

Consultation on Reproductive Health Technologies in Crisis Settings

Meeting Minutes: May 13-14, 2008

On May 13-14, 2008, the New Technologies for Crisis Settings Working Group (New Technologies Working Group) convened a consultation on new and emerging reproductive health technologies at PATH's headquarters in Seattle, Washington. Jointly hosted by PATH and the Women's Commission for Refugee Women and Children, the meeting fostered dialogue between experts in the fields of reproductive health, emergency health response, and technology development and introduction, with the aim of increasing access to appropriate new and underutilized reproductive health technologies in crisis settings.

The agenda and all presentations given at the meeting are posted on the Inter-Agency Working Group (IAWG) webpage: <http://iawg.net/technologies/presentations.html>.

Day 1

Welcome

Jane Hutchings from PATH welcomed the participants to the Consultation and introduced them to PATH. Lorelei Goodyear from PATH provided an overview of the objectives of the meeting which were to:

- (1) *Identify gaps and challenges in reproductive health service delivery for populations in crisis settings.*
- (2) *Identify and prioritize two or more new or underutilized reproductive health technology solutions to improve reproductive health and service delivery in crisis settings.*
- (3) *Articulate a process for developing, adapting, piloting, and introducing reproductive health technologies for appropriate use in crisis settings.*
- (4) *Discuss procedural issues involved in making reproductive health technologies available for program use.*
- (5) *Develop a plan of action for next steps by the Working Group on New Technologies for Crisis Settings.*

MISP for Reproductive Health

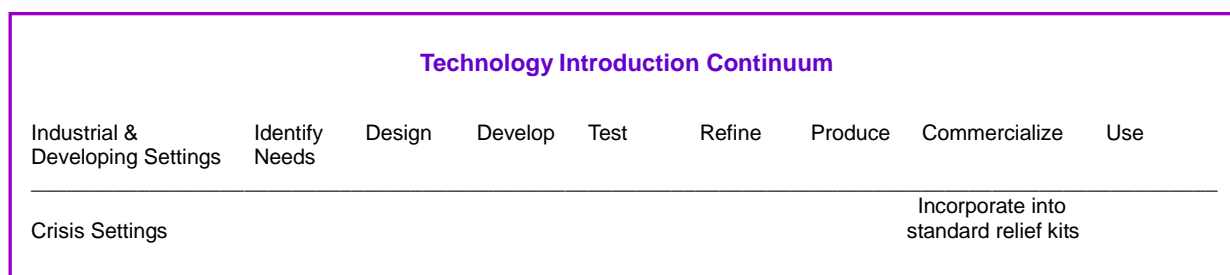
Sandra Krause from the Women's Commission for Refugee Women and Children led a discussion on the contextual factors underlying the humanitarian context and how the presence of such characteristics defined crisis situations. Participants brainstormed the characteristics of the acute phase overall, and those specific to displaced persons. A similar exercise was conducted for chronic and protracted crises. Participants identified some of the dilemmas in humanitarian assistance, including the need to establish or support health systems and the risk of prolonged aid delivery. They also noted the different vulnerabilities and opportunities that existed in protracted settings, such as increased entrepreneurial activity. Following the discussion, Ms. Krause introduced the Minimum Initial Service Package (MISP) for Reproductive Health, which is a set of priority interventions to be implemented at the early days of a new emergency. The five core components of the MISP are to: 1) identify an organization and/or individual to coordinate the implementation of the MISP; 2) prevent sexual violence and provide appropriate assistance to survivors; 3) reduce the transmission of HIV; 4) prevent excess maternal and neonatal mortality and morbidity; and 5) plan for the provision of comprehensive reproductive health services. In 2006, the Women's Commission developed a [distance learning module](#) to assist practitioners and other key stakeholders to effectively implement the MISP. Participants were encouraged to complete the module and the online post-test.

Prioritizing RH Technologies for Introduction in Relief Settings

Harshad Sanghvi of JHPIEGO discussed prioritizing reproductive health technologies for introduction in relief settings. He mentioned some harmful, ineffective and costly technologies that have been introduced faster than promising innovations, including routine episiotomy, therapeutic course of antibiotics for prophylaxis after Cesarean sections, among others. He also recognized some effective technologies that are languishing, such as emergency contraception (EC), Post-Exposure Prophylaxis (PEP), implants, Depot Medroxyprogesterone Acetate (DMPA), Magnesium Sulfate for eclampsia prevention, vacuum extractor, and others. Dr. Sanghvi described the questions to ask in defining the need for reproductive health technologies for crisis settings, including the extent the problem is a major public health concern, the challenges of introducing the technology, and the availability of existing technologies/solutions. He listed post-partum hemorrhage (PPH)-related technologies and other technologies that have potential for introduction in relief settings, including Misoprostol for abortion and treatment of incomplete abortion, and job aids for mixed-level providers. A systematic approaching is needed to take innovations to scale. Resistance must also be addressed in order for people to use technologies. Dr. Sanghvi encouraged that early adopters be targeted; namely, those who are willing to champion new technologies, to use, teach and advocate for their greater use.

Session 1: What are the RH needs in crisis settings?

Lorelei Goodyear introduced a Technology Introduction Continuum that starts with the identification of needs (see table below). During the course of the Consultation, participants referred to the Continuum to identify how far specific technologies have advanced toward being used to improve health outcomes.



Jessica Fleming of PATH moderated this session in which participants identified a list of reproductive health needs and service delivery challenges in crisis situations. The topical areas were based on *Reproductive Health in Refugee Situations: Inter-agency Field Manual*. Note that blanks do not necessarily imply lack of service delivery challenges; some were not raised due to limited time.

Safe Motherhood

Reproductive Health Need	Service Delivery Challenges
<ul style="list-style-type: none"> Skilled delivery, Emergency Obstetric Care (EmOC), Post-abortion Care (PAC) 	<ul style="list-style-type: none"> Lack of skilled providers and materials for normal deliveries; EmOC; referrals Lack of training in Manual Vacuum Aspiration (MVA)
<ul style="list-style-type: none"> Awareness over seeking care; need and access 	<ul style="list-style-type: none"> Method of community communication, trust Language, cultural issues Proof of status, cost, language, cultural issues, politics, sex of provider
<ul style="list-style-type: none"> Safe pregnancy—nutrition, focused antenatal care (e.g. Intermittent Preventive Treatment for malaria (IPT)) 	<ul style="list-style-type: none"> Lack of tools/supplies; blood products, diagnostics, medicines/vaccinations Life cycle of a product, cold chain and shelf life should be considered
<ul style="list-style-type: none"> Vital statistics/records for births/deaths 	
<ul style="list-style-type: none"> Family planning (FP), post-delivery care, social support 	

