This document provides an overview of proposed approaches for assessing the safety of antiretroviral (ARV) drugs used during pregnancy and the breastfeeding period. It is intended for national HIV/AIDS programme managers and implementing partners, such as non-governmental organizations and academic institutions, that are responsible for implementing systems to monitor the safety of ARV drugs. The proposed approaches include the development and maintenance of (i) a prospective pregnancy-exposure registry; (ii) a birth-defect surveillance programme; and (iii) a prospective monitoring of cohorts of mother–infant pairs, during the breastfeeding period at sentinel sites.1

Main messages

1. The July 2013 World Health Organization (WHO) consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection now recommend the tenofovir/lamivudine/efavirenz fixed-dose combination, first-line regimen for adults, including in pregnant and breastfeeding women, and older children.

2. The new recommendation is that all pregnant and breastfeeding women initiate antiretroviral therapy (ART) — a once-daily fixed dose combination of tenofovir + lamivudine (or emtricitabine) + efavirenz is recommended as first-line regimen — and continue this as lifelong treatment (option B+), or stop when the risk of mother-to-child transmission of HIV has ceased, i.e. when breastfeeding is no longer used (option B).

3. On the basis of current evidence, WHO determines that the benefits of using ARV drugs during pregnancy are considerable, in terms of both avoidance of infant HIV infection and benefits to the mother, and greatly outweigh the potential low risks, including the risk of congenital malformation. However, to decrease uncertainty and provide more confidence around the level of risk, if any, and strengthen the motivation of both health-care providers and patients to use ART during pregnancy and the breastfeeding period, the guidelines recommend that toxicity surveillance activities and additional research be conducted.

4. Surveillance of the toxicity of ARVs during pregnancy and the breastfeeding period aims to assess the risk of adverse reactions in pregnant women and adverse effects to the fetus exposed in utero and to the infant exposed to ARV drugs during breastfeeding.

5. Three surveillance approaches are suggested to assess ARV toxicities, namely: (i) a prospective pregnancy-exposure registry; (ii) a birth-defect surveillance programme; and (iii) a prospective monitoring of cohorts of mother–infant pairs, during the breastfeeding period in sentinel sites.
6. The national decision on whether surveillance of the toxicity of ARVs during pregnancy and the breastfeeding period should be undertaken, and on which approach to use, should be informed by local needs; health-system characteristics; treatment-seeking behaviour of women; the available financial, human and technical resources; and the ability to link the required recording systems.

7. To ensure that the data provide prompt, robust evidence for policy-makers, nationally and internationally, the data collected should be of consistently high quality. To ensure that data can be pooled, so that they can inform national and international policies, it is desirable that they be collected in a standardized manner.

8. The commitment and support of national policy-makers, programme managers and health-care staff at sentinel sites are critical to the success of any of these approaches.

9. The sustainability of the surveillance system depends critically on communication and feedback of the data and findings to relevant stakeholders, including women and their communities; health-care providers; drug regulators and other policy-makers; donors; and international agencies.

10. WHO provides advocacy tools, technical guidelines and technical assistance to countries and technical organizations planning to implement ARV toxicity surveillance during pregnancy and the breastfeeding period. WHO also collaborates with scientific and research agencies to implement strengthened surveillance and research in the area of toxicity of ARV drugs in pregnancy and during breastfeeding, to inform future guidelines on the use of ARV drugs.

**Why is surveillance of the toxicity of ARV drugs in pregnancy and during breastfeeding important?**

The 2013 *WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (2) recommend that:

“all pregnant and breastfeeding women infected with HIV should initiate triple ARVs (ART [antiretroviral therapy]), which should be maintained at least for the duration of mother-to-child transmission risk. Women meeting treatment eligibility criteria should continue lifelong ART . . . A once-daily fixed-dose combination of tenofovir + lamivudine (or emtricitabine) + efavirenz is recommended as first-line ART in pregnant and breastfeeding women, including pregnant women in the first trimester of pregnancy and women of childbearing age. The recommendation applies both to lifelong treatment [option B+] and to ART initiated for PMTCT [prevention of mother-to-child transmission of HIV] and then stopped [option B].”

