# Q&A For Mother-Baby Pack

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For use in preparing for media interviews and for general audiences

Overview

Q: What is the Mother-Baby Pack?

A: In collaboration with the World Health Organization, UNITAID and global partners, UNICEF has developed an innovative pack of medicines for pregnant women living with HIV, HIV-positive mothers and their infants in the context of prevention of mother-to-child transmission of HIV -- a process known as PMTCT.

The Mother-Baby Pack contains efficacious drug regimens (antiretroviral medicines and antibiotics) for prevention of HIV transmission from mother to child; these are in line with
Option A of the 2010 World Health Organization recommendations to protect the health of an HIV-positive mother and her baby. The drugs in the MBP cover a period of about 7 months - from 14 weeks of pregnancy until 6 weeks after delivery. Since the MBP contains drugs for infants that cover the first 6 weeks of breastfeeding, UNICEF is supporting national programmes to provide additional medicines (Nevirapine suspension and cotrimoxazole) for the breastfeeding period beyond 6 weeks.

The medicines in the pack serve only to protect against transmission of the virus from the mother to the baby and against opportunistic infections (for the mother and the baby) -- not to treat HIV.

Q: What are the WHO recommendations to prevent HIV transmission from the mother to the child?

A: WHO 2010 guidelines recommend two prophylactic options for HIV positive pregnant women who do not yet need treatment for their own health, Option A and Option B.

Option A recommends the provision of a combination of three different antiretroviral medicines (ARVs) to HIV positive pregnant women starting at 14 weeks of pregnancy until the immediate post partum, and to their infants during the whole breastfeeding period. These medicines are Zidovudine (AZT) during pregnancy and the combination of Zidovudine (AZT), Lamivudine (3TC) and Nevirapine (NVP) during labour and immediate postpartum to the mother and Nevirapine to the infant during breastfeeding.

Option B recommends the provision of a triple ARV prophylaxis for the mother (a similar combination to lifelong treatment regimens – all three drugs at the same time) starting from as early as 14 weeks of gestation and continued until delivery, or, if breastfeeding, continued until 1 week after all infant exposure to breast milk has ended. The difference with lifelong ARV treatment is that the mother will stop ARV prophylaxis at the time of delivery, or, if breastfeeding, until 1 week after all infant exposure to breast milk has ended.

Q: How are the Mother-Baby Packs to be distributed?

A: Workers in antenatal clinics and maternity wards will distribute the packs to pregnant women who have tested positive for the virus, and whose immune systems are strong enough that they do not yet need HIV treatment for their own health.

Q: How much does the Mother-Baby Pack cost?

A: The cost of the Mother-Baby Pack is approximately 70 US Dollars. Countries which distribute the pack must also estimate an additional cost for customs clearance, storage and distribution – usually totalling about 10% of the cost of the medicines themselves.

Q: Why is it necessary?

A: A woman living with HIV can pass the virus to her baby during pregnancy, labor and delivery or breastfeeding. A combination of antiretroviral medicines – along with the
antibiotic cotrimoxazole – may be given during these stages to protect the health of both mother and child, and reduce the risk of HIV transmission to the child.

But the right medicines must be taken at the right times at every stage if transmission is to be prevented. Not all mothers and babies complete this preventive treatment, leaving gaps between the number of women who start PMTCT (taking an HIV test) and the number who finish it (providing preventive medicines to HIV-positive pregnant women and mothers and their infants).

These gaps exist for a variety of reasons – including weakness in national health systems and mothers who are unable to access care.

The following gaps have been observed:

- **Between the number of mothers entering antenatal care and the number starting PMTCT.**
  
  Not all pregnant women who make a first antenatal visit to a health clinic and test positive for HIV will go on to receive the necessary medicines for PMTCT. Those who begin taking the medicines may not continue to the end.

- **Between the number of mothers enrolled in PMTCT programmes and started on anti-retroviral medicines to reduce transmission risk, and the number of their babies started on anti-retrovirals after delivery to reduce transmission risk.**
  
  Not all babies of mothers living with HIV receive medicines to prevent transmission, even though the mothers may themselves be on antiretroviral medicines. If mothers do not bring their babies to a clinic for a post-natal visit, the babies will not be prescribed the medicines they need to prevent transmission.

