

African Region

Clean Delivery Kit Workshop Report

Nairobi, Kenya

March 2-4, 1999



Supported By:
The William H. Gates Foundation

PATH Kenya
30 Ole Odume Road
PO Box 76634
Nairobi, Kenya

PATH Seattle
4 Nickerson Street
Seattle, Washington 98109
USA

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Background

As a result of the growing interest in Africa in the use of clean delivery kits in preventing umbilical cord infection (which can lead to maternal and newborn mortality and morbidity), PATH organized a Clean Delivery Kit Workshop in Nairobi, Kenya, March 2-4, 1999.

The purpose of the clean delivery kit workshop was to convene traditional birth attendants (TBAs), medical providers, policy makers, and donor representatives with experience in maternal and child health (specifically, delivery of newborns in Africa) to discuss the use of clean delivery kits.

The workshop, supported by funds from the William H. Gates Foundation, had the following objectives:

- provide a forum to share information among users of various types of clean delivery kits;
- provide information to interested non-users (kit development, local assembly, marketing);
- develop recommendations for improvements in the kit and its promotion, including technical improvements in kit components, educational materials, marketing strategies; and
- develop policy recommendations regarding use of clean delivery kits in the prevention of maternal and child mortality and morbidity.

Issues addressed during the three-day workshop included:

- how to determine the need for clean delivery kits,
- the local design and development of delivery kits,
- experience using clean delivery kits,
- evaluation of the effectiveness of kits in preventing cord infection,
- the role of traditional birth attendants (TBAs) in the use and distribution of kits, and
- the financial sustainability of delivery kits.

The approximately 25 workshop participants included representatives from nongovernmental organizations (NGOs) interested in the development of clean delivery kits for use in their prenatal delivery and maternal and child health services. Other participants included: medical provider trainers; nurse-midwives, TBAs, and physicians with experience conducting deliveries using clean delivery kits; policy makers; and donors concerned with clean delivery kits.

The Problem: Neonatal Cord Infection

Of 8.1 million infant deaths worldwide, almost two-thirds are neonatal deaths (i.e. deaths occurring in the first month). Although infant mortality has been decreasing steadily all over the world, changes in neonatal mortality have been much slower. Almost two-thirds (2.8 million) of newborn deaths occur within the first week of life, and many of the deaths that take place after that time are due to perinatal causes. (WHO/FRH/MSM, 1996.)

In 1993, 42 percent of all newborn deaths were due to infections, including neonatal tetanus and sepsis. Two-thirds of those infections were related to the birth process. Infants delivered at home without a trained birth attendant and without precautions of hygiene are particularly at risk, as are their mothers. (WHO/FRH/MSM, 1996.)

The Role of Clean Delivery Kits in Reducing Infection

Each year, 60 million women worldwide give birth with the help of an untrained TBA, a family member, or with no help at all. Because of these circumstances, a clean delivery kit for use at home represents an innovative, cost-effective way of promoting hygienic deliveries. World Health Organization (WHO) research indicates that pre-assembled, clean delivery kits with instructions for use could be a vital component in the reduction of neonatal and maternal mortality and morbidity due to cord infection, tetanus, and puerperal sepsis. Therefore, WHO and other organizations have been promoting and supporting the use of clean delivery practices.

What Are Clean Delivery Kits?

Clean delivery kits are simple kits containing essential items to minimize infection during the delivery process. The components of the kit are meant to promote WHO's hygienic birth practices called "clean delivery and cord care." These practices mean "observing the principles of cleanliness throughout the labor and delivery and after birth until the separation of the cord stump." (WHO/FHR/MSM, 1996.) Essential components of a simple clean delivery kit include: clean razor blade, cord ties, plastic sheet, soap, and pictorial instructions for using kit components correctly.