Family Planning

Reproductive Health Need	Service Delivery Challenges
<ul style="list-style-type: none"> • Products/Supplies • Long-term methods such as Intrauterine Contraceptive Device (IUCD) and DMPA • Levonorgestrel EC • Implants: DMPA • Short term methods: Depo-Provera, oral contraceptives, and Levonorgestrel EC • Postabortion care • Condoms for dual protection • Good compatible methods • Good methods for sterilization of instruments/standard precautions • Good waste disposal • Cheap, easy pregnancy testing 	<ul style="list-style-type: none"> • Lack of integration of HIV/FP • Lack of abortion services • Need for Information, Education Communication (IEC) on methods for population—CBD—peer counseling • Need for provider education • Need to ensure accessibility for all women; young, single, etc. at risk, too. • Need for choice of method (informed choice) • Taking into account cultural context • Vasectomy, sterilization • Missed opportunities to include FP • FP compliance issues • Need for client confidentiality

Sexually Transmitted Infections (STIs) including HIV

Reproductive Health Need	Service Delivery Challenges
<ul style="list-style-type: none"> • Point of care: diagnosis/treatment • Prevention and awareness • Surveillance/data • Couples-based approach • Method mix • Peer counseling/education: adolescents, sex workers • C.T. plus PMTCT and HAART • Contraceptives including male, female condoms 	<ul style="list-style-type: none"> • Logistics and supplies • Privacy issues • Standard of care • Providers • Cultural barrier—decision maker and female empowerment • Universal precautions • Reuse of female condoms • Community-based care

Sexual and Gender-based Violence (GBV)

Reproductive Health Need	Service Delivery Challenges
<ul style="list-style-type: none"> • Medical care for survivors—EC, PEP, presumptive STI treatment, counseling • Informing communities—empowering women, working with men • Prevention—latrine access, security, path lighting, escorts, police • Shelter/legal protection • Pregnancy care for wanted and unwanted pregnancy • Replacement clothing • Child sexual abuse 	<ul style="list-style-type: none"> • Health care providers are trained and available • Referral systems with 24/7 access; PAC • Access to safe abortion • Failure to seek care including people not knowing benefits, where/how to get care, whom to trust • Cultural barriers, social/stigma • Psychosocial services • Confidentiality and anonymity • Mandatory reporting requirements • Legal support • Lack of women as camp managers, planners

Other RH Concerns

Reproductive Health Need	Service Delivery Challenges
<ul style="list-style-type: none"> • Communication and coordination • Adolescent reproductive health 	<ul style="list-style-type: none"> • Cervical cancer diagnosis, treatment • Waste management

<ul style="list-style-type: none"> • Malaria Control • Community awareness of reproductive health services that are available • Access and proper use • Menstrual hygiene and disposal • Sanitation and hygiene • Access to clean water 	<ul style="list-style-type: none"> • Fuel/firewood • Water • Safe injections; infection control; universal precautions
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Session 2: Criteria for Setting Priorities

Susan Purdin of the International Rescue Committee (IRC) moderated the session that aimed to identify: 1) the criteria for the Working Group to use in selecting priority reproductive health needs and service delivery gaps for technology fixes; 2) characteristics that make a technology appropriate for use in crisis settings, and 3) ways to facilitate field input into Working Group deliberations.

1. Criteria for Selecting Priority Reproductive Health Service Delivery Gaps

Participants in this group discussed the criteria for selecting and prioritizing reproductive health service delivery gaps rather than the limitations of the technology or challenges in delivering the technology itself. A noted issue was the need to determine who was selecting and the extent of donor involvement. The following list was developed, although not in order of importance:

1. Magnitude
 - Morbidity and mortality
 - Size of the population-affected
 - Risk
 - Population distribution
 - Gaps enhanced by crisis
2. Existence of a potential solution or can a sustainable/low-tech solution be envisioned?
3. Cross-cutting gaps for reproductive health and non-reproductive health issues (e.g. infection prevention)
4. Health economics
5. Primary prevention, secondary prevention
6. Empowers user (e.g. EC)
7. Addresses issues of marginalized/ignored populations
8. Availability of funding (should be weak priority)
9. Political/religious/cultural issues
10. Immediate v. long-term and current v. projected issues (e.g. SARS)

For “marginalized/ignored populations,” participants discussed that the decision to intervene on their behalf (i.e., address the reproductive health service delivery gap) should not be donor driven; on the contrary, experts and other individuals should be driving the agenda. Populations as defined by “size” and “marginalized/ignored populations” are not necessarily contradictory, given that a problem/condition could be widespread among the displaced population as a whole or common among the particular vulnerable group.

“Politics” was raised as a particular concern, as while many noted that it should not dictate the conditions for selection, political influences cannot be ignored in what determines whether or not a reproductive health service delivery gap is addressed. Participants also saw that it was not simply politics, but religious and cultural influences; hence they suggested the need to package the problem well and to frame messages strategically.

Regarding “immediate v. long-term and current v. protracted issues,” there was general consensus that it would be helpful to look at the reproductive health needs in the future, and what can catalyze those technology solutions that are expected to achieve the greatest impact.

2. Characteristics for technologies appropriate in crisis settings

This group discussed the characteristics and issues specific to technologies that would determine or influence their appropriateness for use in crisis settings. In no particular order of priority, characteristics include:

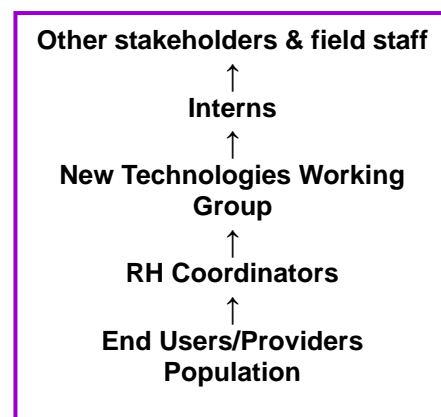
1. Cost-effectiveness and needs-based (addresses significant need)
2. Simplicity (few pieces, low maintenance, adherence)
 - Easy to use, learn
 - Easy to administer
 - Low training burden; possible use by community provider
3. Durability, shelf life, storage (security)
4. Facilitates monitoring and evaluation, information technology (data collection)
 - Inventory/supply chain management
 - Accountability
5. Point of Care/rapid—facility independent (Not dependent on electricity, water, etc.)
6. Evidence-based/validated
7. Versatile/adaptable, useful for many applications (desirable but not essential)
8. Little or no waste
9. Risk of failure/safety, including misuse and non-use
10. Ease of distribution (compact configuration)
11. Local procurement (supplementary and long-term, such as birth kits)
 - Potential for local manufacture, (e.g. Plumpy'nut a ready to use therapeutic food)
12. Simplified license expansions
 - Licensing in-country and patenting issues
13. Patent facilitation
 - Pooling of patent is being discussed. There is a relationship between patenting and licensure. In emergency situations, governments can enforce a “government clause” which will allow them to use affordable life-saving medicines regardless of an existing, valid patent.
14. Quality control
 - Low quality counterfeiting, making sure technologies are truly effective. Specification for procurement purposes.
15. Transition Plan
 - Considering the life-span of a technology; opportunities for upgrades.