- **Between mother/baby pairs receiving the most effective drug treatment and those receiving less effective treatment.**
  
  The 2010 WHO guidelines call for mothers in PMTCT programmes to receive a combination of medicines to prevent transmission and guard against opportunistic diseases. This is currently the most efficacious and effective PMTCT drug regimen. But in line with earlier guidelines on preventing transmission, some mothers and babies still receive less efficacious regimens such as only a single dose of one drug, Nevirapine, or a short course of AZT without prophylaxis during breastfeeding. UNICEF’s goal is to see all women and babies in PMTCT programmes move to the combination drug regimen, including actual antiretroviral therapy for pregnant women in need of treatment for their own health.

- **Between different national health systems regarding effectiveness in managing drug supplies and procurement.**
  
  Not all national health systems can ensure the availability of the full supply of medicines needed for consistently effective PMTCT programmes.

The Mother-Baby Pack responds to these problems by:

1) Providing a full set of PMTCT medicines to start at 14 weeks of pregnancy -- or the earliest opportunity thereafter – through to six weeks after birth. The baby’s Cotrimoxazole, included in the Pack, is given starting at six weeks after birth.

2) Including medicines for both mother and baby

3) Using medicines in line with the 2010 WHO guidelines for PMTCT
4) Packaging in a single box all essential medicines for PMTCT for one mother and baby. These medicines will last until the baby’s visit to a health care facility for immunisation at six weeks. The WHO recommends that babies born to women living with HIV be tested for the virus within two months after birth, and that test may be conducted during the immunization visit.

Q: Why would UNICEF create a Mother-Baby Pack for WHO option A and not Option B?

A: The WHO has recommended two treatment options for women who are living with HIV but do not yet need treatment for the virus with antiretroviral medicine. The drug regimen used in the Mother-Baby Pack is consistent with one of these options, known as Option A.

In UNICEF’s view, both options are effective and equally valid, as explained in the WHO guidelines. Each country must choose the option best suited to its own health system and population. UNICEF in no way wishes to influence governments in choosing between these options, and will support countries using either one. UNICEF’s goal is the scaling-up of PMTCT around the world, using the most efficacious drug regimens – not the promulgation of one option over the other.

The Pack is an added innovation available to countries for their PMTCT programmes. It uses medicine based on Option A simply as an initial proof of concept of the value of co-packaging.

Following the initial implementation of the Mother-Baby Pack, and based on lessons learned, UNICEF, in collaboration with WHO and other organizations, will explore the possibility of packs consistent with the other Options.

Q: How great is the problem of HIV transmission from mothers to their babies?

A: Every day, more than a thousand infants worldwide are infected with HIV during pregnancy, labour, delivery or breastfeeding. Without medical intervention, at least half of these babies will die before their second birthday.

A full course of PMTCT medicines for mother and child (as recommended by the 2010 WHO guidelines) can cut the virus’ rate of transmission to just 5 per cent or less among mothers who breastfeed their children. Without any interventions, the chance of transmission is about 30 per cent.

For PMTCT to succeed, pregnant women and infants born to HIV-positive mothers must be tested for the virus. If mother and child enter a PMTCT programme, both must receive all the medicines needed to prevent transmission and stop opportunistic infections. But many do not get the medicines required. This can happen because need is forecasted poorly in advance, and because drug stocks often run out in some countries.

The Mother-Baby Pack is one response to these obstacles. Among other benefits, it is designed to simplify forecasting by consolidating a set of essential PMTCT medicines into a single pack for one mother and her baby.

Q: In brief, how does the Pack work?
A: When a pregnant woman comes to a health clinic for her first antenatal visit, she is tested for HIV. If she tests positive, and her infection status has not reached the point where she needs HIV treatment herself, healthcare workers can give her a Mother-Baby Pack and instruct her in its use. Mothers should be medically assessed before starting to use the Pack to ensure that they do not need treatment for their own health.