These updated recommendations will result in earlier and more prolonged exposure to ARVs for women, as well as increased exposure to ARV drugs for infants during the breastfeeding period (4). The likelihood of first-trimester exposure of the fetus to the new recommended regimen will increase, as women newly diagnosed with HIV initiated on treatment during one pregnancy are likely to remain on treatment during subsequent pregnancies. In addition, the 2013 guidelines recommend starting ART earlier (CD4 count of 500 cells/mm³ or less) and regardless of CD4 cell count for all people with HIV with active tuberculosis, with severe hepatitis B and for serodiscordant couples. This will also increase the number of infants born following exposure to ARVs during the first trimester of pregnancy. The first trimester is a critical period of exposure because organogenesis occurs during this time and exposure to teratogenic medicines can cause major congenital anomalies (3). While, on the basis of current data, WHO currently determines that ARVs do not, or minimally, increase the risk of congenital anomalies, more data would provide confidence around the level of risk, if any (2). Finally, pregnant women are known to be at increased risk of side effects of drugs, in particular those that affect the liver, kidney and blood pressure and psychiatric side effects.

The 2013 guidelines (2) consequently recommend that toxicity surveillance and additional research be conducted on the safety and acceptability of lifelong ART for pregnant and...
breastfeeding women, and their infants, especially in low-resource settings, where malnutrition and comorbidities are more common that in resource-rich countries.

**Goals and objectives of monitoring the toxicity of ARV drugs in pregnancy and during breastfeeding**

The goal of toxicity surveillance in HIV/AIDS programmes is to ensure that the ART regimens are safe, including for PMTCT by pregnant and breastfeeding women and for their babies.

To obtain reliable national data that contribute to national treatment guidelines and global policies, surveillance of the toxicity of ART during pregnancy and the breastfeeding period would need to include the following three areas of focus:

- **maternal health outcomes**: serious toxicities associated with ART in pregnant women;
- **birth outcomes**: on the fetus in utero, manifesting as stillbirths, preterm births and low birth weight or manifesting as birth defects;
- **infant and child outcomes**: health outcomes in infants and young children exposed to ARV drugs via breast milk, including impact on growth and development.

**Specific objectives are to:**

1. determine the incidence of important drug toxicities associated with the use of (and introduction of new) ARV drugs, including maternal mortality, in women exposed to ARV drugs during pregnancy;

2. monitor birth outcomes including preterm births, stillbirths, low birth weight and infant mortality in women exposed to ARV drugs during pregnancy, compared to women not exposed to these medicines during pregnancy;

3. assess the nature and risk of major congenital anomalies in the infants of women exposed to ARV drugs during pregnancy, compared to women who are not exposed to these medicines during pregnancy;

4. monitor the effect on growth and development in infants of exposure to ARV drugs via breast milk, and toxicities associated with such exposure, compared to infants not exposed to ARV drugs.

Important areas where data are needed, as identified in the 2013 guidelines (2), are presented in Box 1.

**Surveillance approaches**

Every point of contact from the first antenatal clinic visit, to delivery, and until the end of the breastfeeding period, is an opportunity to collect data on the toxicity of ARVs (or lack thereof) in pregnant women and infants. Opportunities to collect data occur during:

- antenatal visits at clinics or hospitals;
- labour/delivery at a health-care facility or hospital;
- postnatal visits for postpartum care, immunization clinics and other paediatric services.

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**BOX 1 PREGNANCY-RELATED TOXICITY CONCERNS**

The 2013 *WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (2) identified that more data are desirable on the:

1. severe skin rash and hepatic reactions in pregnant women exposed to nevirapine;
2. severe neuropsychiatric effects and seizures in pregnant women exposed to efavirenz;
3. preterm delivery, stillbirths and small for gestational age births associated with different ARV regimens used during pregnancy;
4. very low risk of neural tube defects in infants exposed in utero to efavirenz;
5. renal and bone toxicity in infants exposed in utero or during breastfeeding to tenofovir;
6. severe anaemia in pregnant women exposed to zidovudine, and the impact on birth outcomes.