Other suggestions included technologies that cross sectors with multiple benefits, and acceptability to the community.

3. Mechanisms to facilitate field input

This group discussed how to garner input from frontline field workers into the process of identifying and prioritizing reproductive health service delivery gaps. Feedback or input is needed from end users, health providers, community leaders, decision makers, policy makers (in-country and international), program managers, reproductive health focal points, agencies and universities. The group agreed that feedback could be solicited on gaps/needs, priorities, standards of care, coping mechanisms, innovative adaptations, existing resources and technology appropriateness.

To the extent possible, field staff should be involved in Working Group meetings and processes. At the field level, field staff can communicate with the reproductive health focal points within their agencies on technical issues, lessons learned, and feedback on training. When Working Group members and IAWG on Reproductive Health in Crises members conduct field visits and meet with reproductive health focal points, they can ask questions about needs and challenges. These standardized questions could be incorporated into field assessment tools. The information can be channeled to a central repository where an intern will collate, analyze and share the data to the Working Group. The results can be



shared with a variety of stakeholders and field staff to complete the feedback loop.

A participant suggested the use of SurveyMonkey and other existing tools to obtain additional feedback. Others suggested conducting a feasibility pilot and working with national and regional schools of technologies, the latter to make this a sustained initiative. In emergency settings, there is a lot of bilateral aid; another participant also noted the need to map who is partnering with whom.

Session 3: Examples of New or Underutilized Reproductive Health Technologies

This session was moderated by Paul LaBarre from PATH. For more details of the presentations, please see PowerPoint presentations.

1. MOM (Mobile Obstetric Medic) Project: Maternal Health Interventions among IDPs in Eastern Burma: Blood Transfusion

Tom Lee of the Global Health Access Program (GHAP) housed within University California-Los Angeles (UCLA) presented on the Mobile Obstetric Medic (MOM) Project, specifically on the issue of blood transfusions. Dr. Lee described the context of eastern Burma where the backpack teams operate, including the limited mobility and poor health indicators of the communities. The MOM project emphasizes the mobility of providers to bring services to communities; hence, the backpack teams move on foot. Interventions focus on basic emergency obstetric care (EmOC); selected antenatal care (ANC); clean delivery, post-natal care, family planning; and blood transfusions.

The MOM Project's transfusion program uses rapid diagnostic tests for low resource settings, combined with community education. The "Walking Blood Bank" recruits donors during ANC, but there are issues such as the lack of confidentiality. Counseling and treatment thus are provided for screened diseases. Blood is screened sequentially for malaria, syphilis, Hepatitis B, Hepatitis C and HIV, although simultaneous testing is conducted during emergencies. The work of the MOM project has offered possibilities to rethink the appropriateness of limiting transfusions to referral centers and to provide mobile services to dispersed populations.

The MOM Project has used the Kiwi Omnicup for vacuum extraction, although the device has posed technical challenges for health workers. Some mechanical problems encountered include breakage of parts and loss of suction with reuse. Proposed future avenues for blood screening include the one-sample donor screening test or the "black-box" screening test, and heat stability studies.

2. Vacuum Extraction: Kiwi Omnicup

Wilma Doedens of the United Nations Population Fund (UNFPA) presented on the Kiwi Omnicup, a device used for vacuum extraction. Vacuum extraction, rather than forceps, is the method of choice for deliveries; the vacuum extractor (VE maelstrom) is included in the Inter-agency Reproductive Health Kit for MISP implementation. The Kiwi Omnicup can be administered by one person, is now reusable, and is smaller than the traditional manual vacuum extractor. Additional advantages of the Kiwi Omnicup as compared to the traditional VE include similar performance and the potential lesser risk of breakage. The disadvantages include staff still requiring training; the risk of small parts getting lost; and unknown durability. Challenges also exist in the process to include the Kiwi Omni-cup in reproductive health kits, such as the need for World Health Organization (WHO) recommendation/support, the lack of multiple manufacturers, and the need to examine the utility of the reusable version in crisis situations. Medecins Sans Frontieres (MSF) is conducting operations research on the durability, ease of use, and cleaning and sterilization issues, and results from the study are expected to be released in due course. Experiences so far include product breakage and difficulties abiding by the recommended cleaning process. Adaptations have been made however, and the technology is promising given the high interest from obstetricians, midwives and MSF.

3. Oxytocin and Uniject with Time-Temperature Indicators

Steve Brooke from PATH presented the overview and status of Oxytocin in Uniject, an injection device developed by PATH in 1987 to improve injection delivery with minimal wastage. The Uniject device consists of a blister, valve, needle and cap, and is for a single dose. It is pre-filled and sterile, and has a built-in quality control mechanism to prevent reuse. It is commercially available from Becton Dickinson. Making drugs available in Uniject is challenging however, as it is both a drug and a delivery device. Uniject has already been applied for the Hepatitis B vaccine, Tetanus Toxoid and Oxytocin in various developing countries. PATH has focused on Oxytocin in Uniject given the proportion of maternal mortality attributable to post-partum hemorrhage (PPH), and the promising contributions of a prefilled easy-to-use device for the active management of third-stage labor (AMTSL) in rural settings and home deliveries. The WHO recommendation is 10 IU of Oxytocin as part of AMTSL for the prevention PPH. PATH is planning to conduct operational research with partners in South Africa, Argentina, Latin America, India, among other countries specifically for Oxytocin in Uniject. The issue with Oxytocin however, is the need to preserve the cold chain; the challenge is to track exposure to heat during transport or storage. PATH has also worked with partners to develop the Time-Temperature Indicators (TTIs) to address this, an indicator which permanently changes color with cumulative exposure to heat. TTIs allow for more flexible transport and storage options, and also minimize the use of spoiled product or waste of good products. Various companies are expecting to obtain registration of Oxytocin in Uniject with national bodies and are applying for the new Oxytocin prequalification process.

4. Misoprostol: A Life-Saving Technology

Jennifer Blum of Gynuity discussed the possibilities of introducing Misoprostol in crisis settings. Misoprostol is a heat stable, off-patent, easy-to-store, easy to administer, inexpensive drug (synthetic prostaglandin analogue) that can be used for a range of reproductive health conditions. There is growing evidence that oral Misoprostol is effective in preventing PPH in resource-poor communities, although it has not been listed for PPH indication on the WHO Model List of Essential Drugs. It is only listed for medical abortion with Mifepristone and for labor induction. WHO recommends that for AMTSL with a skilled attendant, Oxytocin is preferred over oral Misoprostol and Ergometrine for PPH prevention. If there is no AMTSL, a uterotonic drug should be offered by a health worker trained in its use for PPH prevention. Ms. Blum suggested the possible inclusion of Misoprostol in the Inter-agency Emergency Health Kit or Inter-agency Reproductive Health Kits for both PPH and PAC,¹ although she noted potential barriers. These include the issue that no Misoprostol product has been registered for either PPH² or PAC; providers not being able to procure or use a drug for “off-label” indication in many locations; and the lack of operations research that shows the potential use of the drug in relief settings. Possibilities for its use in relief settings exist however, as it could potentially reduce maternal morbidity and mortality associated with PPH prevention and treatment of unsafe abortion; empower women and providers with another treatment option; and reduce doctors’ workloads and the cost of surgical care, IV infusions and referrals. Currently, the Cochrane Collaboration is undertaking a full review of the use of misoprostol alone for postabortion care. This document should be available in late 2008 or early 2009.

