Essential medicines for reproductive health: developing evidence based interagency list

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Abstract

Objectives: Although poor reproductive health constitutes a significant proportion of the disease burden in developing countries, essential medicines for reproductive health are often not available to the population. The objective was to analyze the guiding principles for developing national Essential Medicines Lists (EML). The second objective was to compare the reproductive health medicines included on these EMLs to the 2002 WHO/UNFPA list of essential drugs and commodities for reproductive health. Another objective was to compare the medicines included in existing international lists of medicines for reproductive health.

Methods: The authors calculated the average number of medicines per clinical groups included in 112 national EMLs and compared these average numbers with the number of medicines per clinical group included on the WHO/UNFPA List. Additionally, they compared the content of the lists of medicines for reproductive health developed by various international agencies.

Results: In 2003, the review of the 112 EMLs highlighted that medicines for reproductive health were not consistently included. The review of the international lists identified inconsistencies in their recommendations. The reviews' outcomes became the catalyst for collaboration among international agencies in the development of the first harmonized Interagency List of Essential Medicines for Reproductive Health. Additionally, WHO, UNFPA and PATH published guidelines to support the inclusion of essential medicines for reproductive health in national medicine policies and EMLs. The Interagency List became a key advocacy tool for countries to review their EMLs.

In 2009, a UNFPA/WHO assessment on access to reproductive health medicines in six countries demonstrated that the major challenge was that the Interagency List had not been updated recently and was inconsistently used.

Conclusion: The addition of cost-effective medicines for reproductive health to EMLs can result in enhanced equity in access to and cost containment of these medicines, and improve quality of care. Action is required to ensure their inclusion in national budget lines, supply chains, policies and programmatic guidance.

Keywords: Reproductive health, Essential medicines, World Health Organization, Interagency list

Introduction

In 1977, the World Health Organization (WHO) launched its first Model List of Essential Medicines ("the Model List"). The Model List was designed to prioritize the most important medicines from a public health perspective and was the centerpiece of a

strategy to enhance their availability, especially in developing countries. Essential medicines are selected on the basis of a set of guiding principles, which includes; a review of the latest evidence of safety and efficacy of a particular treatment for the most common diseases in a given country, and summarizing the recommended use in a standard treatment guideline¹. They are

a critical tool for improving and maintaining health, as essential medicines lists (EMLs) give priority status to medicines that address a country's most pressing public health problems whilst taking into account the cost component of the treatment. After immunization for common childhood illnesses, appropriate use of essential medicines is one of the most cost-effective components of modern health care². For almost three decades, WHO has devoted substantial effort to support essential medicines programmes that seek to improve access to the most needed medicines.

Reproductive and sexual health problems, such as early and unwanted childbearing, HIV infection, sexual transmitted infections (STIs), and pregnancy-related illness and death account for a significant part of the disease burden among adolescents and adults in developing countries³. Reproductive and sexual ill-health (maternal and perinatal mortality and morbidity, cancers, STIs and AIDS) account for nearly 20 per cent of the global burden of ill-health for women of reproductive age and some 14% for men^{4,5}. These statistics do not capture the full burden of ill-health, however. Gender-based violence, gynaecological conditions such as severe menstrual problems, urinary and faecal incontinence due to obstetric fistulae, uterine prolapse, pregnancy loss, and sexual dysfunction – all are currently underestimated in present global burden of disease estimates. In poor resource settings, WHO estimates unsafe sex to be the second most important global risk factor to health^{6,7}.

Essential medicines for reproductive health include medicines to ensure healthy pregnancy and delivery, contraceptives and medicines for prevention and treatment of STIs and HIV/AIDS. Although poor reproductive health constitutes a significant proportion of the disease burden in developing countries, essential medicines for reproductive health often are not available to the majority of the population. A survey estimated that some 210 million couples at risk of unintended pregnancy who would like to space or limit their births are not using modern contraception to do so^{4,8}. In 2005, WHO estimated that globally there were 448 million new cases of the four sexually transmitted infections: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, syphilis and *Trichomonas vaginalis*, in adults between the ages of 15 and 49⁹. Lack of access to medicines including contraceptives threatens the well-being of individuals, families, and communities. In 2000, in response to a growing need for access to reproductive health medicines, United Nations Population Fund (UNFPA) and its partners presented a strategic approach called A Global Strategy for Reproductive Health Commodity Security (RHCS). The strategy draws largely on the experience of implementation of the essential medicines concept and national medicine policy approach introduced by WHO in the 1970s¹⁰.

