAEA; PAHO; FAO; WMO; EC, NEA/OECD, EUROPOL, INTERPOL, OCHA, OOSA, UNEP, ICAO, IMO and UNSCEAR.

The Joint Plan describes the inter-agency framework for preparedness and response to an actual, potential or perceived radiation emergency irrespective of its cause. The IAEA has the prime responsibility to activate this inter-agency response system. Any participating international organization that receives a request for assistance in response to a radiation emergency will inform the IAEA and the other relevant international organizations and coordinate the provision of assistance with them. If a State requests IAEA's assistance under the Assistance Convention, the IAEA will:

- inform the relevant international organizations which could provide assistance;
- evaluate the situation, in coordination with relevant international organizations, and may send an initial assessment team;
- develop, in coordination with other international organizations, a detailed assistance action plan;
- upon acceptance of this plan by the requesting State, obtain authorization from relevant competent authorities and international organizations for deployment of assets.

The IAEA's global Response Assistance Network (RANET) is a resource to co-ordinate the provision of assistance within the framework of the Assistance Convention. RANET is a system of Competent Authorities capable and willing to provide, upon request, specialized assistance by appropriately trained, equipped and qualified personnel with the ability to respond timely and effectively to nuclear accidents or radiological emergencies and other nuclear or radiological events. It is a compatible and integrated system for provision of international assistance to

¹¹ See Joint Plan document at http://www-pub.iaea.org/MTCD/publications/PDF/JPLAN2006_web.pdf

minimize actual or potential radiological consequences of an incident or emergency for health, environment and property. RANET does not affect co-operation arrangements defined in any bilateral and/or multilateral agreements¹². RANET's areas of assistance include advisory, assessment and evaluation, monitoring and recovery. More information about RANET can be found in EPR-RANET 2006 publication and its three attachments¹³:

Complex emergencies may result from natural disasters, technological accidents or deliberate events. WHO epidemic/pandemic alert and response (EPR) outbreak mechanisms, procedures and systems are largely the same, while players may be different. In radio-nuclear events, coordination mechanism for international arrangements should be implemented according to the Joint Plan¹⁰. If a humanitarian crisis arises, the Inter-Agency Standing Committee (IASC)¹⁴ will coordinate the delivery of humanitarian assistance.

While IAEA coordinates the global response to radiation emergencies, WHO is the leading international organization on public health and the only UN agency with a specific mandate for health. Environmental Health Emergencies (EHE) constitute an important aspect of public health. Since efficiency and efficacy of strategic stockpile management is essential in EHE, WHO should take the leadership of organizing stockpiling around the world and for managing its mobilization.

6. ISSUES ADDRESSED BY THE RNWG

During the meeting, the working group discussed the following issues:

1. Meeting outputs
2. Assumptions
3. Scenarios for use of the stockpile
4. Concept of Operations (ConOps): Conditions under which the stockpile would be used, and the overall strategy and goals for its use
5. The need to create a policy and set of guidelines for use of the stockpile, including establishment of a doctrine of use
6. Content, amount, and consistency of the stockpile: the formulary

¹² The question about how would RANET respond in a mass casualty event was mentioned. No definite answers were proposed and further discussion concerning mass casualty management is still needed

¹³ EPR-RANET 2006 http://www-pub.iaea.org/MTCD/publications/PDF/Ranet2006_web.pdf
 RANET Assistance http://www-pub.iaea.org/MTCD/publications/PDF/Ranet2006_att1_web.pdf
 RANET Registry http://www-pub.iaea.org/MTCD/publications/PDF/Ranet2006_att2_web.pdf
 RANET Tec. Guidelines http://www-pub.iaea.org/MTCD/publications/PDF/Ranet2006_att3_web.pdf

¹⁴ The UN Office for the Coordination of Humanitarian Affairs (OCHA) has the mandate of coordinating humanitarian response, policy development and humanitarian advocacy. OCHA carries out its coordination function primarily through the Inter-Agency Standing Committee (IASC), which is chaired by the Emergency Relief Coordinator (ERC).

7. Cost, sources of supply and on-going resource commitment
 - a. Stockpiles at the regional logistic hubs
 - b. MS pledges for stockpile support
 - c. Manufacturers' pledges for stockpile support
8. Personnel, staffing, training, maintenance and support needed to implement the WHO SP concept of operations
9. Requirements of host/user nations to support and interface with the stockpile
10. WHO's operational interface with WHO Regional Offices and non-WHO organizations
11. Ongoing evaluation and assessment of the stockpile and its relevance to evolving treatment protocols, world environment and missions
12. Miscellaneous: including but not limited to indemnification and liability, insurance, compensation of responders (emergency response differentials), restocking of used supplies, roles of contractors and consultants.

Please note that the report further elaborates on above points 1-12.

7. OUTPUTS OF THE MEETING

Outputs from the RNWG deliberations include:

- This report which endeavors to either answer or better define the issues raised in 1-10, above. It summarizes the conclusions from the discussions and provides selected recommendations on what might be the next steps for WHO (See also Annex 1, this report);
- a generic list of supplies/equipment (formulary) that should be made available internationally (if requested) for radiation emergencies (included in this report);
- a sub-list of these supplies that should be pre-positioned at UN warehouses to be dispatched to MS requesting/accepting assistance (to be included in subsequent reports);
- the use of additional supplies (other than those in the WHO stockpile) including “off the shelf” supplies held by manufacturers, other stockpiles if volunteered, etc (not included in this report—requires additional research);
- a set of requirements for education/training/exercise to make use of the WHO stockpile (not included in this report—requires additional research).