The manufacture and distribution of low-cost, clean delivery kits address critical perinatal and neonatal health problems such as tetanus and sepsis by potentially making clean delivery equipment accessible to large numbers of women. Clean delivery kits help women protect their own health, as well as their baby's. Beyond the immediate health effects, local development, production, and distribution of clean delivery kits can help establish and/or strengthen local women's organizations and help strengthen community health workers' involvement in health care. Lastly, the kits can be designed and distributed in ways to promote linkages between women and trained TBAs.

It is important to state that while delivery kits play a critical role in promoting hygienic deliveries, there are many variables in the delivery environment that impact cord infection. These include dressings that are applied to the cord stump such as dung, ghee, or unclean rags. Thorough handwashing remains one of the most important hygienic practices in delivery situations.

Home vs. Facility Clean Delivery Kits

Clean delivery kits are useful not just in home settings, but at health facilities in poor urban centers as well. Many of these facilities lack appropriate emergency care equipment and supplies. Delivery equipment may be unclean because of inadequate sterilization or inappropriate storage, or it may be totally unavailable. Women may be expected to bring their own delivery supplies when they go to a hospital to deliver their baby. For these reasons, clean delivery kits may be appropriate not only in rural areas where women deliver alone or with trained or untrained TBAs, but also in resource-poor hospitals in urban areas where supplies for clean delivery (as well as other medical procedures) are scarce.

PATH's Work in Nepal as a Springboard for the Workshop

Since 1988, PATH has worked in Bangladesh and Nepal with the Christian Commission for Development in Bangladesh, Save the Children, UNICEF, NGOs, and private agencies to design, develop, and distribute simple, clean delivery kits for use in the home. Beginning in 1993, PATH has worked on delivery kit development in Nepal with two key Nepali agencies, Save the Children-US and Maternal and Child Health Products Pvt. Ltd. (MCHP). Key staff in these two agencies, Chanda Rai of Save the Children-US, and Sumitra Bantawa and Renuka Munankarmi of MCHP, have unique and extensive experience related to delivery kits. This includes conducting qualitative research to determine the design of the kit, issues in kit development and contents, quality assurance of kit production, marketing and distribution of commercial kits, the incorporation of kits in TBA training, and many other issues. Given their rich experience and their recent research on the effectiveness of the delivery kit in Nepal, PATH felt that an opportunity to share experiences with colleagues working on similar issues in Africa would benefit delivery kit advocates in both regions.

Therefore, in 1998, PATH requested funding from the William H. Gates Foundation to organize a small international workshop in Africa for the purpose of sharing experiences related to the design and development of clean delivery kits. The funded workshop provided a unique opportunity for Nepali colleagues to visit Africa for a South-to-South sharing of delivery kit experiences.

The main goal of the workshop was to provide a forum to share experiences among various African countries regarding the design and development of delivery kits and to make recommendations to improve the quality, impact, and access to clean delivery kits by TBAs and pregnant women. An additional goal was the provision of a forum for a South-to-South sharing of delivery kit ideas and experiences among agencies in Nepal (Maternal and Child Health Products Pvt. Ltd.; Save the Children-US); and ministries of health and NGOs in Africa.

Workshop Recommendations and Key Issues

Following are recommendations and key issues as discussed during the workshop.

Recommendations

Access

- Simple, easy-to-use, affordable, clean delivery kits should be available in all resource-poor situations (including rural homes and urban medical facilities) to aid in preventing neonatal cord infection.
- Ministries of health should include clean delivery kits in their official list of *essential medical supplies*.
- Governments should subsidize clean delivery kits for the very poor (through UNFPA support, for example), but should also promote the purchase and use of kits by those who can afford to purchase them from TBAs and/or local retailers.

Government and NGO activities

- Where the percentage of rural deliveries is high, governments and nongovernmental organizations should support technical assistance for the design, development, and evaluation of clean delivery kits.
- The development and distribution of delivery kits should not be a vertical (top-down) program; it should be linked with existing prenatal and community health services.
- Government health workers and NGO staff should be trained in qualitative research skills to enable them to conduct research that results in appropriately designed delivery kits. These qualitative research skills can later be used to evaluate the actual use of the kit in their programs or can be transferred to other related projects.

