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**Revised list of drugs and supplies for reproductive health, maternal and infant and child health to strengthen the health supply chain in Belize**

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## Glossary

EDL	Essential Drugs List
MoH-BLZ	Ministry of Health of Belize
WHO	World Health Organization

## I. Introduction

The Salud Mesoamerica 2015 (SM2015) Initiative is an innovative public-private partnership between the Bill & Melinda Gates Foundation (BMGF), the Carlos Slim Health Institute (ICSS), the Spanish Agency of International Cooperation for Development (AECI), the Inter-American Development Bank (IDB) and the countries of the Mesoamerican region. The SM2015 Initiative seeks to improve the health of women and children under five in the 20 percent of the poorest households in the Mesoamerican region, through the implementation of evidence-based practices in the areas of reproductive health, family planning, maternal, newborn and child health, including immunization and nutrition services; strengthening information systems and capacities for the provision of health services.

In February 2015, the Bank signed a contract with the government of Belize to finance operations under BL-G1002 aimed at improving reproductive health, maternal and child health through better access, use and quality of health services. The implementing agency (EO) of the operation is the Ministry of Health of Belize (MoH-BLZ).

With the aim to support the Ministry of Health of Belize in the implementation of the operation, IDB hired John Snow, Inc. to provide technical assistance (TA) to the MoH-BLZ to improve the management of the supply chain for reproductive health, maternal and child health medicines and supplies.

## II. Importance of the National Essential Drugs List (EDL)

The Essential Drugs List is the must-follow reference tool for prescribers and dispensers, as well as for the Committee of Rational Drug Use and Health Supplies (CRUHS) to document good practices of prescription, dispensation, use and managing of essential medicines.

The EDL plays a key role in the supply chain:

- III. **Logistics management:** allows programming, procurement, storage and distribution of a variety of drugs and health supplies.
- IV. **Rational use:** promotes use of cost - effective drugs among prescribers, dispensers and the general public.
- V. **Ensures access to medicines** with proven quality and reduces out-of-pocket household spending.

Medicines and other health supplies play an important role in providing quality services, including prevention, diagnosis, healing and relief. In order to improve the quality of services, the Ministry of Health of Belize needs to improve the availability of those medicines and health supplies that will target the most prevalent illness and the priority programs that will help the health system reduce the maternal and child health morbidity and mortality in the mid and long terms.

To accomplish this task, the MoH-BLZ needs to continue reviewing and updating the current EDL. This effort, already initiated during this consultancy, will follow some steps (described later) that will result in the inclusion or exclusion of drugs, based on to the national health policy, standard treatment guidelines, national drug policy, and eventually, the registration and procurement of those medicines with high cost-effectiveness and of proven efficacy.

## III. Objective

Review and update the formulary/essential drugs list and health supplies for reproductive health, maternal and infant and child health, with the support of a local team of experts and representatives of all health regions.

## IV. Steps proposed to review the EDL

In the following pages, we describe the process to update the EDL, including the steps that managers should follow to review the list for any health care service (i.e. MCH Program, chronic illness, etc.). The end-result will be the updated list that responds to national policy, technical standards and epidemiological profiles of the country, which will help the MoH to complete the drug registration process initiated in August 2015 and procure the necessary drugs and health supplies for the MCH Program to cover demand in 2016.

### A. Establishing a national technical committee

During the consultancy, we identified a technical team of MoH-BLZ officials from the central level, who are responsible for implementing, monitoring and evaluating the use of medicines listed in the Drug Formulary and Therapeutics Manual. (**Attachment 1: Members of the technical committee**).

Given the short length of the JSI consultancy, we were not able to identify other members who could provide their knowledge and input to this technical committee. Therefore, JSI suggests that the MoH-BLZ and the MCH Program include other key personnel as they deem appropriate.

### B. Defining the criteria for the selection of medicines and supplies.

In order to consider a drug or health supply part of the list, drugs have to meet the following criteria:

- The drugs and supplies are included in the 19th WHO medicines list for maternal, infant and childhood health as this list contains drugs with proven efficacy and safety. See **Attachment 2: WHO Model List of Essential Medicines 19th list (April 2015, amended in June 2015) and WHO Drug List (2011)**.
- The selected drugs and supplies are available and have the same concentration described in the Belize Drug Formulary and Therapeutics Manual (ninth edition, 2009-2011).

- The medicines and supplies are described in guidelines, protocols and standards treatment guidelines and address health problems in primary care, with a focus on care during pregnancy, childbirth, postpartum, newborn at low risk and children under 5 years of age.
- The medicines and selected health supplies have either national registration or marketing authorization in the domestic market.

### C. Updating the essential drugs list for selected medicines and health supplies.

The following steps describe the process that was initiated by the JSI consultants and those steps that need to be completed by the MoH-BLZ in order to finalize the list.