Chapter 7 of the WHO 2013 guidelines (2), "Clinical guidance across the continuum of care: antiretroviral therapy" describes evidence from the systematic reviews conducted on the safety of ARV drugs in pregnancy and breastfeeding.
Based on the priority toxicity issues to be addressed by the surveillance system, health-care-seeking patterns of pregnant women and mothers, and available resources, surveillance systems could comprise of any or all of the following approaches:

- a prospective pregnancy-exposure registry (PER) for toxicity in pregnant women and neonates;
- a birth-defect surveillance (BDS) system for assessing birth outcomes;
- a prospective monitoring of cohorts of mother–infant pairs for toxicity from birth throughout the breastfeeding period, including significant growth and developmental delays.

In all of the above approaches, the recruitment and assessment of a concurrent group of controls comprising pregnant women not exposed to ARV drugs (i.e. women not infected with HIV) is essential, in order to understand the relative contribution of ARVs to the toxicity of interest and establish whether there is any additional risk. As many of the adverse outcomes of interest are rare, it is important to pool the data collected from several sites across several countries, to obtain sufficient data to determine whether or not treatments contribute to the risk of these rare adverse outcomes. Therefore, standardized data-collection approaches that are compliant with the norms and standards of surveillance (5), including the use of standard terminologies such as the International statistical classification of diseases and related health problems, 10th revision (ICD-10) (6) for defects of interest, should be used to enable the pooling of core data across sites and countries.

The value of any surveillance system is measured by its ability to determine the risks associated with drug exposures; to inform the strategic use of ARVs for HIV treatment and prevention, both nationally and globally; and to improve the quality of care provided to pregnant women and their neonates at the surveillance sites and beyond.

### Basic technical requirements for the three surveillance approaches

#### Prospective pregnancy-exposure registry

At selected antenatal clinics, pregnant women are enrolled from their first antenatal visit and followed up to term, including delivery.

At the first visit, information is obtained from the woman on her medical, obstetric and drug-exposure history.

Since risks are being compared between women exposed to ARVs and those who are not exposed, the fewest number of women are enrolled if there are an equal number of exposed woman (cases) to unexposed women (comparators). This approach (1:1) is recommended. ³

At each later antenatal visit, information on infections, treatments and folate supplementation⁴ is updated, and any new clinical conditions or diagnoses are recorded.

#### Birth-defect surveillance

A few facilities are selected that provide good obstetric care and where rates of delivery are high.

All women presenting for labour at these selected facilities are included.

At delivery all liveborn or stillborn babies have a standard, surface examination, which establishes any external and visible birth defects and identifies neonates in need of immediate medical or surgical attention.⁵

These data are recorded on standardized data-collection sheets.

Photographs are taken for all suspected major congenital anomalies.

Diagnoses of any birth defects are later provided from experts in birth defects, on review of the documentation and photographs.

The data are analysed to determine whether there is any additional risk of adverse outcomes in infants that can be attributed to the exposure to ARV drugs during pregnancy.

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³ Sample-size estimations based on background incidence, case/comparator ratio and anticipated risk, including continuity correction are documented in the protocol for a drugs exposure registry for implementation in resource-limited settings (7). See also the European Medicines Agency Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling (8).

⁴ Folic acid supplementation is recommended before pregnancy and in the first 3 months, to prevent neural tube defects and other congenital malformations in the fetus in all women (9).

⁵ The WHO Tropical Diseases Research and Reproductive Health and Research Programme has produced a video guide to a stepwise surface examination of neonates, to train health-care workers to assess a neonate for birth defects (10). It supports a new protocol for a pregnancy registry (7).
BOX 2 PROSPECTIVE PREGNANCY REGISTRY IN SOUTH AFRICA

South Africa is implementing a national pregnancy registry to assess the safety of the ARV regimens and other medicines commonly used in pregnancy. Concerns about medicines such as cotrimoxazole and anti-tuberculosis drugs, and other conditions that may predispose women to risks of adverse birth outcomes, have dictated the need for a prospective approach with a scope beyond ARV drugs.