8. ASSUMPTIONS

The RNWG considered and adopted the following assumptions during the course of deliberations. These assumptions defined the concept of operations of the WHO SP:

- First response is provided by local authorities;
- WHO SP anticipated to arrive no sooner than 48 h after the event
- WHO SP sized to treat approximately 200 people for ten days
- MS with the advice/assistance from IAEA (if required) are responsible for environmental exposure monitoring and assessment;
- WHO SP will include supplies for biodosimetry and bioassay sampling and coordinate processing abroad if needed;

- Radioactive waste management is provided by local authorities;
- Affected MS has at least basic/modern health-care facilities;
- Conventional drugs (e.g. to treat conventional injuries) are available locally.

The RNWG realizes that these assumptions may (and should) be re-evaluated on a regular basis and if found to be inappropriate, the RNWG recommends they be updated, based on experience and further discussion.

9. INITIAL SCENARIO AND POTENTIAL EVENTS REQUIRING RESPONSE

The following scenarios were considered:

- Nuclear reactor accidents;
- Radiological industrial accidents;
- Accidental over-exposure of radiotherapy patients;
- Exposure to lost/stolen sources
- Transportation accidents
- Radiological Dispersal Device (RDD, e.g. dirty bomb)
- Radiological Exposure Device (RED, e.g. deliberately concealed source)

The RNWG agreed specifically to exclude a WHO response to an intentional or accidental nuclear weapons explosion (from modern military weapon or an improvised nuclear device or IND¹⁵). The RNWG assumed that, if a nuclear weapon or IND is detonated, the entire world will mobilize to assist the affected population and that the world's superpowers will be on heightened security. In this case, WHO would play a supportive role rather than act as the lead international agency. Clearly, WHO will assist in the international medical/public health response to mitigate the consequence of the detonation¹⁶. In addition, the RNWG agreed to exclude events that are within the ability of the affected nation to resolve using their own resources. Examples include events in nations capable of mounting a radiological response (arbitrarily defined as those nations with their own nuclear power generation capability), and events of such small or limited scale that they can be handled by local resources and infrastructure.

This is not to say that WHO would not be involved in these events. However, use of the WHO stockpile would generally not be considered appropriate under these conditions. The stockpile should not be designed or optimized to address the above situations.

¹⁵ Improvised devices may be radiological (IRD) or nuclear (IND). It could be roughly estimated that an IRD could result in around 50 people involved while an IND would involve more than a hundred people.

¹⁶ This statement induced some debate. It was recognized that removal of the threat and crisis management are outside the scope of WHO's mission. However, if WHO does not plan to utilize its stockpile for an IND, who will provide the needed medical supplies, pharmaceuticals and equipment? What role will be played by agencies such as the Red Cross and will stockpiles maintained by member states become available? Someone else will be providing expertise? Red Cross?? If conventions on assistance includes nuclear detonation: why is WHO out?

9.1 EXAMPLES (CASE STUDIES) AND REPRESENTATIVE EVENTS

9.1.1 Representative examples of radiation emergencies

Representative examples of radiation emergencies were presented and discussed as case studies. Each presentation included: description of the event; number of people affected; type of care required (short- and long-term); human resources and materials needed; risk communication (public and media information) and other related issues. The following events were presented:

- Goiania incident: very similar to the scenario of a Cs-137 dirty bomb.
- Polonium incident in Great Britain: impact on the population; media issues; public health issues
- Institute of Biophysics in Moscow: examples of radionuclide contamination
- Tokai-mura incident: very early treatment of ARS patients

a) The Goiania radiation accident in Brazil: past and present

On 13th September 1987 two scavengers removed and broke the rotating assembly of a ^{137}Cs radiotherapy device from an abandoned clinic in Goiania, Brazil. They sold pieces of the violated equipment (contaminated with ^{137}Cs powder) to junkyards and distributed contaminated fragments among relatives and neighbors. As a result of this, many people were exposed to ionizing radiation and people and places were contaminated. Although some of them requested medical assistance because they had developed clinical signs and symptoms (acute radiation syndrome and local radiation injuries), these manifestations were not recognized as radiation-induced (e.g. some patients were diagnosed as allergic dermatitis). The accident was identified more than two weeks later and:

- 20 people were hospitalized for acute radiation syndrome (ARS), cutaneous radiation syndrome, external and/or internal contamination;
- 28 people developed cutaneous radiation syndrome
- 46 patients were treated with Prussian Blue
- 4 people died with severe ARS;
- 112 800 people were screened for external contamination (15 % of the Goiania population);
- 3500 m³ waste generation (1347 boxes, 4223 drums, 10 sea containers, 8 concrete drums, 7 houses demolished);
- huge socio-economic impact
- great psychological impact
- 1035 people are still under long-term follow-up

Caesium contamination was caused mainly by ingestion and penetration through local radiation injuries. Prussian blue was administered to 46 patients at daily doses from 3-10 g (2 - 6 times per day at minimum intervals of 2 h). Four patients received 20g during one day, but gastric complaints led to this being discontinued.

Although drug administration started from day 19 or even later, it was still effective with an average reduction of ^{137}Cs T_{1/2} biological of 69% (adults), 46 % (adolescents), 43% (children) irrespective of their daily dose. Side effects were not severe (hypokalaemia, intestinal constipation, dyspepsia). Prussian blue's efficacy in reducing Cs burdens was monitored by undertaking about 4000 urine/faeces bioassays.

b) The ^{210}Po Poisoning Incident in London: HPA Response

This event had a great impact on the population and media worldwide.