Local development and qualitative research

- Clean delivery kits should be locally developed, culturally appropriate, contain only essential components, be simple to use, affordable, and should contain a pictorial insert suited to the literacy level of the kit users.
- Qualitative research (including focus groups with TBAs and pregnant women; in-depth interviews with women who have used delivery kits during delivery; husbands; medical workers; and retailers) should be conducted early in the delivery kit design process to assure a pragmatic and culturally appropriate kit design.
- Information, education, and communication (IEC) technical skills should be promoted among public- and private-sector health staff during the design, development, distribution, and promotion of the use of clean delivery kits.

Kit components

- New, appropriate technologies should be investigated for inclusion in simple delivery kits intended for use in resource-poor medical settings. These technologies might include: a single-dose tetracycline dispenser and/or a single-dose oxytocin injection device such as the UniJect™ system¹, a single-sided razor blade (not commonly available in some countries), and a dose of vitamin A for the mother.
- Local implementing organizations should take a more active role in determining and evaluating the components of the clean delivery kit in their local programs.
- The appropriateness of the design of the UNICEF delivery kit for use in rural conditions by trained TBAs should be re-evaluated. A simpler kit, designed locally to ensure cultural appropriateness in different regions, should be carefully considered by UNICEF program managers and policy makers.

Information sharing

- Additional workshops and meetings should be held regionally and internationally to share information and experiences related to clean delivery kit issues.
- A complete “how to” manual providing technical guidelines on the design, development, and evaluation of delivery kits should be published and distributed to ministries of health, NGOs, and maternal and newborn care programs throughout the world.
- Internet-based delivery kit data should be developed to enable improved exchange of information and experiences.

Key Issues

Following are key issues raised by workshop participants regarding kit design, development, and utilization.

- There is a need to develop kits that are unique for a particular country, (e.g., Kenya, Zambia, and Mali would have their own kits), and unique for the targeted user—whether trained or untrained TBAs, or the mother delivering alone.
- A mechanism should be developed to ensure resupply or replenishing of kits.

Policy

- Delivery kit distribution should be integrated with other health services.
- Cost-sharing mechanisms should be devised.
- A stock control system should be devised, and supplies management improved.

Who will actually use the kit?

To initiate the process of designing a delivery kit, it is critical to first *identify who will use the kit*. The kit user may include: the pregnant woman who gives birth alone; untrained or trained TBAs; medical personnel in resource-poor facilities; and, in some cultures, husbands. In several countries, the kit user is designated by government policy. Kit users must be included in initial qualitative

¹ UniJect is a prefilled, nonreusable injection delivery system, and is a registered trademark of Becton Dickinson and Company.

research to determine kit contents and cost (amount people are willing to pay), as well as to design the pictorial insert.

If the primary users of the kits are trained TBAs, it is important to include the delivery kit in TBA training programs to ensure familiarity with and correct use of the kit contents. Incorporation of kits into formal TBA training programs improves kit distribution and increases its perceived value to the TBA and the pregnant woman. TBAs can be important distributors of the clean delivery kit and, thus, raise community awareness of its importance in decreasing neonatal cord infection.

Using qualitative research as a tool to determine kit contents and use

- The first step in designing a clean delivery kit is examining the traditional beliefs and rituals associated with labor and delivery. To understand the cultural background, qualitative research methods such as focus groups or in-depth interviews should be conducted with kit users, including pregnant women and trained and untrained TBAs. When developing commercial kits, it is important to conduct in-depth interviews with husbands (who often are kit purchasers) and commercial distributors, wholesalers, and retailers.
- Qualitative research with kit users will identify which kit components are essential and how to present those components so that they are culturally appropriate and cost-effective. Such research also determines the design of the kit package, ensuring that the packaging is durable, practical, attractive, and culturally appropriate. For example, in-depth interviews can be conducted with women who have used the kit as part of a pilot study to determine how they liked the kit, whether they understood the pictorial insert, how they used kit components, whether they would use it again, and their recommendations for improving the kit.
- *Pretesting* is a qualitative technique essential to developing effective kit instructions.