One of the goals agreed at the International Conference on Population and Development was to achieve universal access to reproductive health by 2015^{8,11}. In 2003, WHO Department of Medicines Policy and Standards (WHO/PSM) in collaboration with WHO Department of Reproductive Health and Research (WHO/RHR) reviewed 55 national medicine policies and 112

national Essential Medicines Lists (EMLs) of WHO member countries to determine the degree to which they facilitate access to reproductive health medicines¹².

The WHO framework for access to essential medicines addresses factors that ensure evidence based selection of medicines, sustainable financing and affordability and reliable supply chains that deliver quality products. Hence, the first step in improving access to essential medicines for reproductive health would be to ensure that these items are included in national medicine policies and essential medicine lists, and in equitable financing mechanisms and budget lines².

Hence, the study objectives were to analyze the guiding principles and procedures for developing each national EML as defined in the national medicine policy. Another objective was to compare the selection of reproductive health medicines included on these national EMLs to the 2002 draft WHO/UNFPA list of essential drugs and other commodities for reproductive health services (called "the UNFPA List")¹³. The third objective was to compare the medicines included in existing international lists of medicines for reproductive health.

Methodology

The authors collected 112 national Essential Medicines Lists and calculated the average number of medicines for each of the following clinical groups: reproductive and maternal health, family planning, sexually transmitted infections (STI)/reproductive tract infections (RTI) and HIV/AIDS and compared these average numbers of medicines with the number of medicines per clinical group included on the UNFPA List. Additionally, the authors compared the content of the lists of medicines for reproductive health developed by various United Nations (UN) agencies involved in reproductive health programmes. This review conducted in 2003 compared the content of the following lists: (1) the 13th WHO Model List of Essential Medicines, 2003 ("the 13th Model List")¹⁴, (2) the draft WHO/UNFPA List of Essential Drugs and Commodities for Reproductive Health Services, 2002 ("the UNFPA List")¹³ and (3) the Draft Interagency UNFPA/UNAIDS/WHO Reproductive Health Medicines and Commodities List, 2002 ("the Interagency List").

Results

The findings of the study highlighted that although the national medicine policies in those countries allowed for evidence based selection of medicines for the development of a national EML, essential medicines for reproductive health were not consistently included in national EMLs, even when strong evidence for their effectiveness existed. For example, magnesium sulfate is a cost-effective medicine for preventing pre-eclampsia and treating eclampsia, one of the leading causes of maternal morbidity and mortality¹⁵. Approximately 3.2% of all pregnancies are affected, resulting in more than 63,000 maternal deaths worldwide each year.¹⁶ Yet magnesium sulfate was included in only 45 (40%) national EMLs reviewed. Table 1 compares the

Table 1. Comparison between the average number of reproductive health medicines included in 112 national Essential Medicines Lists (EMLs) and the 2002 draft WHO/UNFPA list of essential drugs and other commodities for reproductive health services, 2003

	Number of medicines in the 2002 draft WHO/ UNFPA list	Average number of medicines listed in 112 national EMLs
Reproductive and maternal health (eg., antihypertensives, oxytocics, antimalarial)	111	75
Family planning (hormonal contraceptives and condoms)	9	3
STI/ RTI medicines (antibiotics and antifungals)	22	12
HIV/AIDS medicines (ARVs and OI medicines)	27	5

number of medicines per clinical groups included on the UNFPA list with the average number of medicines found on national EMLs. On average, only three out of nine family planning methods surveyedⁱ could be found in the EMLs reviewed. Zidovudine, an essential antiretroviral, part of the nucleoside reverse transcriptase inhibitors, was included in only 19 (17%) of national EMLs. Condoms, an important barrier method in preventing unwanted pregnancy and the primary method for preventing transmission of STIs, including HIV, were listed in only 31(35%) of national EMLs. Out of 22 STI/RTI medicines and 27 HIV/AIDS medicines surveyed, only 12 (55%) and five (18%) respectively, were found on the EMLs reviewed¹².

The review of the international lists identified various inconsistencies, as reported in Figure 1. Thirty seven medicines were included in either one or two lists but not in all three. The Interagency List included 25 medicines that were not on the 13th Model List or on the UNFPA List. The UNFPA List included seven medicines that were not on the 13th Model List or on the Interagency List.

Discussion

The inconsistent inclusion of effective essential medicines for reproductive health in the national EMLs surveyed acted as a barrier to the access to life-saving medicines in those countries. Discrepancies among international lists not only posed a serious barrier to variation in supply, but had the potential to lead to inconsistent technical assistance in recipient countries. The outcome of the two reviews became the catalyst for collaboration among key international agencies in the development of a harmonized evidence based interagency

Figure 1. Distribution of 37 discrepancy medicines identified in international lists of medicines for reproductive health, 2003

¹The 13th WHO Model List of Essential Medicines

²Draft WHO/UNFPA List of essential drugs and other commodities for reproductive health services

³Draft interagency UNFPA/UNAIDS/WHO Reproductive Health Medicines List

list of essential medicines for reproductive health that is fully aligned with the WHO Model List.