At sentinel sites, all new antenatal women are recruited into the registry, regardless of time to delivery or HIV status. The maternity case records used at the sites facilitate systematic collection of relevant information on drug exposure, occurrence of adverse reactions at each antenatal visit, comorbidities, ultrasound and other diagnostic tests, and birth outcomes. A bright sticker on maternity records identifies the woman as a pregnancy registry woman, signals that she is a woman who is tracked until the birth of the baby, and allows referral facilities and other sites to rapidly recognize women who are part of the registry. These sites can then inform the pregnancy registry site coordinator, so that the neonates are assessed similarly and data can be captured into the registry database.

Health-care staff at the sentinel sites are trained to (i) elicit and document medical, obstetric and drug histories and other clinical information in the maternity case records; (ii) conduct and document a systematic surface examination of each neonate, using training materials developed by WHO; and (iii) take photographs and record birth defects and refer infants appropriately. A national birth-defect panel will review all reported major congenital anomalies and determine whether the cases should be included in the analyses related to teratogenicity.

The National Health Research Ethics Council has waived the need for informed consent by women enrolled in the registry, except for permission to photograph babies born with a birth defect.

BOX 3 BIRTH-DEFECT SURVEILLANCE IN MALAWI

Malawi is planning a birth-defect surveillance system in two hospitals with high rates of deliveries (i.e. >10 000 deliveries per year). The system aims to establish a baseline prevalence of major birth defects among neonates and compare this to the observed prevalence in ARV-exposed pregnancies. All births, both live and stillborn, delivered at the participating institutions, will be systematically assessed for birth defects within a few hours of birth and definitely before discharge. The sample size will be calculated based on assumptions regarding the prevalence of HIV, prevalence of major birth defects and the percentage of women exposed to ARVs. The time period for the surveillance programme would be four years. A structured data-collection form, including photographs, will be used at the sites to record the assessment of every birth at these facilities. There will also be a uniform approach to ascertaining ARV exposure in the first trimester. These data are analysed to determine whether there is any additional risk of adverse outcomes in infants that can be attributed to the exposure to ARV drugs during pregnancy.
Prospective monitoring of cohorts of mother–infant pairs, during the breastfeeding period

Cohorts of mother–infant pairs (infants exposed and unexposed to ARV drugs during pregnancy and breastfeeding) are enrolled at birth and followed up over the course of the breastfeeding period (approximately 18 months to 2 years).

Depending on the regimen used in breastfeeding women and infants, case definitions should be developed to assist health-care staff in identifying targeted toxicities that should be monitored.

Enrolled infants are assessed in a standardized, systematic manner, for bone growth, renal function (where feasible), neurological development and HIV infection, at all facility visits (e.g. immunization visits, pediatric services, emergency room visits or hospitalization) over the course of the breastfeeding period, at specific points in time.

All findings, including reports of HIV infection, growth parameters, fractures, seizures, hospitalizations, are recorded.

The data are analysed, to determine whether there is any additional risk of adverse outcomes in infants that can be attributed to the exposure to ARV drugs during breastfeeding.

Settings with a fairly stable population, with reasonable access to care and where home-based follow-ups are possible are the most suitable for this approach.

Important considerations when developing a surveillance system

Before any decision can be made on which approach would be more suitable for a particular setting, it should be asked whether any kind of perinatal ARV drug toxicity surveillance is relevant within a specific setting. Countries with a moderate to high prevalence of HIV infection among pregnant women, and high coverage of ART during pregnancy, for PMTCT; countries using efavirenz- or nevirapine-based regimens as first-line treatment in pregnant women and women of childbearing age; and those adopting option B or option B+ as a policy for PMTCT should consider implementing such systems of surveillance.

Decision-makers need to prioritize the key toxicity issues of concern. If there are toxicity issues concerning the pregnant woman (e.g. risk of hypersensitivity reactions with nevirapine), then a pregnancy-exposure registry should be considered. If the priority concerns are around birth outcomes, then birth-defect surveillance or pregnancy-exposure registry would be suitable. If there are concerns about breastfeeding exposure, then prospective cohorts of mother–infant pairs is appropriate. Logistical issues, such as availability of surveillance staff, budget, timelines for funding, and sample-size requirements, will need to be considered, to assess the feasibility of the different approaches. The process for decision-making around which of these approaches to adopt at a national level depends on various factors; these are summarized in Figure 1.