5. Question and Answers

Discussions focused around the Kiwi Omnicup and Uniject. Dr. Sanghvi commented that the manual for the Kiwi Omnicup is currently available in 22 languages, with the guidance sound and training expected to be available. A participant asked when **Depo-Provera (Depo)** will be available in Uniject. Mr. Brooke of PATH noted that Pfizer has made a corporate commitment to manufacture Depo for subcutaneous Uniject, and is currently applying for US Federal Drug Administration (FDA) approval. The timeframe for which this is expected to become available is 2010/2011. For Uniject to become available in non-developing countries such as the US and Europe, needle stick protection is required.

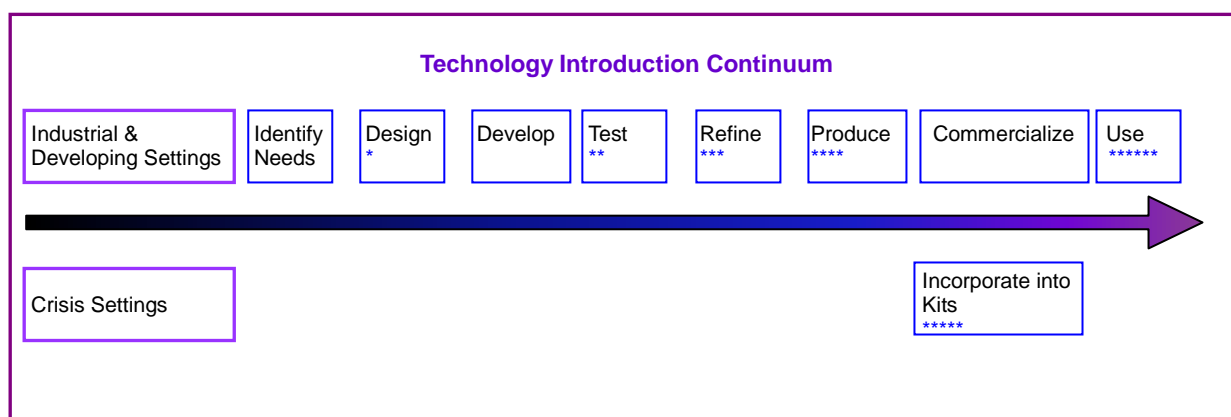
Regarding **Misoprostol**, Helene Möller from the WHO noted that PPH was reviewed for the Essential

¹ Gynuity is planning to collaborate with Venture Strategies to submit an EML application for PPH and will also work on an application for PAC.

² Dr. Ndola Prata from Venture Strategies for Health and Development and The University of California, Berkeley, used this opportunity to clarify to the participants that misoprostol has been registered for PPH indication in Nigeria, Tanzania, Uganda, Nepal, and Bangladesh. For more information on the subject please visit www.venturestrategies.org.

Medicines List, but there was insufficient evidence at the time for inclusion. There are many issues such as dose and route of administration, and the level of skill needed to use a particular treatment. The quality of the evidence supporting different approaches differs.³ If a drug is not on this list, procurement agencies face tremendous challenges in accessing the drug. Another participant also commented that at the field level, “off-label” use is not a significant problem, as people will purchase and use products that are on the market, regardless of whether or not the indication is listed. Moreover, Dr. Sanghvi noted that off-label use already exists for Misoprostol; the issue is more that it cannot be procured if the indication is not listed.

At the end of this session, participants brainstormed underutilized technologies currently available in reproductive health kits and possible new additions for inclusion in the kits (reproductive health kits, not the Interagency Emergency Health Kit). These suggestions were plotted on PATH’s Technology Introduction Continuum, and voted (three per person) for prioritization. The outcomes were as follows (numbers in brackets denote votes):



***Design**

- New antibiotics for STIs, such as gonorrhoea (3)

****Test**

- Non-Pneumatic Antishock Garment (NASG) (4)
- New formulation, delivery pump for Magnesium sulfate (4)

*****Refine/Produce**

- Gentamicin in Uniject. Two doses for the treatment of neonatal sepsis

******Produce**

- Oxytocin in Uniject (6)
- Bed nets for Intermittent Preventive Treatment (IPT)

******* Incorporate into Kits**

- Misoprostol for PPH and PAC (14)
- Neonatal kits with cloth/blankets (7)
- Rapid diagnostic tests for gonorrhoea, syphilis, HIV (6)
- Hand-carried portable ultra-sound for hospitals and health centers (5)
- Contraceptive Implants (1)
- Bag and Mask for neonatal resuscitation—now in Kit 11, but add to Kit 6

*******Use**

- Magnesium Sulfate for eclampsia (5)
- Condoms, female condoms (4)
- Emergency Contraception (2)

³ WHO guidance on the use of misoprostol for the prevention of PPH is presented in the following guideline, with a summary of the available evidence as of 2007: www.who.int/reproductive-health/publications/pph/recommendations_pph.pdf.

- Reusable kiwi Omni-Cup (2)
- Manual Vacuum Aspiration (MVA) syringe for PAC and safe abortion care (1)
- Post-Exposure Prophylaxis (1)

Session 4: Encouraging Product Use and Considering Product Research Ethics in Crisis Settings

This session was moderated by Sandra Krause of the Women's Commission for Refugee Women and Children, to address the constraints to technology introduction or use. Participants divided into two groups; one to discuss the overarching barriers to the use of currently available technologies and suggestions for expanded use; the other to examine the potential ethical and pragmatic issues related to product development and pilot testing with vulnerable populations.

1. Overarching Barriers of Use for Currently Available Technologies

This group listed constraints hindering the use of available technologies in reproductive health kits. One issue discussed was the confusion around directions and indications for use, and how ultimately, **job aids** would be useful in helping service providers better understand use. For service providers, long-distance learning, e-learning and books were mentioned as useful in settings where reading was the norm and information technology available, and vocal reminders and similar technologies in other settings. Participants mentioned that job aids can be translated into multiple languages, especially given an exiting web tool that enables pictorial translation using software that can translate both pure text and captions to pictorial material that is all linked on a web page to a number of other languages on demand of the reader. If such software were included in a **CD of communication tools that contained job aids and IEC materials**, they could be available for quick dissemination.