**3.1 As a first step that took place during the month of November**, the technical team from members of the central level reviewed two lists: a) the drugs and health supplies that should always be available in all the health units based on the national health policy And b) the list of priority medicines for mothers and children recommended by the Department of Maternal, Newborn, Child and Adolescent of the World Health Organization - WHO - OMS (March 2011). The analysis of both lists showed that all essential drugs for the comprehensive health care of women and children with a focus on sexual and reproductive health are part of the revised list for the MoH-BLZ.

**3.2 As a second step**, we reviewed the Belize Drug Formulary and Therapeutics Manual (2009-2011), to ensure it contained all medicines and supplies needed to address health issues related to maternal and child health, including newborn, postpartum, and children under 5. As a result of the revision, Table 1 shows the updated list which includes 24 drugs and 3 health supplies (condoms, implants and IUDs) for maternal and child health.



**Table 1: Updated List of Medicines and Supplies proposed for the MCH Program**

<b>Drugs and supplies for Maternal Health</b>	
1.	Crystal G. 1,000,000 IU Benzylpenicillin. Sterile Powder. FAM. IV
2.	Amoxicillin 500 mg. tablet / oral capsule
3.	Powder Ampicillin 1G. FAM. I.V
4.	Cephalexin 500 mg, oral capsule
5.	Nitrofurantoin 100mg Tablet / oral capsule
6.	Albendazole 400 mg. Oral Tablet Chewable
7.	Hydralazine 20 mg / ml solution for injection AMP / FAM.2ML IM. I
8.	Folic Acid 5 mg. Oral Tablet
9.	5% dextrose in water solution for injection. Bottle/Bag 1000 ML. I.
10.	Hartman Solution for Injection (NaCl+ClK+Cl2Ca+NaHCo3)(0.6+0.03+0.02+0.31). Jar. 1000 ml. I.V
11.	Sodium Chloride (Solution physiological) injection solution IV 0.9% Bottle / Bag 1000 ml.
12.	Synthetic Oxytocin 5 or 10 U.I / ml. Injection solution. AMP. 1 ml. I. M. I.V.
13.	Ergometrine (ergonovine) 0.2 mg / ml (200 mcg / ml) AMP. IM. IV
14.	Pregnancy Test
15.	Dexametasone or Betamethasone solution for injection 4 mg (as sodium salt), in 1 ml ampoule
16.	Atropine or Epinephrine solution for injection, 1 mg (sulfate) in 1 ml ampoule
17.	Docycycline 100 mg. Tablet or capsule
18.	Diazepam Solution for injection 5 mg/ml in 2 ml ampoule, tablet 5 mg
19.	Calcium Gluconate injection 100 mg/1 ml in 10 ml ampoule.
20.	Mebendazole 500 mg Oral Tablet
21.	Prenatal Tablet/Vitamin A capsule:4000 UI B1: 1,6 mg, B2:1,8 mg Nicotinamide:19 mg, B6: 2,6 mg, Pantothenic Acid: 10 mg., Biotin: 0,2 mg. B12: 4 mcg, C: 100 mg. D: 500 UI, E: 15 Mg, Folic Acid
<b>Drugs and supplies for Infant and Child Health</b>	
1.	Oral Electrolyte Solution reduced osmolarity (245 ml osmol / l) powder for oral solution (anhydrous Glucose 13.5 g / L (75 mmol / L) Sodium Chloride 2.6 g / L (45 mmol / L) Potassium Chloride 1.5 g / L (20 mmol / L) trisodium citrate dihydrate 2.9 g / L. ENVELOPE
2.	Amoxicillin Oral Suspension 250 mg / 5 ml. Jar. 100 ML
3.	Erythromycin ethylsuccinate 250 mg / 5 ml. Bottle100 ml oral suspension
4.	Gentamicin sulfate. Solution for injection 40 mg / 1 mL. AMP.2ML. I. M. / I.V.
5.	Ferrous Sulfate 60 mg + folic acid 400mcg. Tablet / caplet

6. Retinol (Vitamin A) Solution 25,000- 50,000 IU / Drop
7. Retinol (Vitamin A) Soft Capsule 100,000 IU
8. Ophthalmic Oxytetracycline or Chloramphenicol eye drop 0.5 % 10 mls, ointment 1%
9. Phytomenadione or Vitamin K injection 1 mg/1 ml,
10. Benzylpenicillin G. benzathine 1,200,000 IU Sterile Powder. Fam.I.M
11. Albendazole Oral Suspension, 10-20 ml., bottle
12. Ferrous Sulfate (Elemental Iron/carbonyl iron) Oral Solution 15mg / 0,6ML.30 ml bottle
13. Sulfate / Gluconate Zinc 50mg tablet and solution
<b>Contraceptives for men and women of reproductive age</b>
1. Medroxyprogesterone Acetate Sol. Injection 150 mg / 1 ML. I.M.
2. Levonorgestrel + Ethinyl Estradiol 0.15 + 0.03 MG. Tablet / Caplet
3. Norethisterone enanthate + estradiol valerate. Sol. Injection 50 MG + 5 MG / 1 ML.I.M.
4. Male natural rubber latex condom, width ≥ 52mm
5. Intrauterine device Copper T 380A (TCu 380A) with T frame compound of Low Density Polyethylene and Barium Sulphate (15% - 24%) wound with 176mg of 0.25mm diameter copper wire, and two copper sleeves on horizontal arm providing a surface area of 380mm <sup>2</sup> ± 23mm <sup>2</sup> .
6. Implanon, etonogestrel implant 68mg

Even though steps 3.1 and 3.2 were completed during the JSI visit, it's important to note that the MoH-BLZ should continue the review process and continue with steps 3.3, 3.4 and 3.5 in order to complete the revision of the essential drugs list based on the knowledge and experience of the health personnel from the health regions.