Should the razor blade be clean or sterile?

- Disagreement has surrounded the issue of whether the cord-cutting instrument—usually a razor blade—should be *clean* or *sterile*². According to WHO, a *clean cutting instrument is sufficient to prevent cord infection*. Some experts believe that sterilizing the razor blade is both costly and unnecessary to prevent cord infection, whereas others feel that a sterile razor blade is essential.
- In some countries such as Zimbabwe, MOH policy mandates that a sterile cutting instrument be used. In Nepal, after much discussion, it was decided to include a clean razor blade in the kit. The Nepalese felt that sterilizing the razor blade would increase the cost of the kit and the sterility could not be guaranteed in field conditions.

Commercial vs. subsidized clean delivery kits

Commercial and subsidized delivery kits require very similar approaches in their design and development; however, there are some major differences:

²*Clean* is a non-sterile environment in which as many micro-organisms as possible have been removed through a range of disinfectant or cleaning processes. The process of *sterilizing* aims to create the total and complete destruction and killing of any and all micro-organisms. Because it is an absolute term, it is also an ideal. There can be no degrees of sterility—no item can be partially sterile. In: *Disinfection, Sterilization, and Preservation*. Seymour S Block, Febiger L, 1977, Philadelphia, PA. 2nd edition, p.11.

Commercial kits

The development of commercial kits (i.e., kits sold privately) requires:

- marketing research during the kit design process to determine the level of demand, cost, and where buyers would purchase it, e.g., TBAs, retailers, or clinics.
- establishing a reasonable kit cost by conducting qualitative research with intended users or purchasers such as pregnant women, husbands, and TBAs to determine what they can afford; keeping the design simple; and minimizing kit components.
- developing commercial, governmental, and social marketing distribution channels.
- conducting consistent promotional efforts to maintain potential users' awareness of the kit, and to maintain kit sales by wholesalers and retailers, thus, motivating them to stock and sell the kit.
- maintaining a reasonable profit margin that serves as an incentive for distributors, retailers, and wholesalers.
- manufacturing and selling additional products that will offset the low profit margin of the kit.

Because commercial kits are extremely difficult to maintain due to the low profit margin and overhead costs, there may be situations where donor agencies will purchase large quantities of kits from a small, local manufacturer to provide kits to trained TBAs in the government's health programs. While these donor purchases initially help the small manufacturer by providing needed capital, in the long term, flooding the market with subsidized kits undermines the sale of commercial kits.

Subsidized kits

The development of subsidized kits (i.e., those in which one or more components are supported by a donor agency or health ministry) is similar to the commercial kit, with the exception of the source of support. Alternative sources of funding may be used to ensure consistent kit supply. Occasionally, in commercial kits, there may be one or two items that require subsidy in order to be included in an otherwise low-cost kit. Examples of these items include gloves or vitamin A capsules. In kits intended for resource-poor medical facilities, the inclusion of single-dose injectors containing oxytocin, tetracycline for eye prophylaxis, and gloves may require subsidy.

Differences between commercial and subsidized delivery kits are shown in the chart below.

Commercial	Subsidized
Financially sound; product sustains itself.	Need for continuous external assistance, otherwise service stops.
Quality of components guaranteed.	Quality of components may be compromised to sustain the service.
Commercial marketing.	Social marketing.
Expensive for the poor.	The poor can afford.

Both commercial and subsidized kits require:

- maintaining the quality of the kit through training of production/assembly staff in quality assurance guidelines and production activities.
- determining where the kit fits into government health programs.
- training TBAs in the correct use of the kit components.

What factors should determine clean delivery kit contents?