Inside the box, the mother finds a complete set of medicines to prevent mother-to-child HIV transmission, packaged to make it easy to administer the right doses to herself and her baby at the right times. The pack’s design and colour-coding make it easy for mothers to give themselves and their babies the appropriate medicine throughout treatment.

Mother and child return to the clinic several weeks after birth, during the breastfeeding period, for routine checkups and for the baby to be tested for HIV. Testing is recommended within two months of birth if the clinic is using a PCR test to detect the virus, or at 18 months if an antibody test is used.

The Mother-Baby Pack contains medicines to be taken starting from 14 weeks of pregnancy, or at the earliest opportunity thereafter, and continuing through to six weeks after delivery -- the point at which mothers should bring their babies to a clinic for their first immunization visit. The pack also contains a six-week supply of the antibiotic cotrimoxazole for the baby, to be started at six weeks of age.

If a mother makes her first antenatal visit to a clinic later than 14 weeks after gestation, health workers will need to remove some of the medicines from the Pack to customise its dosages to the patient’s needs.

Q: Can mothers who themselves need treatment for the virus use the Pack?

The Mother-Baby Pack is only for HIV-positive pregnant women who do not need treatment for their own health. It is provided for just one reason: to prevent transmission from an HIV-positive mother to her infant. Women who need treatment for their own health will receive appropriate care according to their country’s national guidelines.

Zambia provides one example of a country using the Mother-Baby Pack’s medicine in tandem with medicine for treating a pregnant HIV-positive woman for her own health. For these women, the Zambian government is planning to augment the Pack with additional medicine specifically intended to treat the mother.

Q: Will mothers in the developing world really administer these powerful medicines to themselves and their babies on schedule and in the correct doses?

A: The ability of mothers to correctly administer pre-measured and pre-packed PMTCT medicine has already been established in Lesotho, where mothers successfully used medicine prepared by health workers and bundled in plain paper bags. That innovation inspired the Mother-Baby Pack.

The design of the Pack, and the training that goes with it, add an extra level of safety and accuracy to the process. They are specifically aimed at making the Pack easy for all women to use and understand, regardless of their level of literacy or medical understanding. To provide further support, we will enlist the participation of peers and community members to help mothers start PMTCT and see it through to the end.
The fathers of the babies the Pack protects will also be involved. Male partners of women using the Pack will be encouraged to support the mothers by participating in HIV testing, disclosure of HIV status and prevention of mother-to-child transmission. UNICEF partner organisations, including mothers2mothers in Kenya, will work to involve men in the process.

Pregnant women in developing countries have demonstrated a strong commitment to protecting their babies from HIV. UNICEF has encountered mothers who will walk for a day or more through rugged terrain while pregnant, simply to reach a clinic for a first antenatal visit. These women are dedicated to having healthy babies, and will do whatever is necessary to make that possible – including following the Mother-Baby Pack instructions.

Q: If this idea is both simple and effective, why wasn’t it tried years ago?
A: Because we didn’t know then what we know now. Today, we have significant fresh evidence on PMTCT, as well as new information on optimal timing for starting antiretroviral drug therapy. This fresh evidence led WHO to revise its guidelines on more efficacious medicine regimens for PMTCT in 2010. The updated recommendations will guide the development of innovation to support the delivery and treatment of pregnant women living with HIV. It is one of our strongest steps towards the elimination of mother-to-child transmission of HIV -- and an HIV-free and AIDS-free generation.

Rollout and Phased Implementation

Q: How is the Pack being rolled out?
A: The rollout involves a process known as “phased implementation with validation.” In lay terms, that means the Mother-Baby Pack will be implemented in phases, starting in a limited number of selected health districts, with its performance closely monitored.

The first phase is taking place in four sub-Saharan African countries – Cameroon, Kenya, Lesotho, and Zambia -- and is scheduled to run through mid-2011. Once that initial phase is complete and a review of the implementation is undertaken, the Pack will be expanded to other sites and to other countries that have chosen WHO guideline Option A for PMTCT.

During phased implementation, only a limited number of health centres will distribute Mother-Baby Packs. These centers all deliver antenatal care to a large number of women, and are situated in countries with a high HIV prevalence. They will be closely monitored.