The pregnancy-exposure registry has the potential to collect information on serious adverse reactions occurring in women during their pregnancies. The ability to detect and collect information on such reactions depends on the diagnostic capacity available at the antenatal clinic, awareness of safety issues among health-care staff, record linkages, and continuity of care between clinical services (e.g. emergency rooms, medical wards) and antenatal services. Programmes need to consider these issues, as well as the priority toxicity concerns in pregnant women, when determining the type of data that are collected during the pregnancy as part of the pregnancy-exposure registry.

The birth-defect surveillance approach in a setting with high HIV prevalence, high coverage with ART during

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**BOX 4 MALAWI BREASTFEEDING COHORT**

In Malawi, a surveillance programme will monitor infant growth and neurocognitive development within a cohort of breastfeeding mother–infant pairs receiving tenofovir- and efavirenz-based regimens. Active surveillance will be conducted for parameters that are indicative of growth and development problems in infants exposed to ARV drugs via breast milk. This component has been introduced in two ongoing cohort studies conducted in Malawi that will each recruit and follow up about 1500 to 2000 HIV-infected pregnant women until 18–24 months postpartum. All women in these cohorts will receive ART (tenofovir, lamivudine and efavirenz) according to the Malawi national protocol. The studies will implement interventions to improve retention of mothers throughout the postpartum period but no additional drugs or other ARV drugs will be offered as part of the studies.
FIGURE 1 PARAMETERS FOR PLANNING FOR A TOXICITY SURVEILLANCE SYSTEM OF ANTIRETROVIRAL DRUGS DURING PREGNANCY AND BREASTFEEDING

Prospective pregnancy-exposure registry

Birth-defect surveillance

Prospective monitoring of cohorts of mother-infant pairs during breastfeeding

Parameters for decision-making

- HIV prevalence and coverage of ARV drugs for preventing mother-to-child transmission
- National safety priorities for the use of ARV drugs for preventing mother-to-child transmission
- Concerns about other potentially teratogenic or harmful drug exposures
- Concerns about direct toxicity to pregnant woman
- Treatment-seeking behaviour during pregnancy and breastfeeding (e.g. home-based delivery, rates of losses to follow-up)
- Human and financial resources
- Sample size requirements
- Presence of electronic patient record systems
- Data-management capacity
- Record linkage system between HIV/AIDS treatment services, antenatal care, PMTCT and medical services

Tools available from WHO

- Pregnancy registry protocol
- Training modules
- Procedures for systematic examination of neonates
- Model case-record forms
- WHO/CDC/ICBDSR joint manual for birth-defect surveillance
- Core data fields to facilitate data pooling

Adapted for national use

Into practice

CDC: Centers for Disease Control and Prevention; ICBDSR: International Clearinghouse for Birth Defects Surveillance and Research.

pregnancy, and many deliveries will allow reporting on a large number of births more quickly. If there is good record-keeping and record linkage between antenatal, labour/delivery and postnatal care, and where drug exposures during pregnancies are systematically recorded, birth-defect assessment at the hospital and organizing the data flow may be the only incremental efforts required to set up birth-defect surveillance.

Both pregnancy-exposure registry and birth-defect surveillance require rigorous examination of the neonate, accurate information about drug exposure and comorbidities during pregnancy, and a large number of assessments to assess the risk to the fetus of exposure to ARVs.

The breastfeeding mother–infant cohorts also require proper assessment of the infant, drug exposure, breastfeeding patterns, and clinical history-taking throughout the breastfeeding period. Standardized but simple assessments for growth and neurological development need to be implemented at specific time points during the growth of the breastfeeding infant. Ongoing
validation and quality-assurance activities need to be implemented, to ensure that the data continue to be of good, reliable quality.

Before initiating any approach, it will be important, to consult with the national health research ethics committees on whether there is any need for written informed consent from pregnant women included in the pregnancy-exposure registry or birth-defect surveillance, or whether written informed consent can be waived on the grounds that surveillance forms part of routine care and is in the interest of patient safety. Even when a waiver is granted, written or oral permission to take photographs of babies with a birth defect is likely to be required.