**3.3 Third step:** analysis of each of the drugs and supplies using the criteria defined in step No. 3.2 of the review process. **(Use Attachment 3: Matrix with defined criteria that allows easy review and analysis)**. For example, in the case of those drugs that are not included in the WHO Model List of Essential Medicines 19th list, the MoH technical committee should analyze the benefits of including the drug in the EDL, given the potential impact on the population's health. This is the case of the Crystal G. 1,000,000 IU Benzylpenicillin, Sterile Powder.

**3.4 Fourth step:** determine the inclusion of other medicines and supplies that the technical team led by the MCH program considers relevant and vital to be included in this list.

**3.5 Fifth step:** validation of the proposed list with staff in the health regions (service providers, administrative managers and supply chain managers).

In coordination with Sharon Anderson - Chief Pharmacist for the MoH-BLZ, we had access to a list of tracer drugs monitored by the central level. The list of core/tracer drugs include 9 medicines and supplies that we already included in this exercise and which are monitored by Chief Pharmacy office.

During this process, we found out that medicines and health supplies don't have a registration in Belize. Since August 2015, the MOH is participating in technical meetings with SE-COMISCA in El Salvador and with COFEPRIS (Mexico, Federal Commission for the Protection against Sanitary Risk) to learn how to establish a sanitary registration in Belize and start the process of sanitary registration for health products.

In an interview with technical staff of Pharmaceutical Inspection of MOH, they mentioned that the suppliers don't submit sanitary registration of the products they procure on behalf of the MoH-BLZ and this poses a health risk to the population. However, suppliers mentioned that they will be able to present the registration in case there's a quality issue reported by the MoH. This seems to be a catch-22 situation for the MoH as the Ministry doesn't have a quality control laboratory to determine the quality of the products.

**V. Conclusions and recommendations to improve EDL for MCH medicines**

1. As a result of the review and updating of the list, it is necessary to include six drugs in the doses listed below for maternal and child health services. It's important to note that Table 1 already includes these drugs; Table 2 only describes these drugs separately, as part of the recommendation.

**Table 2: Recommended drugs for inclusion in the current drugs list for the MCH Program**

Maternal Health	Child Health
Mebendazole 500 mg Oral Tablet	Benzylpenicillin G. benzathine 1,200,000 IU Sterile Powder. Fam.I.M.
Prenatal Tablet/Vitamin A capsule:4000 UI B1: 1,6 mg, B2:1,8 mg Nicotinamide:19 mg, B6: 2,6 mg, Pantothenic Acid: 10 mg., Biotin: 0,2 mg. B12: 4 mcg, C: 100 mg. D: 500 UI, E: 15 Mg, Folic Acid	Albendazole Oral Suspension, 10-20 ml., bottle
	Ferrous Sulfate (Elemental Iron/carbonyl iron) Oral Solution 15mg / 0,6ML.30ml, bottle
	Sulfate / Gluconate Zinc 50mg tablet and solution

3. Continue and complete the registration process of all medicines and health supplies for both the public and private sectors to ensure the procurement of quality products, to allow the MCH program to estimate and procure those drugs and supplies of proven quality and efficacy and protect the health of the population of Belize. In the case of the proposed medicines list, the MCH Program needs to complete the process with the relevant staff at all levels and once the process is completed, the national formulary/essential drugs list and therapeutics manual, protocols and standard treatment guidelines need to be updated. In addition, the registration of drugs needs to be completed in country.
4. The list of drugs on Table 12 should be presented to and discuss with authorities at different levels of the Ministry of Health. The proposed list contains 21 drugs and supplies for maternal health, 13 drugs and health supplies for infant and child health, and 6 contraceptives. Some of the maternal health supplies can also be used for infant and child health (i.e. solutions)
5. Review and define with the Pharmacy Department the list of core drugs to be monitored on a regular basis, to harmonize the list and agree on the key performance indicators (KPI) for the supply chain.

## VI. References

1. Belize Drug Formulary and Therapeutics Manual 9<sup>th</sup> edition (2009-2011).
2. [www.who.int/mediacentre/news/notes/2011/mother\\_child.../es/](http://www.who.int/mediacentre/news/notes/2011/mother_child.../es/)
3. [www.news-medical.net/news/20110323/12485/Spanish.aspx](http://www.news-medical.net/news/20110323/12485/Spanish.aspx)
4. WHO Collaborating Centre for Drug Statistics Methodology, Guidelines for ATC classification and DDD assignment 2012. Oslo, 2011.