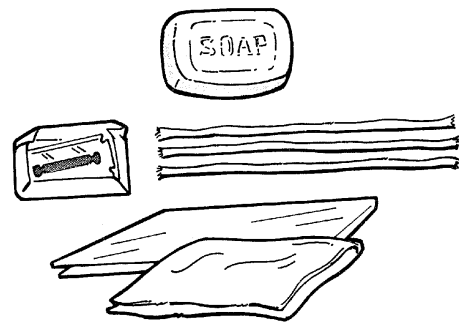
- The type of kit user influences the contents of the kit. For example, if the kit is intended for use by a family member during a home birth, the contents should be simple and disposable. If the kit is intended for use by medical personnel within a hospital or clinic setting, it might include a wider range of kit items such as gloves and oxytocin or ergometrine.
- In commercial kits, the amount that users of the kit are willing to pay partially determines the kit contents and price.
- In subsidized kits, the contents often are determined by the MOH's policy and the financial resources available.
- Including gloves and other components in kits may be problematic due to their initial and resupply costs, as well as their actual use. There is debate as to whether gloves would be used at all—or, if used, be used consistently and correctly.

Essential kit contents to prevent cord infection

Please refer to delivery kit component tables on pages 11 and 12 for contents of various kits discussed at the workshop.

The following components support WHO's "three cleans" and should be included in every delivery kit—commercial or subsidized:

- clean razor blade
- clean cord ties
- clean surface (e.g., plastic sheet) for delivery
- soap (clean hands)
- pictorial insert illustrating correct use of kit components



Some kits may also include:

- gauze
- gloves
- sanitary pads
- fingernail-cleaning sticks
- cutting surface
- tetracycline eye ointment
- baby wraps
- vitamin A capsules

Delivery kits for medical facilities

Delivery kits designed for use in medical facilities would ensure the availability of essential delivery supplies in resource-poor facilities. Delivery kits in medical facilities could be sold to the pregnant mothers during prenatal visits or upon arrival for delivery. The cost of the kit could be subsidized by the medical facility. However, the funds recovered from sales of the kit could be used to support additional manufacture/supply of the kits or to cover transportation costs for urgent medical referrals.

Workshop participants felt that *gauze* was the only component that should be added to a clean delivery kit for home use to convert it to a delivery kit for use in a medical facility.

Possible components for medical facility delivery kit:

- clean razor blade
- clean cord ties
- clean surface (e.g., plastic sheet) for delivery
- soap
- gauze
- pictorial insert illustrating correct use of kit components

Non-essential components for medical facility delivery kit (will vary according to the supplies at the facility):

- plastic sheet (depends on availability of the macintosh in the delivery rooms)
- tetracycline eye ointment in single-dose dispensers
- UniJect™ syringe with single-dose oxytocin or ergometrine is used in many health facilities post delivery (use may be controversial, as some women presenting at the medical facility may have already ingested herbs that also impact the delivery process).
- vitamin A capsules for the mother

Community involvement

Community involvement in the development, distribution, and use of delivery kits should be achieved through advocacy by government agencies and NGOs, with the following objectives:

- Identify pressure groups, such as religious institutions and women's groups, to assist in the awareness-raising and promotion of the delivery kit.
- Raise community awareness of the benefits of clean delivery kits through health campaigns.
- Involve the community in development of the delivery kit components.
- Explain the kit's economic advantages to the mother, to the family, to the community, and to the nation at large.
- The extended family members—especially the mother-in-law—should be included when explaining the advantages of using the clean delivery kit.

Men's involvement

- Increase men's involvement to ensure healthy delivery kit outcomes.
- Encourage the use of the term *Family and Child Health* as opposed to *Maternal and Child Health*, as has been adopted at some centers so as to include men in the service.
- Address gender issues. Because the only control many women have is in the area of childbirth, many are not keen to share this information with men; they should be encouraged to inform their husbands about the delivery kits and other aspects of pregnancy.
- Conduct peer education with men at workplaces and other places where men congregate. In many parts of Africa, men work in towns with the women remaining in the rural home.

- Men's input during development of the kit and its contents would make them aware of the delivery process and, therefore, more useful in case of an obstetric emergency.
- More research is required on strategies and channels of communication most effective in reaching men.