Q: Explain “phased implementation”
A: This refers to the roll-out and distribution of the Pack in phases for use by mothers and babies. By starting with a phase involving only four countries, UNICEF can closely monitor supply, distribution and the Pack’s acceptance by mothers. It can also track management of the Pack by healthcare providers. The lessons learned will inform rollout and implementation in other countries.

As a preliminary step leading up to release, UNICEF field-tested the Mother-Baby Pack’s external packaging to ensure that the product works correctly. This test was conducted among women and health workers in Malawi, Rwanda and Zambia in 2009 to confirm that they understood the product’s visual messages about which medicines to take and when to take them.
The concept underlying the Pack – distribution of pre-packaged, pre-measured PMTCT medicines to mothers and babies – has already been proven to work in its original format in Lesotho. This real-life test of the idea behind our Mother-Baby Pack is considered in the product’s pilot phase.

Q: What is “validation?”

We want the Pack to be as good as possible, so we will monitor it closely as pregnant women and new mothers and their infants use it during the first stages of phased implementation. By ‘validating’ the process – tracking the Pack’s use and results – we can confirm that it works as expected. Communities where the Pack is distributed will be involved in the validation process.

Q: How will the Pack be provided to women?

A: Pregnant women living with HIV can get the Mother-Baby Pack only through a trained health worker. This may happen at an antenatal care clinic, in a setting where delivery takes place, or at the community level.

Health workers distributing the pack will receive special training. They include nurses and midwives, community health workers, lay counsellors and peers appropriately trained in community health and according to national policies.

The Pack should only be given to a pregnant woman living with HIV who does not yet need drug treatment for her own health. Because the Pack serves only to prevent transmission of the virus, the medicines it contains are not designed to provide HIV treatment for the mother.

Q: How will health workers help mothers to use the Mother-Baby Pack safely and effectively?

Workers who have been specially trained to explain the Pack’s correct use will provide instruction to pregnant women who receive this product.

Design

Q: What does the Pack look like?

A: The Mother-Baby Pack is a rectangular cardboard box broken down into three sections by colour, with each colour representing a different stage in the PMTCT treatment process: pregnancy (blue), labour and delivery (yellow) and breastfeeding (pink). Each section also carries a simple graphic representation of a woman and the baby at the corresponding stage.

Inside are antiretroviral medicines and antibiotics measured into doses appropriate for mother and baby at each stage. These are packed in containers marked with the stage’s graphic illustration and colour.
The design provides visual cues that make it easy for mothers to administer the right medicines at the right time. These cues support the instruction mothers receive when they first receive the pack from health workers. The Pack also includes a patient information booklet for mothers.

Q: Won’t the Pack’s distinctive appearance cause problems for mothers in places where HIV-positive people are stigmatised?

A: To help users avoid HIV-related stigma, a plain fabric cover (bag) keeps the Pack’s unique design scheme hidden from view. The box is designed for convenience in transport, and for ease of storage among household belongings. Countries implementing other packs (e.g. the “mama pack” for clean delivery) are encouraged to explore how to include the Mother-Baby Pack within existing packs to reduce stigma. In addition, community groups, support from other mothers as well as from husbands and partners must be mobilised to provide additional help for mothers, including women living with HIV.

Q: Is the Mother-Baby Pack available in local languages?

A: Currently, no. The first batch of 10,000 Mother-Baby Packs is in English only. UNICEF is working to create a new bilingual English/French version, with text on the boxes and in the enclosed patient booklet appearing in both languages. Because so few Mother-Baby Packs are being distributed in each country at this point, the supplier is unable to provide customized versions in each local language. However, UNICEF recommends that countries develop a local-language version of the patient information booklet themselves. Printing within the country has the added benefit of keeping costs down.

Contents and Distribution

Q: Which medicines does the Pack contain?

A: The content of the pack is in line with Option A of the 2010 World Health Organization recommendations for prevention of HIV transmission from mother to child. The drugs in the MBP cover a period of about 7 months - from 14 weeks of pregnancy until 6 weeks after delivery.