The public health response was focused on prevention of further exposure of the public, risk assessment to those exposed, identification of people to be followed-up and reassurance to the public. There was an early need for clearance/remediation reference levels e.g. 10 Bq cm^{-2} for hard surfaces. Where possible all mobile contamination was removed. Several sites were identified : hospitals, crime scenes and public areas. Limited fixed contamination was found in hospitals and dealt with. Potential intakes by inhalation, ingestion or skin cuts from body fluids from the contaminated patient who died were evaluated by urine measurements on hospital staff. A detailed description of the results of monitoring other places was presented: traces of radioactivity in some offices, planes, cars, hostelrys and entertainment places. Some high spots in crime scenes and in two restaurants also necessitated urine measurements on staff).

An individual monitoring strategy was developed for measurements of ^{210}Po in 24h urine samples from persons with the highest potential for exposure. This enabled ^{210}Po intakes to be confirmed, or often refuted, and also provided information that could be extrapolated on potential exposure of other people in similar situations to those sampled. Main sites of contamination were identified and questionnaires were developed to detect individuals most at risk of having intakes. As a result of this, although initially only a few tens of people at 2 hospitals and one restaurant were sampled, it rapidly expanded to hundreds of additional locations. For dose assessment, the excretion of ^{210}Po in 24h urine (Bq/day) was the input into the biokinetic model to calculate the intake and, hence, the dose in mSv. A minimum reporting level of 30 mBq/day was established. According to this criterion, the results were classified into four categories:

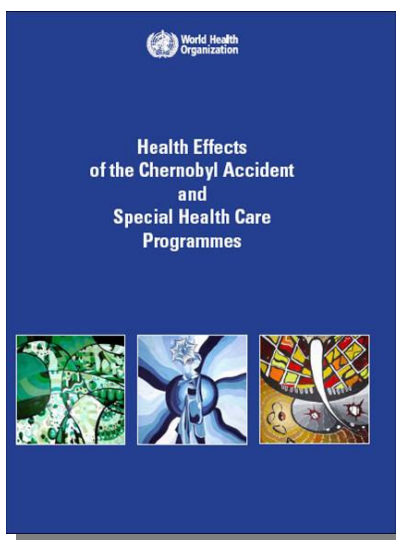
- 1.- below reporting level ($< 30 \text{ mBq/day}$);
- 2.- over reporting level ($> 30 \text{ mBq/day}$) but the dose is $< 1 \text{ mSv}$;
- 3a.- dose 1 - 6 mSv no concern; and
- 3b.- dose $> 6 \text{ mSv}$, of some concern, to be followed-up as long as worthwhile by 3 monthly urine samples.

The ^{210}Po Poisoning Incident in London, November 2006: HPA Response



c) Institute of Biophysics in Moscow: experience on radionuclide contamination

The experience of using potassium iodide (KI) and Prussian blue treatments during the Chernobyl accident was briefly presented. Experience in administration of Barium Sulphate (30 g/day) for treating internal contamination with radio-strontium in Mayak cases, and more recently, external contamination with ^{210}Po was detected in three patients at the Biophysics Institute of Moscow. This last event was related to the London incident and these patients were externally treated with 5% BAL solution for removing the radionuclide from skin. Since traces of radioactive contamination were found in biological samples (urine, blood and faeces) of one of these patients¹, he was treated with a daily dose of 1 g BAL IM during several days. The drugs, produced by a local manufacturer (Farmzasshita), had a presentation that differed from that used in other countries i.e. KI tablets 40 mg and 125 mg; potassium perchlorate tablets 250 mg; and Ca-DTPA (Pentacinum®) 5% solution for injections in ampoules, 5 ml/ 250 mg.



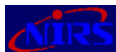
d) Medical aspects of criticality accident at Tokai-Mura, Japan

The criticality accident that occurred on 30 September 1999 at the Tokai-mura uranium conversion facility was summarized. Three workers were severely exposed to a mixed neutron/gamma field with estimated doses of 24.5 Gy/Eq (worker A), 8.3 Gy/Eq (worker B) and 3 Gy/Eq (worker C). Peripheral blood stem cell and cord blood transplantation were performed on workers A and B, respectively. Despite medical efforts they died with multiple organ failure on days 83 and 211, respectively. People living/staying within 350 m of the facility were evacuated (total: 150 people) and 310 000 people within a 10 km radius were advised to stay indoors for 18 hours.

No information concerning the characteristics of the accident was provided to medical staff so that physicians and nurses at first wrongly assumed that the patients were externally contaminated.

A multi-parametric approach was applied for dose assessment: kinetics and severity of prodromal symptoms, blood cell counts, ^{24}Na activity in blood and total body (whole body counter), chromosome aberrations and serum amylase.

Lessons learned were discussed, including psychological and socioeconomic impact, public information and media communication issues.



MEDICAL ASPECTS OF CRITICALITY ACCIDENT AT TOKAI-MURA, JAPAN

Makoto Akashi, M.D.

National Institute of Radiological Sciences



9.1.2 Examples of existing approaches to national stockpiles

A very brief discussion was held on different existing approaches to national stockpiles in some MS.(e.g. USA, UK, Japan, Germany, Sweden, Russian Federation, China, Finland, Brazil and Argentina).

The contents of available national stockpiles are similar, including at least KI, Ca-DTPA, Zn-DTPA and Prussian Blue. In some countries stockpiles include other specific agents (e.g. DMPS) or generic products according to their protocols.

The logistics of stockpile storage and distribution differs among MS (central /regional warehouses, pre-positioned supplies at nuclear power plant, local hospitals and surroundings). A strategic national stockpile has been established in the U.S. to supplement and re-supply state and local public health agencies in the event of a national emergency¹⁷.

In most of the countries the KI tablets are produced nationally, with differing presentations e.g. double-scored tablets x 130 mg individually foil sealed.