Participants also recognized that the communities themselves may benefit from information, as rape treatment can be underutilized, for example, if survivors are not aware of the benefits of seeking care or know where to seek care. **How to inform communities on service availability** such as EmOC was thus raised as a challenge; a participant mentioned that there is no time to pretest messages, but such **information could be handed out with non-food items (NFIs) and/or included with kits**.

Participants suggested **printing messages on kit boxes**, although it was pointed out that while it would work for the autoclave, other boxes are used as storage. The IAWG Academic Partnership, an initiative between IAWG and formal training institutions that aims to institute training on reproductive health in emergencies for humanitarian staff on a regular and sustainable basis, is now working to reach out to communities through offering mobile trainings. Other suggestions included community sensitization campaigns, posters and pictorals, with female and male condoms noted as an example containing instructions on packaging. The CD with translation software was noted to benefit the demand side, too.

Logistics and supply management was a third major issue discussed, especially in regards to third party supply management versus relying **on government health systems**. With kits, it is important to have those that are familiar with its content, customs cleaning procedures, and storing options responsible for them. **Coordination of ordered supply** was also mentioned, as there can be an imbalance of stock, especially if service providers become dependent on kits for too long. A challenge noted was the institution of a proper line for supply and resupply, as government supply chains may not be functional, despite their being responsible for stocking in some settings. Suggestions included having a basic package for continuum of care or separating kits for consumable versus non-consumable items, but one participant noted that vaccines are provided by global resources in many developing countries, perhaps it was too early to expect crisis-affected countries to be self-sustaining immediately post-crisis. Participants acknowledged the **need to develop simple ways for governments to institute a supply system to address the gap between the acute emergency and when health systems became functional**. They also recognized that crises can offer **opportunities for improved health services**, as in some settings, displaced populations have better access to care than host communities, and such interventions can become standards for national adoption and roll-out. With new technologies, stock inventory can be computerized.

Other practical issues raised on the supply side were the sex of the health provider, lack of privacy, and product life cycle and storage. In-country politics was also discussed, as was faced for MVA mistaken for abortion services, and PEP, which had to be packaged separately. Participants agreed that there was a need to agree on what was useful, necessary and indeed provided, and Dr. Doedens from UNFPA informed the group that a tool is now being developed for this purpose. The priorities of the MISP can be mapped such that “yes, we have post-rape care” indeed implies the clinic is stocked with and staff can administer PEP, EC and all other standard components.

2. Ethical Issues Related to Pilot Testing

Participants discussed the principles of informed consent and the appropriate types of research that can be conducted in humanitarian settings. Questions asked included whether or not control trials were appropriate in crisis settings, whereby the group seemed to agree that phased clinical trials were not. The **appropriateness of new product development processes in acute emergencies** was also discussed, including the challenges in the ability to control the degree of intervention, and efficacy. Participants acknowledged that given the different actors and conditions, results seen in stable settings may not translate well in crisis situations. The role of evaluations in determining the effectiveness of products/interventions was noted, including the importance of service delivery questions, such as the most effective ways of delivering EC.

The **challenge of identifying community representatives** for local ethical review of research protocols was raised, as in some such settings, there is no local university overseeing research. Participants suggested that they could perhaps identify independent reviewers, similar to the Global Health Access Program seeking academic review from Johns Hopkins University on research to determine the obstacles to delivering Misoprostol and basic EmOC.

Participants felt that there was limited guidance on research in humanitarian settings, although they acknowledged that some discussion was taking place. Some types of research were important, as without it, there would be little evidence base. In crisis settings, there could potentially be higher loss to follow-up and a higher burden on service providers to collect data.

Day 2

Recap from Day 1

Jessica Fleming from PATH summarized the proceedings of Day One. She noted that Magnesium Sulfate was voted as a high priority for enhanced use, followed by condoms. Regarding technologies not in the reproductive health kits, Misoprostol, Oxytocin in Uniject and the neonatal resuscitation kit were suggested. A neonatal resuscitation kit is already included in Kit 11 for hospital level deliveries. Participants discussed the appropriateness of adding an additional resuscitator to Kit 6 for clinic level deliveries and also whether a warming blanket should also be added. It was clarified that blankets are already included for new born care. Participants also mentioned some lower cost options for neonatal care, including Vitamin A; chlorhexidine; and behavior change communication messages for cord care, wrapping/drying the baby, and early breastfeeding.

Session 5: Making RH Technologies Available Through Standard Kits

This session was moderated by Wilma Doedens from UNFPA. For more details of the presentations, please see PowerPoint presentations.

1. Non-Pneumatic Antishock Garment (NASG) for Relief Settings

Suellen Miller from University California-San Francisco (UCSF) presented on the Non-Pneumatic Antishock Garment (NASG) as an example of a technology that is not yet available in relief kits. The antishock garment works by applying pressure to the lower body—where blood collects during shock—to return blood to the vital organs. The US Army still uses the Pneumatic Antishock Garment (PASG), but the device requires two people to apply it, including inflation with a foot pump, and problems include compartment syndrome and tissue necrosis from over inflation as well as unintended deflation. The NASG was designed by the National Aeronautics and Space Agency as an improvement on the; it is made of neoprene and does not require inflation. The NASG is light-weight and reusable, and resuscitates central circulation and reduces hemorrhage in the lower body. In terms of uses, it stabilizes the patient for transportation or referral care, has been used safely for up to 48 hours, and may decrease the need for blood transfusions. It does not however, avert the necessity for evaluation to identify the cause of shock, manage fluid and blood replacement, and provide appropriate therapy for coagulopathy. Four studies on the NASG have been published with clinically promising results, including faster recovery, shorter time of oxygen deprivation, and lower blood loss than standard treatment; no studies have been conducted specific to crisis settings. Barriers to its introduction in relief settings include the need for institutional capacity, as facilities must be able to provide tertiary care; the need for provider training and retraining; and the need for strict adherence to referral protocols. Cleaning is another issue, as are other care and maintenance procedures. Community acceptance of the device is another necessary consideration. Currently, a National Institute of Health (NIH)/Gates Foundation funded randomized cluster trial is underway in Zambia and Zimbabwe, for its application at peripheral clinics. With a sample size large enough to show 50% decrease in morbidity and mortality, the study will take approximately three years to be completed.

Questions and Answers

Dr. Miller noted that the NASG has already been approved by the FDA for use in the United States. She also mentioned that the sole manufacturer charges \$170 per garment. It can be washed and reused up to 50 times, but thorough cleaning could be challenging in water limited settings.