The pack includes the antiretroviral medicines Zidovudine (AZT) tablet, Nevirapine (NVP) tablet and suspension, and Lamivudine 150mg (3TC); these are included at doses appropriate to different stages in the pregnancy, labour and postnatal cycle. The antibiotic Cotrimoxazole is added to prevent opportunistic infections in mothers and babies. All tablets are encased in blister packs.

Since the MBP contains the infant drugs for the first 6 weeks of breastfeeding, UNICEF is supporting national programmes to provide additional medicines (Nevirapine suspension and cotrimoxazole) to cover the breastfeeding period beyond 6 weeks.
Q: Where do the medicines in the Pack originate? Where are they packaged?

A: UNICEF selected the generic pharmaceutical company CIPLA Ltd India to produce the medicines, following an international tendering process in 2009, as well as a technical and commercial evaluation of the firm. The medicines all originate in India and are pre-packed there.

Due to pharmaceutical regulations, drug packaging must be in line with accepted Good Manufacturing Practices, or GMP. Not all countries have plants in line with GMP, and because of this, it is not recommended that medications be packed in the country where they will be distributed.

Q: What is the Pack’s shelf life? How should it be stored?

The Pack has a shelf life of 24 months, and should be stored at a recommended temperature of ≤ 30 degrees Centigrade. Refrigeration is not required.

Q: How will countries get the Mother-Baby Pack?

A: During the phased implementation, UNICEF country offices in consultation with national governments will order the Mother-Baby Pack. UNICEF National Committees have played a key role in raising funds to cover the costs of the Pack for this first phase.

After the phased implementation, countries will need to include the costs for the Mother-Baby Pack in their national budgets. They will be able to purchase the packs through our Procurement Services mechanism, by which UNICEF purchases products on behalf of a particular country based on a Memorandum of Understanding between both parties. Countries can also use their own procurement system. In some countries, provisions for the purchase of the packs are already included in grants from the Global Fund for AIDS, Tuberculosis and Malaria.

A country’s order of Mother-Baby Packs can be split into several deliveries. UNICEF recommends three to four deliveries per year, with quantities adjusted to match the current rate of consumption.

Development and Use

Q: Who created the original Mother-Baby Pack?

A: The idea to separately package PMTCT medicines for clinic-supervised use by pregnant women originated with healthcare workers in Lesotho. That idea was formalised in 2007, when the Government of Lesotho -- with the help of UNICEF and other partners -- introduced a pack of ARVs and antibiotics in line with WHO 2006 PMTCT recommendations. Health workers packaged the medicines in plain brown envelopes and gave them to pregnant women who tested positive at their first antenatal care visit.
Today's Mother-Baby Pack is based on this idea – developed in Africa by African health workers – but builds on it by adding other expertise, access to drug stocks, design ability and production capacity.

Q: Is UNICEF solely responsible for the Mother-Baby Pack?

A: No. The design and contents of the pack were developed though a consultative process with the WHO and key stakeholders as part of the "inter-agency task team (IATT) on the prevention of infection in pregnant women, mothers and their children and care and treatment of HIV-infected children" to increase PMTCT availability in the developing world.

The purpose of the inter-agency task team (IATT) is to help scale-up programmes that prevent HIV infection in women, mothers and their children, in line with UNGASS resolutions, as well as expand the UN comprehensive approach to PMTCT. The IATT accomplishes this by assisting in the development of policy and operational guidance and providing technical assistance to national governments. The IATT formed a Mother-Baby Pack Technical Working Group to guide its development, field testing and distribution.

Key stakeholders include the Clinton Foundation, the US Agency for International Development (USAID), the US Centers for Disease Control and Prevention, The Elizabeth Glaser Pediatric AIDS Foundation, Columbia University’s Mailman School of Public Health, PATH and the Office of the US Global AIDS Coordinator.

UNITAID, a UNICEF partner on PMTCT, has also contributed to development of the Mother-Baby Pack. The organisation has donated funding of US$ 104 million for PMTCT projects in 17 high-need countries.

Q: What was the World Health Organisation’s contribution to the Pack?

A: The antiretroviral medicines and antibiotics in the Mother-Baby Pack are in line with the 2010 WHO option A recommendations for PMTCT. WHO was involved in the development of the contents of the Pack both as co-convenor of the IATT and active member of the IATT MBP technical working group.