Development of a harmonized Interagency List of Essential Medicines for Reproductive Health

Between 2003 and 2004, three interagency consultationsⁱⁱ on the selection and delivery of essential medicines and commodities for reproductive health were convened to discuss the findings of the comparative review of the lists, including identified discrepancies in medicine selection. All parties agreed that, as a prerequisite, the harmonized Interagency List of Essential Medicines for Reproductive Health would be a subset of the latest WHO Model List. Following evidence-based reports on the discrepancy medicines, the interagency working group decided to (1) delete nine medicines from all reproductive health medicine lists and guidelines and (2) prepare evidence-based applications for 14 medicines for inclusion in the 14th WHO Model List of Essential Medicines. Consequently, the interagency working group commissioned systematic reviews of the evidence to prepare applications for inclusion on the WHO Model List. Applications were submitted to the WHO Expert Committee on the Selection and Use of Essential Medicines ("the Expert Committee") for review at its 14th meeting in March 2005 as detailed in Table 2.

In March 2005, the Expert Committee approved the five following reproductive health medicines submitted by the interagency working group: misoprostol, misoprostol and mifepristone, cefixime, clotrimazole and nifedipine as a tocolytic. Ten applications were rejected including four applications for new contraceptives due to lack of superior efficacy/safety in comparison to other contraceptives already on the WHO Model List.

ⁱ Low-dose combined pills, progestin-only pills, spermicides, contraceptive foams/gels, medroxyprogesterone acetate (depot injection), copper intrauterine device, condoms, and diaphragms.

ⁱⁱ Participating agencies included: John Snow International (JSI), Médecins Sans Frontières (MSF), PATH, United Nations Children's Fund (UNICEF), UNFPA, WHO.

Table 2. Medicines suggested for systematic review and applications for inclusion or retention in the 14th edition of the WHO Model List of Essential Medicines to the 14th WHO Expert Committee on the Selection and Use of Essential Medicines, March 2005

	UNFPA List 2002	Interagency list 2002	13th WHO Model List 2003	14th WHO Model List 2005
cefixime (only for gonorrhoea), capsule	-	x	-	x
clotrimazole, vaginal tablet or cream	x	x	-	x
ergometrine, injection	x	x	x	x
estradiol cypionate + medroxyprogesterone acetate, inj	x	-	-	-
estradiol valerate + norethisterone enantate, inj	x	-	-	-
labetolol, tablet	-	x	-	-
levonorgestrel-releasing IUDs	x	-	-	-
medroxyprogesterone acetate, tablet	-	x	x	x
mifepristone + misoprostol, tablet	-	x	-	x
misoprostol, vaginal tablet	-	x	-	x
nifedipine (as tocolytic), capsule	-	-	x	x
oxytocin UNIJECT delivery system	-	-	-	-
salbutamol, tablet (as tocolytic)	-	x	x	-
subdermal contraceptive implants	-	x	-	-

The Expert Committee declined to list several contraceptive medicines and recommended that contraceptives as a class should be reviewed and further (re)submissions should be made at the next revision of the list in 2007¹⁷.

The Expert Committee noted that the approach to provision of contraceptives for family planning was a philosophy of choice which requires a wide list of options. This philosophy is contrary to the Model List of Essential Medicines principles which identify the most appropriate generic medicine that addresses a specific priority health problem. As the provision of additional methods of contraception has an opportunity cost for health services generally, the Expert Committee recommended that in order to facilitate further consideration of contraceptive applications in the future, it would be important to undertake and present to the Expert Committee a systematic review of the evidence supporting the philosophy of informed choice.