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**CHALLENGES AND HOW TO ADDRESS THEM**

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<thead>
<tr>
<th>CHALLENGES</th>
<th>SOLUTIONS</th>
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<tr>
<td>High rates of home births and high rates of loss to follow-up</td>
<td>• Address known barriers to accessing care – e.g. transport, ambulance services</td>
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<td>• Use automated SMS reminders to women during the pregnancy to attend scheduled visits and to prepare for delivery at a health-care facility</td>
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<td>• Train antenatal clinic staff to encourage women to deliver at a health-care facility</td>
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<td>• Train antenatal clinic staff to telephone women who miss scheduled visits</td>
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<td>• Organize home visits by community health nurses soon after a woman’s estimated due date</td>
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<td>Late presentations for antenatal care during pregnancy (pregnancy-exposure registry only)</td>
<td>• Select sites with a high proportion of early presentations</td>
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<td></td>
<td>• Consider a birth-defect surveillance approach only, as the quality of information on first-trimester exposures is unlikely to differ between pregnancy-exposure registry and birth-defect surveillance</td>
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<td>Incomplete/poorly completed antenatal and labour/delivery records or records not routinely collecting the data required for the surveillance system</td>
<td>• Design data-capture forms/systems easy to use</td>
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<td>• Train staff in the use of records</td>
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<td>• Frequently or automatically verify data for completeness at sites</td>
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<td></td>
<td>• Validate data using other data sources</td>
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<td></td>
<td>• Simplify recording of the data and/or assign dedicated staff to surveillance-related data capture</td>
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<tr>
<td>Poor record linkage between antenatal and labour/delivery services</td>
<td>• Flag maternity case records (antenatal cards) to alert staff to link records</td>
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<td>• Introduce an integrated patient-record system used by all sites/services</td>
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<td>Poor-quality data capture from source documents</td>
<td>• Train and supervise staff capturing data</td>
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<td>• Provide feedback to staff involved in recording data on source documents, on issues relating to data recording</td>
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<tr>
<td>Sustainability</td>
<td>• Provide frequent and relevant feedback to facility staff, women, administrators and policy-makers</td>
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<td></td>
<td>• Identify and address site staff concerns about the system, on an ongoing basis</td>
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<td>• Minimize additional responsibilities of routine staff</td>
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<td>• Limit the reporting requirements (e.g. with electronic practice management systems)</td>
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**Improving patient care and informing national and global HIV treatment and prevention policies**

A comprehensive communication strategy that identifies target groups, communication objectives and a practical communication approach
of a national programme for the prevention and care of birth defects before and after birth, and the priority actions recommended to the international community to assist in the establishment and strengthening of these national programmes (11).

In this context, WHO is working with the United States of America’s (US) Centers for Disease Control and Prevention’s (CDC’s) National Center on Birth Defects and Developmental Disabilities, the International Clearinghouse for Birth Defects Surveillance and Research (ICBDSR), EUROCAT and ministries of health in participating countries with high HIV prevalence, to provide technical expertise at the country level for surveillance of birth defects. WHO has already produced a guiding protocol (7) and training video (10) on the conduct of a systematic surface examination of newborn infants, for countries planning to implement a pregnancy registry. A WHO CDC ICBDSR manual on birth defect surveillance for programme managers is in preparation (5).

What is WHO doing?

The Sixty-third World Health Assembly in 2010 endorsed a report by the Secretariat on birth defects. This report describes the basic components with coordinated technical assistance in planning and implementing of birth defect surveillance programmes (12).

WHO provides advocacy tools, technical guidelines and technical assistance to countries and technical organizations implementing ARV toxicity surveillance during pregnancy and the breastfeeding period. WHO encourages countries to include ARV toxicity surveillance activities under the monitoring and evaluation component in the new Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) financing model, to mobilize funding to support ART toxicity surveillance within ARV treatment and PMTCT programmes (13).

WHO collaborates with scientific and research agencies to implement strengthened surveillance and research in the area of toxicity of ARV drugs in pregnancy and during breastfeeding, to inform future guidelines on the use of ARV drugs.

WHO is convening a Steering Group on ARV Toxicity Surveillance, constituted by international experts and representatives of research agencies. The Group will advise WHO on the production of normative guidance and technical updates and enhanced collaboration on toxicity surveillance to inform future the clinical guidelines process.
REFERENCES


USEFUL LINKS