2. The Interagency Emergency Health Kit (IEHK)

Helene Möller from WHO Department of Medicines Policy and Standards presented on the Interagency Emergency Health Kit (IEHK). She explained the process for updating the kit and requirements for quality assurance. The IEHK 2006 is the third version, the first of which was launched in 1990. The

IEHK consists of two sets of medicines; a basic unit for primary health care workers with limited training, and a supplementary unit for professional health care workers and physicians. The content is based on standard WHO treatment guidelines and updated about every four years. The IEHK Review Committee, hosted by WHO as a secretariat, verifies whether the content is in line with the WHO Model List of Essential Medicines. The updating process has been streamlined to ensure wide participation and evidence-based approaches. The next publication is scheduled for release in June 2010. All medicines should appear in the latest version of the WHO EDL. If additions or deletions to the WHO EDL are called for, there is an October 2008 deadline for submitting recommendations for consideration at the March 2009 Essential Medicines List (EML) Committee Meeting. Of particular interest to the next revision are children's medicines. Dr. Möller also discussed the quality assurance system for the procurement of pharmaceutical drugs, with prequalification being one key aspect of the quality assurance process.

Key Dates for IEHK Fourth Edition:

- October 2008 deadline for EML revision requests
- March 2009 EML meeting → July 2009 IEHK meeting
- Submit Feb 2010 for printing → June 2010 publication

Interagency Reproductive Health Kits

Wilma Doedens from UNFPA presented on the Interagency Reproductive Health (RH) Kits, which accompany the MISP but are different from the IEHK. The RH Kits for emergency situations are divided into three blocks, with the first targeting the primary health care level for 10,000 people, the second, the health center level for 30,000 people, and the third, the referral level, for 150,000 people, all for three months. The kits are based on a "standard" population size, with 25% of the population estimated to be women of reproductive age, 20% of pregnancies developing complications, and 5% of deliveries requiring caesarian sections. While not included in the MISP, the kits also address the need to meet pre-existing demand for family planning and syndromic treatment of STIs. The RH Kit contents are reviewed biannually, through a survey that targets consignees and other implementing partners. The survey solicits information regarding the implementation of the MISP, logistics, guidelines and training, and technical feedback on the kit content. Background papers on new technologies are also reviewed, including technologies successfully piloted by partners and those supported by WHO. The IAWG technical focal points review the information and provide recommendations, the RH Kit booklet is then edited and translated, and UNFPA Procurement takes action assembling kits and making them available for order. Since 2005, the RH Kit update process has been consistent with that of the IEHK. Challenges to incorporating new medicines and devices include the time-consuming process for new medicines to be added to the Essential Medicines List; the lack of an "Essential RH Devices" list; and regulatory issues such as quality and specifications. Another significant issue is the question of where to stop, as the kits require much logistics planning and action. Reordering is not cost-effective, and there is a need for a timely, sensible and sustainable "post-kit" supply mechanism.

Questions and Answers

Regarding the survey, Dr. Doedens noted that few responses were related to technology gaps, with more feedback on suggestions such as including a penis model, replacing cord ties with clamps, among others. A question concerned how end-users are notified of changes in kit content, to which Dr. Doedens replied that a new booklet is issued, but changes are not currently highlighted. She added that this process can be better formalized. Dr. Doedens also clarified that the RH Kits can be procured through UNFPA and the IEHK through WHO.

3. Procurement and Supply Chain Management of Kits

Atieno Ojoo of UNICEF discussed the logistics of kits, first reiterating the purpose of kits, which is to simplify product delivery logistics, especially for the acute phase. The supply system context is characterized by programming needs, budget and funds, legislative and regulatory issues, and commercial/trade considerations such as customs duties, patents and licensing. Moreover, tender management, including bid evaluation; quality assurance procedures; logistics, including port clearance, storage and distribution; and information management systems are all part of the supply system. Dr. Ojoo also went through a list of important considerations, emphasizing that there would always be a compromise, as not everything can be included. Other issues mentioned included the need to prevent

kits from replacing routine health care provision. She discussed how the content was selected, including the prevention of duplication with existing kits, the product life cycle, and kit composition and design. Forecasting and procurement, kit assembly, warehousing and transport, and cost were also discussed, with the need to budget for the cost of wastage and destruction of unusable supplies. Given the complexities and many layers of the procurement and supply chain management process, a paper trail is needed, and an inventory updated for each transaction.

Questions and Answers

A question raised was whether problems are created by only having one kit supplier on standby, to which the response was conducting a supplier evaluation in advance would resolve this issue and offer more options. A second question asked was where UNICEF stood in terms of Radio Frequency Identification (RFID) tracking technology. Dr. Ojoo responded that UNICEF is using SAP, an enterprise resource planning software which includes barcoding with information on origin and destination. WHO and UNICEF are currently piloting a telephone tracking device, whereby a cell phone with a barcode reader is being distributed for community-based ordering. Phones for Health is working on this technology, with applicability in emergencies. A third question pertained to the requirements on expiry time for drugs and vaccines. Dr. Ajoo responded that the expiry date of the entire kit is based on the item in the kit with the shortest remaining shelf life. UNICEF does not ship out kits with less than 13 months shelf life.

Another question pertained registration of medicines in the host/recipient country and making sure that kits reach people without delay. UN agencies and international agencies providing humanitarian assistance generally have blanket agreements with countries (mostly least developed countries with limited capacity in regulatory agencies) to waive registration requirements. In countries with more mature regulatory agencies, procedures exist for obtaining these waivers. In emergencies, prior research is needed to have the information in advance, or experts in the field need to be consulted to avoid delays. Emergency kits are mostly supplied from external sources. Local assembly does take place, but mostly in the recovery phase support. Some countries have legislation that prohibits importation. In these situations kits can be assembled locally, but it requires as much as possible planning in advance. Some kits need to be culturally appropriate and can benefit from local or regional packing and assembly, e.g., education kits packed in Palestine during the Iraq War. Although disasters are difficult to predict, unstable situations are being monitored. In conflict situations the importance of preplanning and prepositioning supplies should not be underestimated.

Session 5 Wrap-up

Participants discussed how as a group, they could contribute towards the early inclusion of new technologies such as the NASG in WHO guidance documents. Dr. Möller recommended that the Essential Health Technology Department at WHO can be contacted and the case made for their inclusion in appropriate treatment guidelines.

Another question was raised about limitations to the content of the Essential Medicines List, as most items included on the list are medications and not devices. Dr. Möller clarified that devices are not included in the medicines list, mostly because they are regulated in a different way and the methods and models used in/for the evidence based selection of essential medicines can not be applied to medical devices. WHO did facilitate a publication on Essential Medical Devices and consumables for use in reproductive health. This document is more advisory by nature and is intended to highlight what might be needed when implementing existing RH treatment guidelines. The publication was delayed because of confusion about its purpose, but now it had been released and we should see its publication in 2008.

A third topic for discussion was next steps to adding Oxytocin in Uniject and misoprostol for PPH and PAC indications to the Essential Medicines List. Dr. Möller thought that Oxytocin in Uniject could be added to the List as the dose and dose frequency are not affected. The Uniject is merely an administration device. Dr. Möller suggested that the concept should be marketed, such as advising suppliers to register at the UN Global Marketplace for Suppliers, and WHO prequalification for quality assurance to be obtained. For misoprostol, she suggested that relevant departments at WHO be contacted to ensure submissions to the EML committee before the deadline.