Main manufacturers/suppliers were identified as follows:

- Heyl Lab (Germany): Prussian blue (Radiogardase®) capsules x 500 mg, Ca-DTPA (Ditripentat® Heyl) ampoules x 1 g and Zn-DTPA (Zinc-trinatrium-pentetat® Heyl) ampoules x 1 g. The manufacturer holds the German health authority's approval (BfArM) for these products. FDA approved Radiogardase® for use in the US. In some countries a special authorization was given for purchasing limited quantities (e.g. Argentina) and in Japan only physicians from NIRS are authorized to use these products.
- Hameln Pharmaceuticals GmbH, Germany: Ca-DTPA ampoules x 1 g and Zn-DTPA ampoules x 1 g. This company holds FDA approval and is contracted to supply the US national stockpile.
- Farmzasshita, Russian Federation: Ca-DTPA (Pentacinum® NPC) ampoules x 250 mg, KI tablets x 40 mg and tablets x 125 mg, Prussian Blue (Ferrocinum®) capsules x 500 mg
- National production by armed forces' pharmacy (e.g. under development in Brazil)

¹⁷ Waselenko J.K. et al. Medical management of the acute radiation syndrome: recommendations of the strategic national stockpile radiation working group. Ann Int Med 140(12):1037-1051

9.2 TYPE AND SCALE OF EVENT

Scenarios were discussed within the framework of the type of event and the scale of the event:

SCALE OF THE EVENT	WHO STOCKPILE (WHO S.P.)
Small/isolated radiological incident (less than 25 victims)	WHO SP not used
Medium size incident (26-99 victims)	WHO SP used
Large incident (100-200 victims)	WHO SP used
Mass casualty event (more than 200)	WHO's role is in public health coordination

10. CONCEPT OF OPERATIONS

The CONOPS is vital and necessary and must be approved by WHO leaders prior to purchasing the pharmaceuticals, medical supplies or equipment. The CONOPS will detail:

- the structure of the stockpile (SP), where it resides organizationally, the chain of communication flow in emergency
- how the SP is assembled (based on operating assumptions—please see above; #1 Assumptions);
- how and when the SP is deployed;
- who can request the use of the SP—the request protocol will require detailed information for MS;
- staffing requirements (how the staff will operate, the composition of the staff, and their duties, responsibilities and professional requirements);
- how and when an event is considered to fall within the scope of the SP and protocols for post-event (or exercise) reporting.
- how the quality assurance, quality control and evaluation units within the SP will be organized;
- how the communications from the SP will link-up with field deployed teams to WHO HQ and how those teams will communicate with other non-WHO entities including the MS itself.
- the make up and training requirements for the field teams which accompany the SP to the field during a deployment.
- the security and intelligence requirements for the SP;

- how scientific and medical input is given to the WHO SP leadership and how the formulary will change as a result of such input;
- how the SP will integrate into the overall WHO emergency response fabric and organization; and
- the inventory management system for tracking supplies, pharmaceuticals and equipment.

The CONOPS will explore different feasible organizational approaches before drugs and medicines are purchased. For example, WHO will decide how to involve the WHO Regional centers and the UN warehouses around the world. WHO leaders must meet with leaders from MS and secure pledges of cooperation, understanding and agreement concerning policies for use of the SP. Some MS may pledge supplies, equipment and pharmaceuticals and personnel.

In addition, WHO should meet with pharmaceutical companies/manufacturers and prime vendors to ascertain what they may be willing to pledge (supplies, equipment, assistance during an emergency, storage and warehousing space, rotation of product in the SP inventory, etc). Potential problems with the SP (e.g. supply failure, manufacturer moving, production faults) should be identified and prevented. Diverse strategies to improve the industry interface should be explored to find other ways and means to release materials rapidly (e.g. engage suppliers through arrangements/ agreements). To consider a stockpile's vendor managed inventory (VMI) as an approach to deal with events requiring additional surge demands for pharmaceuticals and/or medical supplies.

MS should be encouraged to participate in local, regional and international exercises where the SP is deployed so that as many people as necessary around the world are familiar with how it is deployed, what it looks like, what their responsibilities are when it arrives in country, and how the WHO team accompanying the SP will function.

11. POLICY AND GUIDELINES

WHO must draft policies and guidelines for the WHO SP. These policies and guidelines should define the roles and responsibilities of all entities which deal with the SP. The policy and guideline documents should be similar to the current documents developed for other response units in the WHO.

Intelligence and security: In order to deploy the SP properly and safely, WHO will interface with international law and intelligence communities. These professionals will assist in providing accurate information about the incident/accident so that WHO teams can arrive safely and continue to be safe while conducting their mission.

It is imperative that WHO and IAEA clarify their respective roles for radiological emergencies and work in partnership in the case of major radiological emergencies. The policies and guidelines written in support of the SP must address inter-agency and inter-governmental coordination and cooperation.

12. STOCKPILE FORMULARY

The inventory and formulary of the WHO Radiation Countermeasure stockpile was discussed at length. In general, the medical experts suggested including selected pharmaceuticals (listed in the table below), medical supplies, and equipment based on today's knowledge and practice of medicine. However they cautioned that medical breakthroughs can and must cause the formulary to expand or contract. The RNWG recommended that a watching brief should be kept on any developments that may suggest a review/revision of this formulary. Research efforts should be promoted to identify new effective formulations and/or novel decorporating agents (see under-investigation items below).

The biomedical supplies, support equipment such as specialized diagnostic and administration devices and systems, personal protective gear and equipment and relevant operational and educational guidance needed to make effective use of the WHO stockpile will be described in general terms (below).