Q: What are the Pack’s advantages for national governments and health care systems?

A pregnant woman’s first antenatal visit is a crucial opportunity to protect the health of mother and child, and to bring both into close and regular contact with the national health system.

The MBP is designed to contribute to improving the continuum of care for HIV positive pregnant women, mothers and their infants. During the antenatal period, pregnant women will be encouraged to attend ANC earlier (at 14 weeks), to have more frequent ANC visits (in line with the focused ANC approach), and to deliver in institutions.

National Health Systems

Q: What are the Pack’s advantages for national governments and health care systems?
In the postnatal period, mothers will be counselled and supported to bring their babies to the clinic at 6 weeks, at which point the baby will be tested for HIV and will receive additional doses of nevirapine suspension as well as routine checkups, including immunizations. At this point, the cotrimoxazole treatment will also be initiated.

Because the Pack is attractive – and is presented to mothers as a gift -- it may offer an added incentive for pregnant women to make more frequent use of health services. When pregnant women living with HIV learn from each other that free medicines in a Pack are provided during an antenatal care visit, they may feel a stronger commitment to accessing services.

Q: How does the Pack address drug shortages and weaknesses in health systems?

A: The Mother-Baby Pack offers benefits across several levels of healthcare service. By gathering PMTCT medicines for a mother and child in a single package, the Pack ensures that the necessary medicines are procured, distributed, and dispensed to pregnant women at once. This promotes consistent storage and medicine management by health systems, and reduces the chance that drug stock shortages will affect pregnant women.

The Pack also eases the burden on pharmaceutical providers at the clinic level. There is no need for them to round up supplies from different sources, because the full complement of medicines arrives in one box. And it makes PMTCT easy for mothers, who can get essential medicines they need at a single location, with just one visit.

UNICEF strongly recommends that countries using Option A of the WHO guidelines make Mother-Baby Pack supply a part of their regular PMTCT and HIV/AIDS supply chain, rather than a parallel system.

Drug Overstock and Wastage

Q: Since pregnant women do not always make their first antenatal visit at 14 weeks, won’t the Mother-Baby Pack lead to wastage of medicines?

Drug wastage is an issue that UNICEF takes seriously, and we are aware that the Mother-Baby Pack’s pre-packaged drug supplies may raise concerns about waste. We will monitor this product during the “implementation with validation” phase of its roll-out to assess wastage.

The Pack contains enough medicine for a woman to start protective treatment at 14 weeks of pregnancy, and continue it through six weeks after the birth of her child. Since the MBP contains the infant drugs for the first 6 weeks of breastfeeding, UNICEF is supporting national programmes to provide additional medicines (Nevirapine suspension and cotrimoxazole) to cover the breastfeeding period beyond 6 weeks.

Some pregnant women living with HIV, however, will come for their first antenatal care visit after fourteen weeks' gestation. Depending on how far along the pregnant woman is in gestation during her antenatal care visit, some blisters of AZT tablets will be unnecessary and must be removed by health workers. Encouraging “early booking” – a first antenatal visit at or before 14 weeks – will make it customary for pregnant women to visit a health worker in time to use the Pack’s full set of medicines.
One key objective of UNICEF’s Mother-Baby Pack strategy is encouraging pregnant women to make their first antenatal visit no later than fourteen weeks. This schedule is best for preventing mother-to-child transmission, which is why the Pack’s medicines have been organized around it. We believe that, with community support, the Pack will encourage women to think of 14 weeks as the time when antenatal care should and must begin.

**Q: How will extra medicines from the Pack be handled?**

A: Every country must decide what to do with its unused medicines. In all cases, after removal from the Pack, the medicines must be kept at the health facility where they originate. They can then be collected to ensure that they are destroyed properly, or can be reintroduced into the health system according to national guidelines.

**TECHNICAL QUESTIONS**

Detailed, specific information for specialists

**Supply**

**Q: How was CIPLA chosen to produce these packs?**

A: In 2009, UNICEF conducted competitive bidding for the job of producing the Mother-Baby Pack by issuing a request for proposals. Seventeen qualified companies were invited to bid. Through this process and subsequent stages of product development, UNICEF selected CIPLA Ltd to produce and supply the packs.