Information, education, and communication (IEC)

- Analyze accessibility, availability, appropriateness, and affordability of clean delivery kits.
- Strategize about distribution and marketing.
- Material used must be simple, user-friendly, clear, locally available, and durable.
- Information channels: posters, flyers, radio, traditional media, and traditional drama.

Community awareness on the importance/usefulness of TBA services and clean delivery kits should be supported through activities such as radio programs and jingles, newspaper articles, street drama, etc.

Table 1

Essential Components Delivery Kits in Use in Africa

	Uganda			Kenya		Zimbabwe		Nepal	Burundi
Type of Kit →	MAAMA Kit	CREHP Kit	TBA	Kibiri Kit ⁺	TBA Kit	Home Kit	Health Center*	Sutkeri Samagri	Birth Kits
Kit Components ↓									
plastic sheeting (mother)	2m	yes [#]	2m		1			1	
plastic sheeting (materials)	1m	.5m							
cord ties	yes	yes		2	2		4	3	1
razor blades	2	2	1 package	1	1	1 (new)		1	1
bar of soap	yes	yes	yes		1	1		1	1
pictorial instructions					yes			yes	yes
+Packed in a match box. *This Health Center kit is sterilized. #Sold separately.									

Table 2

Nonessential Components Delivery Kits in Use in Africa

	Uganda				Kenya		Zimbabwe		Nepal	Burundi
Type of Kit → Kit Components ↓	MAAMA Kit	CREHP Kit	TBA†	Health Unit§	Kibiri Kit	TBA Kit	Home Kit	Health Center²	Sutkeri Samagri	Birth Kits
gloves	3 pair	3 pair	5 pair			1 pair		1-mother 2-TM		
gauze pads/rolls	yes		yes					yes		3 rolls
250 grams cotton wool	yes		yes							
1 syringe & needle	yes									
cloth		6 pieces					multiple cloths⁴			1 sq. meter
sanitary pads	8									
empty matchbox					1					
cotton swabs				yes	3			yes		
paper towels						2				
Q-tips (cotton buds)						5				
child health card						1				
large mealie bags							1			
water jug dish (for hand washing)							1			
bottle of surgical spirit							1			

† Kit contents in addition to items listed in Tables 1 and 2: 1 pair scissors, pads, 1 adhesive plaster, First Aid dressing (large size), 2 meters plastic sheeting, 1 surgeon's hand brush with white nylon bristles, towel huck, 1 roll of non-sterile umbilical tape, and 1 Pinard Monoaural foetal stethoscope.

§ Kit contents: 2 artery forceps, 2 pairs scissors—one for episiotomy and one for cord, 1 non-toothed dissecting forceps, 1 sponge-holding forceps, 1 Cusco vaginal speculum, 3 dressing towels, 1 needle holder, needles for repairing episiotomy, 5 gauze mops, catgut, 2 kidney dishes, 2 bowls, and two swabs for cleaning the baby's eyes.

² This Health Center kit is sterilized.

⁴ For mother to lie on, to clean mother, to wrap baby, sanitary towel, and wash/dry.

To get copies of the complete **Clean Delivery Kit Workshop Report** and the **Delivery Kit Workshop Manual**, contact *PATH* directly. The cost for the *Workshop Report* is US\$5 and the *Workshop Manual* is US\$3.

In Africa, write, call, or e-mail

Judy Muturi
PATH Kenya
30 Ole Odume Road
PO Box 76634
Nairobi, Kenya
Tel: (254-2) 577-177
Fax: (254-2) 577-172
E-mail: info@path-kenya.or.ke

Outside Africa, write, call, e-mail

Kimberly Evans
PATH
4 Nickerson Street
Seattle, WA 98109-1699 USA
Tel: (206) 285-3500
Fax: (206) 285-6619
E-mail: info@path.org

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The **Delivery Kit Workshop Manual** was developed to provide background information to the workshop participants on delivery kit design, development, evaluation, and other relevant issues. It is being distributed as a companion document to this workshop report.