STOCKPILE FORMULARY
Generic list of drugs that should be made internationally available
<ul style="list-style-type: none"> • Prussian Blue • Ca- and Zn- DTPA • G-CSF • Potassium Iodide (KI) only for protection of responders <p>Sufficient to manage 200 people during 10-12 days, assuming that these drugs will arrive 48 h after request. This timeframe will be sufficient to make appropriate medical decisions such as SCT, transfer of patients, etc.</p>
DMPS and/or BAL: not included in SP but might be ordered and is included in WHO treatment guidelines for selected conditions/exposures.
Conventional drugs and supplies for ARS/CRS treatment (e.g. antiemetics, analgesics, antifungals, antivirals) will be available in countries with adequate health care system/facilities.
Conventional drugs for internal contamination treatment (e.g. diuretics, saline solutions, sodium bicarbonate, barium sulphate, etc) will be available in countries with adequate health care system/facilities
If the country where the incident/accident occurs does not have the necessary minimal health care level additional medical supplies must be ordered in addition to those in the WHO SP
Investigational Items
<p>The RNWG mentioned some potential candidates to be considered for future inclusion in this stockpile: KGF; amifostine; pentoxifylline; oral DTPA; inhalation DTPA; Stem Cell Factor; TPO-receptor agonist; EPO; IL-3; IL-7; IL11</p> <p>Assays to be considered for sampling: in vivo EPR and biodosimetry assays</p>

12.1 EXPOSURE AND TREATMENT

The following table defines formulary items according to type of exposure. Many of the supplies considered to be routinely available in a hospital/clinical setting must be supplied locally and will not be in the SP.

TYPE OF EXPOSURE	REQUIREMENT FOR TREATMENT
External Exposure with Acute Radiation Syndrome (ARS) / Cutaneous Radiation Syndrome (CRS)	<ul style="list-style-type: none"> ○ Cytokines/ Growth Factors ○ Antiemetics ○ Antimicrobial agents (antibiotics, antifungals, antivirals) ○ Analgesics ○ Anxiolytics
External Contamination	<ul style="list-style-type: none"> ○ Decontamination solutions
Internal Contamination/Incorporation	<ul style="list-style-type: none"> ○ Blocking agents ○ Diluting agents ○ Chelating agents ○ Enhanced decorporation drugs

The RNWG noted that for the Goiania incident, 112,000 people were screened for external contamination by 300 staff members over 3 months. Only 1 person per 1000 was found to be contaminated and of those only 20 persons were hospitalized, mainly due to bone marrow dysfunction and/or local radiation injuries and 46 people received Prussian blue treatment. The RNWG assumed that it would take at least 14 days to screen 20,000 people for external contamination, 200 of whom might require specific therapy. The RNWG suggested that WHO should be prepared to treat 200 victims for 10-12 days. The group was mindful that, many (up to orders of magnitude) more patients would require screening evaluation than those identified as requiring treatment.

13. COSTS AND RESOURCE COMMITMENT

Costs associated with stockpiling include but are not limited to:

- a) the purchase of pharmaceuticals, supplies and equipment;
- b) maintenance of equipment; rotation of supplies to keep them from expiring;
- c) staffing/personnel;

- d) transportation;
- e) storage/warehousing of the WHO SP;
- f) exercises to test the capabilities of the WHO SP and staff;
- g) training of staff who are associated with or attached to the WHO SP;
- h) once deployed, supplies, pharmaceuticals and equipment must be purchased to re-stock the WHO SP;
- i) an inventory management system to track and manage the formulary and equipment;
- j) costs associated with maintenance of a stockpile comprise approximately 25% of the total expenditure

The RNWG discussed but was not able to provide an accurate estimate for the cost of the required pharmaceuticals, supplies and equipment. Funding is also required to cover the maintenance costs: personnel, transportation, storage, rotation of products, inventory, management system, etc.

14. PERSONNEL, TRAINING, MAINTENANCE AND SUPPORT

When planning for the WHO SP et up the following should be kept in mind:

- a) various specialist skills are required (medical staff—physicians and nurses trained in radiation emergency medicine); logisticians; emergency response coordinators; communications experts, laboratory staff (hematology, bioassays, cytogenetics, biomedical engineers/technicians to maintain and calibrate equipment)
- b) training required to meet requirements of the operational concept, plus nationally-customized training courses
- c) maintaining currency; continuing education requirements, licensure
- d) selection criteria for the responder professionals roster; validation of the credentials and skills through a WHO protocol
- e) preparedness at national level and contingency planning.

WHO started the process of developing a global roster of experts for responding to EHE. Expert profiles (e.g. personal skills and qualification) and terms of reference (TOR) should be established according to the characteristic of the event e.g. radio-nuclear, water sanitation, chemical, humanitarian response. Experts may be drawn from international, regional and/or national institutions. Existing networks and collaborating centers (CCs) should be considered e.g. REMPAN. For being eligible, candidates should be readily deployable¹⁸ to support international response to EHE. Experts deployment may be requested:

- at short notice during major emergencies, disasters or humanitarian crises;
- at a later stage, to provide support to recovery and/or reconstruction efforts.

¹⁸ Concerning medical/public health response in EHE, WHO may deploy an expert team to the field upon request of a MS. In case of radio-nuclear emergency WHO will coordinate with IAEA for the harmonization/integration of their respective roles (e.g. WHO teams and RANET teams)

The deployed expert team should be able to conduct health risk assessments; to advise national authorities on public health measures (immediate and long-term); to coordinate the international environmental health response and to respond to MS capacity building and supply needs. To go with the stockpile, these teams should include people who understand what to do (technical knowledge e.g. medical use of SP) and who have good health communication skills. Experts from the roster as well as WHO Regional office staff and WHO HQ staff may be considered to take part of these teams.