Session 6: Tours of PATH's Lab and Shop

Tour Guides: Matt Steele, Glenn Austin, and Bill Van Lew.

All interested conference guests received a tour of PATH's lab and product development shop.

Session 7: New Technologies to be Developed or Adapted

Glenn Austin from PATH introduced an approach to group brainstorming and decision-making—thinking broadly and creatively, before focusing on details—for the group to determine priorities. Themes and factors brainstormed and voted upon included:

Needs Themes

- **Access**
- **Awareness (received #3 vote)**
- **Communication**
- **Coordination**
- HR/Skills
- Availability
- **Futuristic thinking**
- **Long term (20 years)**
- **Transition phase (received #5 vote)**
- **Prediction of crisis**
- Learning from the past leading to advocacy
- Magnesium sulfate (new delivery)
- **Oxytocin in Uniject and/or Misoprostal* (received #4 vote)**
- Neonatal birth kit: VITA, chlorhexadine, wrapping, drying, cord care, bag and mask
- Job aids
- IEC
- **Safe abortion services (received #1 vote)**
- **Refinement and review of new applications off/for existing technology and evidence base (received #2 vote)**

Factors

- Confidentiality
- Trust
- Language
- Providers
- Logistics
- Feedback
- Patents/licenses
- Politics
- New technology progression

The discussion of Oxytocin versus Misoprostol ended with participants deciding that both added value in different ways. Furthermore, Misoprostol can be used for treatment of incomplete abortion.

The top three votes above were chosen as themes for small breakout sessions. The purpose of the breakouts was to brainstorm creative ideas, setting aside the analytical/critical mind.

1. Safe Abortion

Creative idea: Safe abortion box in medicine cabinet (i.e. advance prescription) – take it if period is more than three days late.

- Mifepristone/Misoprostol; packed with education insert
- Women would have to be fairly accurate in knowing when they have missed a period—pair it with Persona (ovulation predictor)
- Education and instructions necessary – where to go if taken and problem or still no period.
- How to distribute:
 - Home-based post rape care: STI drugs, PEP, EC
 - If people don't come forward early enough, include safe abortion pills in addition to EC

What if the woman is pregnant before rape?

- Pregnancy tests with algorithms determining pregnancy before vs. after rape will probably be too complex for home use.

- Kits are given to every woman who checks into tent because they usually do not come forward for help after rape.

Post-rape kits would need to meet the needs of women whose pregnancy status varies:

- Non-pregnant women
- Pregnant women who want to keep the baby
- Women who do not know their pregnancy status before being raped

Delivering to inaccessible places:

- Kits are given to authorities/women/figures trusted by the community, with some instruction.
- Give PEP to any group (not based on previous HIV status of locale).

Getting Mifepristone/Misoprostol in kits:

- Do not tell anyone; hope the drugs are not detected in customs.
- Still need staff to be aware of how to use them.
- Adhere Mifepristone to condoms; develop Mifepristone lollipop
- Monthly vitamin regimen; post rape vitamin; anti-anemia/iron fortification

Ways to find help regardless of country laws:

- Communication including how to find a provider
- Women's network or provider network
- Rap song/African folk tale
- Need a way to identify "real" product to avoid black market counterfeits
 - Fizz or change color (linked to real drug molecule) when wet
 - Increase access to drug to avoid black market / counterfeit
- Do not administer if a woman wishes to maintain pregnancy – instructions that could be interpreted in reverse for use by women who wish to terminate a pregnancy
- Harm reduction model – although not 100% effect and some risks, less risks than most other methods of self-induced abortion
- Pharmacists do not necessarily have internet access
 - Cell phone international recorded Misoprostol-use hotline
 - Register online
 - Text messaging for questions and updates
- Low sensitivity pregnancy test for kit (to verify if Misoprostol works)

2. Advancing access to and use of existing RH technologies

- Misoprostol for PPH prevention
- Oxytocin for PPH prevention and treatment
- Chlorhexidine
- Non-pneumatic Anti-Shock Garment (NASG)
- Alcohol rubs, waterless sanitizers and foaming sachets
- Sister to sister post-rape care kit
- Review stability of Oxytocin
- Use of information technology and user involvement in product development
- Talking job aides
- Preset dials on cell phones/GPS phones
- Green technology and minimal waste generation
- Messages for newborn care including promoting longer, exclusive breastfeeding for child spacing; putting nothing on the cord.
- Training to recognize PPH
- Refugee camp planning to minimize incidence of sexual assault
 - Alternative fuels to firewood, including fuel efficient stoves and solar cookers
 - Point of care rapid tests (patient-user based), such as pregnancy test kits

3. Access/Awareness/Communication/Coordination

An ideal situation was characterized by the opposite of chaos, where by, there was:

- Order, structure
- Control, predictability
- Ability to plan and decide; empowerment
- Adequate information, knowledge of environment
- Security, safety
- Accessibility, availability
- Met need
- Service quality—of care, life and reflection of people's voices
- Opportunity for people to voice their concerns and provide feedback

Everything influences access; barriers have to be eliminated for people to access services, including:

- Language, culture, turf, territories and agency mandates

Even in camps, there are islands of security, including:

- Points of access, such as monasteries, a person's own home (**person-to-person**), family networks
- Privacy, convenience, traditions
- Markets, food distribution points
- For pregnant teens, peers, school/social and virtual communities can be points of security

Service providers can benefit from:

- Education, training and job aids—tele-medicine, virtual consumers
- Technologies (with considerations for electricity/energy)
 - Internet (two-way)
 - Touch screens, GPS, video
 - Cell phones (two-way) for help or information
 - CD with translated job aids (one way but cheaper)

Individuals and communities can benefit from:

- Non-food items (NFIs) with **first-aid kits** that include condoms and other supplies
- **Home-based care**, such as care to survivors of sexual violence, where trust, social and community networks exist.
- Education and information on the importance of and where to seek care.
- Psychosocial, safe spaces (youth centers, child friendly spaces, women's centers, etc.)
- Livelihoods, household energy, solar panels, etc.
- Technologies to facilitate the home/individual concept:
 - Referrals (medical)—ATVs, motorcycles, bicycle
 - Phones in camps or catchment areas to call for help, such as for security when collecting firewood, although the issue of lack of access to all available networks and services was discussed, if the phone was not available to all, including the most vulnerable. The issue of communications mechanisms being abused, as during the Rwandan genocide, and confidentiality, were also noted.

Technologies and communication tools are mechanisms that can empower both the provider and the individual/communities.

Session 8: Next Steps

Moderated by Susan Purdin of IRC, participants discussed next steps to the New Technologies Consultation. Three key questions were asked, including, 1) How should the Working Group operate; 2) What are the priority technologies; and 3) How will field input inform the New Technologies Working Group activities? The three technologies to advance were determined as: 1) Cell phones for information and connectivity; 2) Community-based package for post-rape care; and 3) PPH technologies; given the

common interest around home-based care and previously discussed selection criteria. Participants discussed milestones, in addition to immediate next steps (such as drafting a concept notes for fundraising) with designated leadership and determined means of communication.