We wanted to find a company that could not only produce all of the medicines included in the Mother-Baby Pack, but also develop this new product. Of the 17 firms invited to bid, only two were able to fulfill these requirements. CIPLA was one of them.

Our long-term agreement with CIPLA permits UNICEF’s Supply Division in Copenhagen to purchase quantities of the Pack, as needed, directly from the manufacturer.

**Q: Is the Mother-Baby Pack exclusive to UNICEF or CIPLA?**

A: No. Our framework agreement for the Pack specifies that it is not exclusive either to UNICEF or CIPLA. Other manufacturers can develop it, and other buyers can establish contracts for it, subject to the steps in the procurement process required by each buyer.

**Q: What financial and logistical issues should countries keep in mind when ordering the Pack?**

A manufacturing lead time of about 12 weeks is estimated for the first round of orders. UNICEF hopes to reduce this lead time in the future.

Countries should forecast their demand for Mother-Baby Packs in advance to avoid stock shortages. In time, countries can replace their existing procurement of antiretroviral medicine for PMTCT with the Mother-Baby Pack.
Funds must be secured to ensure proper distribution within countries through either government transportation or the private sector. The distribution system must be sustainable.

We recommend shipping the Mother-Baby Pack by air, given its shelf life and the high value of its contents.

**Q: Have the medicine used in the Mother-Baby Pack been approved by the US Food and Drug Administration?**

A: Not all of them. UNICEF is working with colleagues at USAID to fast-track the Mother-Baby Pack for US FDA tentative approval. The WHO has already pre-qualified all of the Pack’s components, except the co-blisters for labour and delivery. We anticipate that the WHO’s pre-qualification will help to speed up the US FDA approval process.

**National Health Systems**

**Q: How were the four countries selected for phased implementation with validation chosen?**

Implementing countries were selected based on the following criteria:

1. **Current national PMTCT policy**

   The Mother-Baby Pack contains medicines for the mother and baby recommended by WHO PMTCT Treatment Guidelines to implement more efficacious PMTCT regimens. PMTCT National guidelines from selected countries should have recommended and implemented the use of these more efficacious regimens in line with the 2010 WHO guidelines for PMTCT. The countries should have adopted Option A of the 2010 guidelines.

2. **Current PMTCT coverage**

   To facilitate the Mother-Baby Pack implementation with validation process, selected countries should have National PMTCT coverage greater than 30% (which means that at least 30% of all pregnant women living with HIV are receiving ARVs for PMTCT).

3. **Current presence of PMTCT partners**

   At least 3 partner members of the Mother-Baby Pack Working Group (PMTCT/ IATT) should be present in the selected country to facilitate the implementation of the Mother-Baby Pack. Partners will be involved in different phases of the field testing process. Key stakeholders include the Clinton Foundation, the US Agency for International Development (USAID), the US Centers for Disease Control and Prevention, The Elizabeth Glaser Pediatric AIDS Foundation, Columbia University’s Mailman School of Public Health, PATH and the Office of the US Global AIDS Coordinator.

4. **Institutional Review Board (IRB) to address Ethical issues is in place**

   When required, the process will seek for approval of the local IRB. Therefore the selected countries should have structures and mechanisms in place for ethical reviews.
Q: How is the MBP linked to the existing health system?

The Mother-Baby Pack -- which provides the medicine for “Option A” until 6 weeks after delivery -- is integrated into national PMTCT, child survival and continuum of care programmes. The mother is advised to return to the health center during pregnancy, delivery and at 6 weeks for maternal and child health services, including routine newborn care and immunizations, Nevirapine suspension for exposed children, cotrimoxazole for mother and baby, as well as access to early infant diagnosis, if available. UNICEF is also working with national programmes to provide additional medicines (Nevirapine suspension and cotrimoxazole) to cover the breastfeeding period beyond 6 weeks. At the 6-week visit, the mother will also receive extensive counseling on infant feeding and family planning, and will be linked to community support systems if they exist.

Q: How does the Mother-Baby Pack account for the need for health workers to take on an expanded range of tasks?