Specific functions, roles and responsibilities within the WHO team should be defined (e.g. coordinator, environmental health adviser, radiation health expert, chemical expert, water sanitation expert, etc)

To be deployable, team members ("environmental health responders") should receive pre-deployment training to ensure they have updated knowledge on technical issues such as environmental health services and specific radiation safety/radiation medicine as appropriate. Training materials should include operational aspects related to environmental health emergencies. An information toolkit, easy for using under field conditions, should be provided to the environmental health responders e.g. fact sheets, leaflets, protocols, handbooks, guidelines. Alternative strategies for preparing the international team should be explored: pre-deployment training courses, training the trainers initiatives, package training materials including CDs, instructional videos (e.g. lectures on TV screen)

15. MEMBER STATES AND REQUESTING HOST NATION REQUIREMENTS

The recipients at the MS also have their own responsibilities. This issue needs further development in terms of common tactics, techniques, and procedures.

16. ROLE OF WHO REGIONAL OFFICES AND NON-WHO ORGANIZATIONS

Roles, responsibilities and interaction with WHO concerning the stockpile must be delineated clearly at the following levels of interaction:

- WHO HQ and WHO Regional Offices¹⁹;
- WHO and IAEA;
- WHO and other International Agencies (both governmental and non-governmental) involved in emergency response;
- WHO and Member States.

¹⁹ Among WHO Regional Offices, only PAHO is involved in Preparedness and Response to Radiation Emergencies (training, appraisals)

17. ASSESSMENTS, UPDATES, EVALUATION OF WHO STOCKPILE FORMULARY, ORGANIZATION, EQUIPMENT, AND CONCEPT OF OPERATION

Maintenance of the SP requires ongoing assessment and evaluation. Not only must the formulary be reviewed continuously and updated appropriately, but advances in logistics, transportation, storage, etc must be reviewed and when appropriate updates must be made to SP systems. The SP must incorporate robust quality assurance and quality control components in order to ensure that the medical supplies, equipment and pharmaceuticals are maintained under the strictest and most appropriate guidelines. Thus the entire SP structure including staff, training, exercises, management and information systems, etc are all reviewed, inspected and reported on regularly.

18. MISCELLANEOUS

Further, other matters of various nature should be considered when developing an operation SP system at the global level:

a. Bio-sample categories (human blood, faeces, urine, organ biopsy)

The requirements for sample management depend on the scenario and victims' condition:

- External exposure (ARS/ CRS): triage according to clinical signs and symptoms including sampling for CBC and cytogenetic dosimetry;
- External radioactive contamination: samples should be obtained from eyes, nose and mouth, open wounds and/or debrided tissues, and urine/faeces.
- Internal contamination: samples should be obtained from blood and as above for "external contamination".

b. Public health monitoring

Public health monitoring includes long-term assessment for stochastic effects and complications from agents used from the SP. It is unclear who should conduct long-term monitoring.

c.. Transportation

Timely response requires aircraft to bring in the WHO team and to bring in the SP; logisticians understand the issues associated with transporting personnel and equipment/supplies and should be part of the WHO team from the beginning.

d. Logistics

How do you package your medications, in bulk or in individual doses? Bulk is less expensive but requires breaking it down into individual doses at the site of the emergency; individual dose packaging is far more expensive but the medications can be given much more quickly on site. The logistic package "Blue box" "Red box" etc...

e. Legal Issues

- Legal framework, roles, responsibilities and interactions between national competent authorities within the country (health authorities/ regulatory bodies); different approaches in different MS and even in different states/provinces within the MS.
- Individual responsibility/accountability, periodic inventories. Security and confidentiality of information, intellectual property.
- Differences between biological hazards and response vs. radio-nuclear hazards and response e.g. biological dosimetry. WHO has a clear mandate: it is the international Public Health agency. Although WHO has the mandate for global response, biological has traditional been its priority.
- Drug approval: generic international criteria with specific national particularities (case by case).

f. The RNWG recommended that a review be conducted of countries which maintain stockpiles. This is for the purpose of understanding best practices, to ensure proper coordination, to ensure participation in exercises, to avoid re-inventing the proverbial wheel, etc.

19. CONCLUSIONS

In the short time provided, it was difficult to address all of the above issues at a depth sufficient to achieve consensus. However, it is vital that the process was begun. While the group did not produce definitive answers to all of the above, all topics were at least addressed. Nevertheless many points were addressed sufficiently and very importantly key areas that require further research were identified.

The two Working Groups (Chemical and Radio-Nuclear) met together in a plenary session on the final day of the meeting.

The Working Groups and WHO Secretariat agreed on the following conclusions:

1. A stockpile is more than pharmaceuticals, supplies and equipment; a wide array of issues must be considered in making the decision to host and manage a stockpile including who will use it, who will staff it (training and personnel requirements, etc) and under what conditions will such a stockpile be deployed.
2. A stockpile of medical supplies and equipment requires ongoing maintenance, storage, packaging and refurbishing. Stock control requires that the pharmaceuticals and supplies must not be kept beyond the shelf-life duration. Provision of a stockpile of medical supplies once purchased requires an on-going financial commitment to maintain it for constant readiness and prompt restocking.
3. Personnel, staffing, training remains an issue that requires further discussion and ultimately a set of decisions by WHO leaders. Please see Section 14, PERSONNEL, STAFFING, TRAINING on pages 23-24, this report.
4. Coordination with IAEA must be done as soon as possible and before a final decision is made on the purchasing of stockpile materials as this may affect the SP content.
5. Not all MS will have licensed the pharmaceuticals of interest for the WHO SP. WHO is encouraged to work with MS to ensure that in cases when selected for the SP pharmaceuticals/supplies/equipment/etc. are off-label in the MS requesting assistance, those items still can and will be used during a response.