Table 3. Contraceptives included in the 5th invitation to manufacturers of reproductive health products to submit an Expression of Interest (Eoi) for a product evaluation by the WHO Prequalification Programme, for the WHO Model List of Essential Medicines and in the WHO reproductive health guidelines, May 2010

Oral hormonal contraceptives
<ul style="list-style-type: none"> • ethinylestradiol + desogestrel, tablet 30 micrograms +150 micrograms • ethinylestradiol + levonorgestrel, tablet 30 micrograms + 150 micrograms • levonorgestrel, tablet 30 micrograms • levonorgestrel, tablet 750 micrograms (pack of two); 1.5 mg (pack of one) • norethisterone, tablet 350 micrograms • norgestrel, tablet 75 micrograms
Injectable hormonal contraceptives
<ul style="list-style-type: none"> • medroxyprogesterone acetate, depot injection 150 mg/ml, in 1-ml vial • medroxyprogesterone acetate + estradiol cyprionate, injection 25 mg + 5 mg • norethisterone enanthate, injection 200 mg • norethisterone enanthate + estradiol valerate, injection 50 mg + 5 mg
Implantable contraceptives
<ul style="list-style-type: none"> • two-rod levonorgestrel-releasing implant, each rod containing 75 mg of levonorgestrel (150 mg in total) • etonogestrel, implant, 68 mg of etonogestrel

Systematic review of contraceptive medicines “Does choice make a difference?”

As recommended by the 14th Expert Committee in 2005, a Cochrane systematic review^{18,19} of the literature was undertaken to examine whether a policy of providing a wide range of contraceptive methods, as opposed to the provision of a limited range, improves health outcomes such as contraceptive uptake, acceptability, adherence, continuation and satisfaction; reduction of unintended pregnancy; and improved maternal health and wellbeing. The results are presented as a hierarchy of evidence, with the cross-cutting concerns of meeting the needs of women through the stages of life, of particular groups (such as adolescents, those infected or at-risk of HIV or with medical conditions), and of those seeking to space birth or limit their families. In 2007, the 15th Expert Committee considered the conclusions of this review and confirmed that it will take an evidence-based approach to listing contraceptives. The Committee agreed to assess new products on a case-by-case basis using the accepted criteria of comparative efficacy, comparative safety and comparative cost, as well as suitability and acceptability¹⁸. Table 3 summarizes the contraceptives included in the 5th invitation to manufacturers of reproductive health products to submit an Expression of Interest (Eoi) for products evaluation to the WHO Prequalification Programme published in May 2010 on the basis of contraceptives included in the 16th WHO Model List published in March 2010^{20,21}.

Table 4. List of activities carried out to improve access to quality essential medicines for reproductive health following the development of the Interagency List of Essential Medicines in 2006

- Systematic review and preparation of submissions of the reproductive health essential medicines initially rejected by the WHO Expert Committee for inclusion on the 15th WHO Model List
- Systematic review of contraceptive medicines “Does choice make a difference?”
- Systematic review of the management of hypertension during pregnancy
- Review of WHO Standard Treatment Guidelines (STGs) for reproductive health. As an example, ketoconazole and itraconazole are two antifungals listed in WHO standard treatment guidelines. It has been suggested that both medicines be replaced with fluconazole, listed on the WHO Model List, on the basis of available evidence.
- Preparation of the review process of the interagency list. The review will occur every two years, subsequently to the review of the WHO Model List.
- Launch of a prequalification scheme by the WHO Prequalification Programme to support the procurement of a core list of reproductive health essential medicines.
- Harmonization of WHO and UNFPA prequalification scheme for male latex condoms and Copper T 308A intra-uterine devices of the WHO essential medicines.
- Preparation of an interagency list of essential medical devices for reproductive health as a tool to support planning for the selection, quality assurance and procurement of medical devices to implement the Maternal and Newborn Health (MNH) interventions.*
- Development of a procurement tool kit for reproductive health medicines by PATH and WHO and dissemination in countries

*Interagency list of essential medical devices for reproductive health, 2008. Document no.WHO/PSM/PAR/2008.1. Available at: <http://www.who.int/medicines/publications/MRfinalmedicaldevskhoct08.pdf>

Publication of the Interagency List of Essential Medicines for Reproductive Health

In 2006, WHO and UNFPA published the Interagency List of Essential Medicines for Reproductive Health (“the Interagency List”) as a subset of the 14th Model List^{22,23}. The Interagency

List only included medicines from the 14th Model List relevant to reproductive health and contains 148 medicines. The Interagency List was officially endorsed by key partners involved in Reproductive Health programmes, including International Planned Parenthood Federation (IPPF), John Snow, Inc (JSI), Program for Appropriate Technology in Health (PATH), Population Services International (PSI), United Nations Population Fund (UNFPA), the World Bank and other members of the Reproductive Health Supplies Coalition (RHSC)²⁴. Once published, it became a key advocacy tool to (1) guide country decisions regarding what reproductive health essential medicines to include in their national EML, policies, guidelines and procurement budget lines and improve access to quality reproductive health essential medicines including a choice of contraceptives, (2) to guide international bulk procurement and support a core list of priority reproductive health essential medicines for inclusion in the WHO/UNFPA prequalification scheme for bulk procured essential medicines.