1. Cell Phones for Information and Connectivity

Steps discussed included the need to:

- Conduct a landscape/feasibility analysis of best/worst practices, and who is doing what where.
 - Literature review (primary and secondary research) of tools used in all different settings
 - Interviews with technology creators and applications experts
- Determine needs and how it relates/potential synergies with other reproductive health technologies/interventions
 - Gather field input to understand need, from both providers and communities on cost-effectiveness, product characteristics
- Prototype on paper (scenario planning to identify obstacles, opportunities)
 - Follow-up with experts; iterative feedback
- Determining cross-agency connectivity
 - Initial concept note
 - Discussion at IAWG annual meeting in November to invite more people and identify champions
 - Liaise with communications cluster
- Identify champions/experts (existing tech)
- Assign Roles
- Identify resources and cost

Next Steps/Action Plan

- Draft concept note for November IAWG annual meeting.
- Leaders: Jennifer Blum (Gynuity) and Glenn Austin (PATH) will work together to designate a leader. The person can contact Phone for Health.

2. Community-based Care for Survivors of Sexual Violence

Take-home package for individual, which can be distributed where access to providers is limited and where the urgency of PEP is high.

- Possible naming:
 - “Community-based post-intercourse”
 - “Management of unplanned pregnancy”
 - “Management of unprotected sex”
 - “Rape” language makes politically more palatable but less appealing to user
- RH kits should be distinct from rape kits.
- Translation to local language is necessary.
- Concern around messaging. Literacy or information session required – need to understand rape; cannot prevent AIDS.

Need for a distribution system

- How to identify provider/sister/trusted community member for distribution--in especially chaotic situations?
- Possibilities include teachers, women’s groups, traditional birth attendants, and women with health worker status, although hard to identify

Kit content

- EC
- PEP – information leaflet
- STI care
- Misoprostol?

Identify one or more groups (NGOs) interested in piloting

- CBOs (women's organizations)

Barriers to initiative

- Political system in each country will be resistant
 - Must be done discreetly; do not advertise.
 - Engage NGO partners.
 - PEP as a valuable commodity.
- Security issues for women
- Balance with monitoring (post-rape situations difficult to trace)
- Providers resist idea of putting medical autonomy in hands of women
- Misoprostol addition

Pilot/Evaluation

- Solicit field input in planning pilot and evaluation
- Need to determine target populations in order to estimate demand/who qualifies as eligible
- Document results
- Develop dissemination/communication plan; dissemination can differ based on area.
- Give results to humanitarian organizations?

Next Steps

- Draft concept paper (for funding)
- Identify resources and costs
- Working Group members include:
 - PATH (Lorelei Goodyear), Women's Commission (Sandra Krause), UNFPA (Erin Kenney, Wilma Doedens), Gynuity (Beverly Winikoff and Jennifer Blum), GHAP (Kate Teela); Venture Strategies (Ndola Prata), IMC (Julie Taft),
 - MSI, MSF, ICRC, IPPF, PSI, DKT (community-based distribution)
 - Individuals involved in promoting safe abortion access
- Communication will be conducted via group **teleconference** at set intervals, the first of which will be scheduled before June 18-20 (RAISE Conference)

3. PPH Technologies (NASG, Oxytocin in Uniject, Misoprostol)

The goal for this group was to develop an "integrated milestone list" for IEHK and RH Kits. The timeline is as follows:

- Apply for inclusion in the WHO Essential Medicines List
- Promote technologies at UN global market place
- Conduct operations research in relief settings
- Present on technologies at IAWG meeting in November
- Integrate products into training materials for IAWG Academic Partnership mobile trainings.
- A Bellagio meeting in 2009 was suggested.

Next Steps

- Ndola Prata (Venture Strategies) and Jennifer Blum (Gynuity) to draft applications for EML inclusion by October 2008.

4. Overall Next Steps

- IRC/Women's Commission to draft matrix on technologies and next steps.
- IAWG New Technologies for Crisis Settings Working Group Leadership Group: Wilma Doedens (UNFPA); Lorelei Goodyear (PATH); Ndola Prata (Venture Strategies); Julie Taft (IMC).

**Consultation on Reproductive Health Technologies in Crisis Settings
May 13-14, 2008, PATH Seattle
Attendees**

Name	Organization	Email address
1. Kate Teela	Global Health Access Program	kateteela@gmail.com
2. Tom Lee	Global Health Access Program	tomlee@ucla.edu
3. Beverly Winikoff	Gynuity	bwinikoff@gynuity.org
4. Jennifer Blum	Gynuity	jblum@gynuity.org
5. Gordon Perkin	Independent consultant	gordon@gordonperkin.net
6. Julie Taft	International Medical Corps	jtaft@imcworldwide.org
7. Mary Pack	International Medical Corps	mpack@imcworldwide.org
8. Tran Nguyen Toan	International Planned Parenthood Foundation	NTTran@ippfeseaor.org
9. Susan Purdin	International Rescue Committee	Susan.purdin@their.org
10. Harshad Sanghvi	Jhpiego	hsanghvi@jhpiego.net
11. Luke Mullany	Johns Hopkins School of Public Health	lmullany@jhsph.edu
12. Heidi Quinn	Marie Stopes International	heidi.quinn@mariestopes.org.uk
13. Glenn Austin	PATH	gaustin@path.org
14. Jane Hutchings	PATH	jhutchings@path.org
15. Jessica Fleming	PATH	jffleming@path.org
16. Jim Litch	PATH	jlitch@path.org
17. Lorelei Goodyear	PATH	lgoodyear@path.org
18. Matt Steele	PATH	msteele@path.org
19. Michael Free	PATH	mfree@path.org
20. Patricia Coffey	PATH	pcoffey@path.org
21. Paul Labarre	PATH	plabarre@path.org
22. Scott Jackson	PATH	sjackson@path.org
23. Steve Brooke	PATH	sbrooke@path.org
24. Elizabeth Scharpf	Sustainable Health Enterprises	ems@sheinnovates.com
25. Suellen Miller	UCSF, Women's Global Health Imperative	suellenmiller@gmail.com
26. Atieno Ojoo	UNICEF	aojoo@unicef.org
27. Wilma Doedens	United Nations Population Fund	doedens@unfpa.org
28. Ndola Prata	Venture Strategies for Health and Development	ndolaprata@gmail.com
29. Helene Möller	WHO	mollerh@who.int
30. Zaitoon Qazi	WHO	qaziz@who.int
31. Mihoko Tanabe	Women's Commission on Refugee Women and Children	mihokot@womenscommission.org
32. Sandra Krause	Women's Commission on Refugee Women and Children	Sandra@womenscommission.org