20. Recommendations to WHO for further steps

1. To further develop WHO policy and concept of operations on implementation, deployment and use of radio-nuclear emergency stockpile
2. WHO should contact the IAEA with the proposal to enhance coordination of their respective roles in a mutually integrated medical/public health response to radiation emergencies.
3. WHO should contact the IAEA with the proposal to encourage and facilitate cooperation among national radio-nuclear regulatory bodies and national health authorities.
4. To develop a questionnaire and conduct a survey/inventory of national/regional stockpiles and compile a list of national formularies for potential use in emergencies.
5. To advocate harmonization and integration of national and international stockpiles and to convene an international meeting to start the process of international agreement/consensus.
6. To provide guidance for MS to establish and use their national stockpiles.
7. To develop a mechanism for WHO to assist MS for drug approval/licensure.

Appendix 1. Formulary Issues

- Prussian Blue. Oral administration of 3 g/day . x 10 days x 200 people= 12000 capsules x 500 mg²⁰
- Pentetate calcium trisodium (Ca-DTPA) and pentetate zinc trisodium (Zn-DTPA), standard presentation ampoules x 1g in 5% solution. Dose:1 g/ day administered in saline solution via IV as soon as possible after internal contamination ("the sooner the better"). The first 3 days 1 g/day Ca-DTPA 3 g x 200 people= 600 ampoules x 1 g). The following 7 days 1g/day Zn-DTPA 7 g x 200= 1400 ampoules x 1 g²¹).
- Ca-DTPA and Zn-DTPA in saline solution. Standard 5 ml ampoules 0,25 g in 5% solution, administered in saline solution via IV. "The sooner the better". The first 3 days 1 g/day Ca-DTPA 4 amp x 3 days x 200 people= 2400 ampoules. The following 7 days 1g/day Zn-DTPA 4 amp x 7 days x 200 people = 5600 ampoules.
- Potassium iodide (KI): in the WHO SP for protecting WHO responders.
- Cytokines: G-CSF 5 µg/kg = 300-400 subcutaneous. Pegylated G-CSF.
- Assumption: infusions e.g. saline solutions and isotonic bicarbonate, as well as conventional products e.g. (antacids, diuretics, etc) are normally available in every countries.
- Antimicrobial, antifungal, antiviral: not in the WHO SP since they should be available locally.
- WHO will continue to monitor promising/potential treatments such as K-GF (it is used for 3 days as prophylaxis for mucositis), amifostine, pentoxifylline, oral DTPA (IND), inhalable micronized DTPA powder, IL-3, IL-7, IL-11, TPO agonist, EPO, Stem Cell Factor (SCF), DMPS/DIMAVAL® pero os and IM (polonium),
- Equipment requirement²²: mobile whole body counters, gamma survey meters, alpha contamination detectors, and potentially others.
- 20 000²³ specialized sample kits (nasal swabs, faeces, urine, sodium heparin or heparinised syringes, blood).

²⁰ Total amount of capsules was calculated for standard packaging e.g. Radiogardase™ Heyl capsules x 500 mg.

²¹ Calculations were based on standard packaging e.g. Heyl DTPA (Ditripentat®) and Hameln Germany DTPA are presented in ampoules x 1g. Other packaging is available e.g. Pentacinum® NPC Farmzasshita Russia are presented in ampoules x 250 mg. Hence, total amount of ampoules may differ according to this.

²² The use of some of these instruments requires special skills: to discuss with IAEA experts

²³ Assumption: Between 2000-20 000 people to be sampled; between 1-10 % (around 200) actually would need to be treated.

- Personal Protective Equipment (PPE) is not a WHO responsibility but the WHO team accompanying the WHO SP should carry with them as part of their personal deployment kit at least a 3 day supply of surgical/medical gowns, masks, syringes, gloves, needles, etc;.
- Every member of the WHO team must be supplied with a personal TL dosimeter to register external exposure²⁴.
- External Contamination: In most instances, 90% of external contamination may be removed by undressing. The other 10 % will be removed by washing with soap and water. This should be done immediately upon exiting the hot zone, hence the solutions for external decontamination will not be included in the SP.
- The RNWG recommends that WHO consider drafting guidelines which detail specific and non-specific external decontamination protocols. DTPA and Prussian Blue may be used for external decontamination.
- The majority of MS would have minimal health infrastructure e.g.: at least a modern hospital available. If, however, a MS did not have a modern hospital, WHO and other response organizations would have to order additional supplies and equipment.
- Antiemetics, steroids, analgesics, antifungals, antimicrobials, antivirals are assumed to be available locally.
- The RNWG recommends that the WHO SP be designed to treat 200 patients for 10-12 days. Beginning on the 5th day post event and continuing through day 10, victims should be evacuated or transported. Each patient who is evacuated should have paper work that clearly states what level of care is (only a few victims will need special healthcare beyond these first 10 days).
- The RNWG agreed that for most patients, within 10-12 days a sound medical decision can be made concerning additional treatment such as stem cell therapy. The RNWG considered as much as a 96 hour delay in the 10-12 day referral/transport window (i.e. if the 10-12 days became 14 days) the patients would suffer short term medical complications but not long term ones.
- When responders arrive on the scene, they can begin therapies/treatment empirically (while waiting for lab results). However, they must have some kind of identification of the radionuclide e.g. previously known RN involved (alpha/beta/gamma emitter) or spectrometry results to make the best medical treatment decisions. Medical personnel dealing with radiation victims must treat patients based on clinical signs and symptoms since lab data will not be immediately available. However, in radiation emergencies

²⁴ To discuss with IAEA experts

biological dosimetry is of paramount importance, particularly in the early stages post event when a rapid estimation of dose exposure is required. Hence, enough supplies for cytogenetic dosimetry should be available at the national level and be considered as a stockpile item for radio-nuclear emergency management.