In addition, WHO/UNFPA/PATH published a guideline in 2006

to support the inclusion of essential medicines for reproductive health in national EMLs. The guideline includes 16 policy briefs providing a summary of the evidence for priority reproductive health essential medicines²⁵.

The guide presents background on the EML process and the importance of including reproductive health medicines on EMLs. It provides an overview of the process for including reproductive health medicines in national essential medicines lists based on the essential medicines concept. It is intended to be used by reproductive health programme managers, national-level essential medicines committees, and those responsible for selecting, procuring, and ensuring quality of reproductive health medicines.

As the United Nations Millennium Project notes, “expanding access to sexual and reproductive health services, including family planning and contraceptive information and services, and closing funding gaps for supplies and logistics are achievable priorities”²⁶. The development of an evidence-based list of essential medicines for reproductive health has led to a significant number of activities focused on supporting improved access to and use of quality reproductive health medicines in countries, as listed in Table 4.

In March 2009, the Expert Committee on the Selection and Use of Essential Medicines at its 17th meeting added misoprostol 200 micrograms tablet for management of incomplete abortion to the 16th WHO Model List. The evidence showed that misoprostol is as effective as surgery and in some settings, may be safer as well as cheaper²⁷. Recently, at its 18th meeting in March 2011, the Expert Committee made recommendations regarding additional reproductive health-related applications. First, after consideration to the evidence for safety and efficacy, the Committee decided to add misoprostol tablet, 200 micrograms to the list as prevention of postpartum hemorrhage in settings where oxytocin is not available or cannot be safely used. Second, the Committee recommended that the term ampoule be deleted from the right end column of the listing for oxytocin to allow consideration of other alternative oxytocin presentations²⁸. These evidence-based reviews of essential medicines for reproductive health by the Expert Committee should be translated more systematically into updated Interagency List to provide up to date information to national programmes. The cost of updating and regularly publishing the interagency list is justified, because it is reliable and could be used for to build reliable and evidence based information. This has also been described in the *WHO Progress Report 2010*²⁹.

In addition, UNFPA in collaboration with WHO undertook in 2008 and 2009, a rapid assessment of the current status of access to reproductive health essential medicines, particularly for maternal and newborn health care and reproductive health, in six countries. These countries were DPR Korea, Ethiopia, Laos, Nepal, Philippines and Mongolia³⁰. This assessment was designed to provide a snapshot of the current situation in the selected countries regarding the availability and use of the selected life-saving essential medicines. The six critical medicines chosen for these studies were selected because they are the WHO

recommended medicines for the prevention and management of three major causes of maternal mortality, as detailed in Table 5. As family planning has a considerable impact on reducing maternal mortality, the assessment included one temporary method of family planning, depo medroxyprogesterone acetate (DMPA) injections (three and one-month formulations).

The assessment was designed to not only develop a rapid assessment methodology, but also guide institutional support and capacity building in the area of reproductive health commodity security including improving access and quality assurance processes. The major challenge, as one of the key findings of the assessment, was that the Interagency List of Essential Medicines for Reproductive Health had not necessarily been updated for a long time and was inconsistently used. However the medicines were available but prone to incidences of stock outs and/or over supply. Standard treatment guidelines were not necessarily available and there existed knowledge to practice gaps. The rapid assessment also found challenges with regulation, quality assurance and storage condition. This shows the importance of linking the production of evidence-based guidance with strong, coordinated efforts to translate that guidance into practice. Without the concomitant level of political will, financial and technical support and effective coordination, the production of evidence-based guidance will not have the desired impact on improving the quality of health care, particularly reproductive health.

Conclusion

The reviews of national EMLs and international lists of medicines for reproductive health showed the lack of consistent inclusion of effective medicines for reproductive health in national lists and of harmonized technical guidance. The addition of reproductive health medicines to national EMLs can result in enhanced equity in access and can improve quality of care. Reproductive health experts must understand the national EML process and invest time and effort to bring about changes in national EMLs on the basis of the regularly updated Model List. Action is required to ensure that essential medicines for reproductive health, including contraceptives are incorporated into national budget lines, national procurement and logistics management systems, national policies, programmatic guidance and pre-service education.

Authors' contributions

SL who was the principle writer of the article has shared with SJ and MUP, the conception of the research. SJ, HM and MUP participated in the reviews, policy analysis and in the writing of the article. HM and KA managed all aspects of the review of status of access to a core set of reproductive health medicines in selected countries and provided comments on the writing of the article. MUP supervised all aspects of the reviews and of the writing.

Conflict of Interest:

The authors declare no conflict of interest.

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