A: One major challenge in the response to HIV has been the shortage of medical staff to cover the needs of people living with the virus. The ability to prescribe medication is often limited to doctors, but in many places where resources are limited, there are likely to be very few doctors available. The Mother-Baby Pack makes it easier for health care workers who are not doctors to provide life-saving medication to women who need it.

It also represents a shift towards recognising the importance of empowering pregnant women to protect their own health, and the health of their children, with medical supervision at key points in treatment. In doing so, it allows doctors, nurses and patients to share in the responsibility of care and establish a richer, more meaningful relationship.

Q: How are monitoring and quality adherence managed when mothers use the Pack at home?

During the first visit, the health worker will ask the mother to always return with the MBP for follow-up visits. Then, at each subsequent visit, it will be possible to check the quantity of medicines taken by the mother during a certain period.

Fundraising

Q: How is the Mother-Baby Pack related to UNICEF National Committee fundraising?

One funding stream for the Mother-Baby Pack is channelled through several of UNICEF’s National Committees, which are offering the Pack for purchase by individual donors as an Inspired Gift. National Committees will ensure that every purchase of a Mother-Baby Pack as an Inspired Gift leads to the creation and distribution of an actual Pack.

National Committees are also supporting Phase One of the Pack’s implementation through funds that are sent directly to the country programmes. These funds cover the costs of this phase’s packs and a contribution towards the country level implementation of the packs as part of a broader national strategy.
Q: Why doesn't the Mother-Baby Pack support all aspects of PMTCT, including nutrition, paediatric health and family planning?

The Pack is designed to do just one thing: provide prophylaxis ARVs and the prophylactic antibiotic cotrimoxazole to a pregnant woman who does not need treatment for her own health, and to the child she carries.

It is not a full PMTCT programme in a box, but rather a box of medicine which make up part of a PMTCT programme supported by a national health system. That system must provide the other components recommended by UNICEF, including early infant diagnosis, nevirapine and cotrimoxazole during the breastfeeding period beyond 6 weeks and infant feeding counseling and support, family planning and nutrition.

Q: Can the medicine in the MBP be taken concurrently with other medicine, including antimalarials or antibiotics?

In principle, yes. But Sulfadoxine Pyrimethamine for IPT of malaria in pregnancy should not be given to women who are HIV positive and who also receive Cotrimoxazole. Rifampicin, a TB treatment, should not be given along with Nevirapine, although just a single dose is used in PMTCT. For more technical details please refer to WHO Guidelines.

Q: Does the Mother-Baby Pack provide support for WHO and UNICEF’s recommendations on exclusive breastfeeding?

Pregnant women and new mothers should receive breastfeeding counselling every time they visit a health center during their antenatal care visits, after delivery and at six weeks following birth.

Mothers known to be living with HIV, and whose infants are either not infected with HIV or of unknown status, should exclusively breastfeed their infants for the first six months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life.

When HIV-positive mothers decide to stop breastfeeding -- at any time -- they should do so gradually, within one month.

If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding as per the recommendations for the general population, that is, up to two years or beyond. Breastfeeding should only stop once a nutritionally adequate and safe diet without breast milk can be provided.

Q: Why doesn’t the Mother-Baby Pack provide support for, and instruction on, exclusive breastfeeding?

The Mother-Baby Pack is being rolled out in four sub-Saharan African countries. Health workers there are providing face-to-face information on safe breastfeeding, along with follow-
up medicines for those dispensed in the Pack. More specifically, health care providers will provide counseling and support for infant feeding, including counseling and support for exclusive breastfeeding when appropriate during pregnancy and the breastfeeding period.

**Q: Why do the Pack's medicines run out after just six weeks, when PMTCT for breastfeeding infants lasts a full year?**

**A:** By providing medicine for only the first six weeks of the baby's life, we create an incentive for mothers to bring their infants to a clinic for a new supply of medicines. During that visit, other maternal and paediatric health measures will be carried out, including routine vaccination, early infant diagnosis of HIV, and instruction on infant feeding.

Our goal is to connect mothers and children with national health systems early -- not to delay the start of this vital relationship by providing take-home medicine for a full year beyond birth.