- To identify 200 people who require treating, probably 2000-5000 people will have to be monitored. This large majority mainly comprise the "worried well". They need to be taken into consideration when the WHO Team arrives because they undoubtedly will demand assistance which will consume staff time and resources.
- The RNWG is aware of the potentially enormous burden a radio-nuclear incident might have on local and national laboratories: How many radionuclide samples could be managed in any one facility? Experts agreed that probably no single institution/ facility will be able to process 2000 samples in a timely fashion. Sometimes, depending on the radionuclide, bioassays may take a long time to process e.g. the WHO Team on site may have to wait 6 days or more for results from urine/faeces samples. The RNWG suggested that in such an emergency an international network of laboratories might be mobilized. Coordinating and ensuring such a network exists and is capable is not within the terms of reference of this Working Group. Nevertheless it is clear that in a large scale event more than one cytogenetics laboratory, for example, will be needed.

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Appendix 3. Meeting agenda

WHO Consultation on the Development of Stockpiles for
Radiation and Chemical Emergencies
14-16 February 2007 - WHO Headquarters, Geneva Switzerland

Day 1 – Wednesday, February 14	
Plenary session 1	
Salle B	
09:00-9:30	<p>Welcome:</p> <ul style="list-style-type: none"> - Dr Susanne Weber-Mosdorf, Assistant Director-General, Sustainable Development and Healthy Environments - Dr Ala Alwan, Representative of Director-General for Health Action in Crises <p>Introduction of participants</p> <p>Department of Public Health and Environment (Dr Maria Neira, Director)</p> <p>Objectives of consultation</p> <p>Adoption of the agenda</p>
09:30-10:30	<p>International health response to emergencies:</p> <ul style="list-style-type: none"> • International Health Regulations (2005) (Dr Max Hardiman) • WHO Epidemic and Pandemic Alert and Response (Dr Michael Ryan) • WHO Health Action in Crisis Situations (Dr Jules Pieters) • WHO Environmental Health Emergency Response (Dr Kersten Gutschmidt, Dr Zhanat Carr)
10:30-10:35	Introduction to working groups
10:35-11:00	Coffee break

Radio-nuclear Emergency Working Group

Day 1 – Wednesday, February 14 Radio-nuclear Emergency Working Group - Session 1. Room M-205	
11:00-11:20	IAEA-WHO collaboration for radio-nuclear emergency response
11:20-11:30	Objectives, task assignments, formation of sub-groups
11:30-12:30	Case studies: <ul style="list-style-type: none"> ➤ Goiania accident ➤ IBPh experience ➤ Polonium-210 event
12:30-14:00	Lunch
14:00-15:30	Working in sub-groups
15:30-16:00	Coffee break
16:00-18:00	Working in sub-Groups
18:30-20:00	Social event

Day 2 – Thursday February 15 Radio-nuclear Emergency Working Group - Session 2. Room M-205	
9:00-9:15	Rapporteurs progress report
9:15-9:30	Case study: Experience from Tokai-mura accident
9:30-10:30	Working in sub-groups
10:30-11:00	Coffee break
11:00-12:30	Working in sub-groups
12:30-14:00	Lunch
14:00-15:30	Working in sub-groups
15:30-16:00	Coffee break
16:00-18:00	Working in sub-groups

Day 3 - Friday February 16	
Radio-nuclear Emergency Working Group - Session 3	
Room M205	
9:00 - 10:30	Final review of radio-nuclear emergency working group outputs
10:30 - 11:00	Coffee break
Plenary Session 2	
Room M205	
11:00 - 11:30	Reports of radio-nuclear and chemical working groups
11:30 - 12.30	Final overall discussion
12:30-13:00	Final overall recommendations, including next steps
13:00	Closure

Appendix 5. Acronym List

Ca-DTPA: Pentetate calcium trisodium.

ConOps: Concept of Operations.

DMPS: 2,3-dimercaptopropane-1-sulfonate.

EC: European Commission

EHE: environmental health emergencies.

EMF: Electromagnetic fields

EPO: Erythropoietin.

EPR: Epidemic and Pandemic Alert and Response.

EUROPOL: European Police Office.

FAO: Food and Agriculture Organization.

G-CSF: granulocyte colony-stimulating factor.

GOARN: Global Outbreak Alert and Response Network.

HAC: Health Action in Crises (HAC).

HQ: headquarters

IACRNA: Inter-Agency Committee on Response to Nuclear Accidents.

IAEA: International Atomic Energy Agency.

IASC: Inter-Agency Standing Committee for humanitarian purpose.

ICAO: International Civil Aviation Organization.

IHR: International Health Regulations

IL-11: interleukin 11

IL-3: interleukin 3

IL-7: interleukin 7

IMO: International Maritime Organization.

IND: Improvised nuclear device.

INTERPOL: International Criminal Police Organization.

IRD: Improvised radiological device.

KI: Potassium iodide.

MS: Member States.

NEA: Nuclear Energy Agency.

OCHA: Office for the Coordination of Humanitarian Affairs.

OECD: Organisation for Economic Co-operation and Development.

OOSA: Office for Outer Space Affairs.

PAHO: Pan American Health Organization.

PHE: Public Health and Environment.

PPE: personal protection equipment.

RANET: Response Assistance Network.

RDD: Radiological Dispersal Device.

RED: Radiological Exposure Device.

REMPAN: Radiation Emergency Medical Preparedness and Assistance Network.

RN: Radio-Nuclear.

RNWG: Radio-Nuclear Working Group.

SCF: Stem Cell Factor

SP: stockpile.

TORs: terms of reference.

TPO: thrombopoietin.

UN: United Nations.

UNEP: United Nations Environmental Programme.

UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation.

WG: working groups.

WHO: World Health Organization.

WMO: World Meteorological Organization.

Zn-DTPA: pentetate zinc trisodium