

Essential medicine required for national SRHR guidelines implementation in Iraq

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ABSTRACT

This study is intended to assess the situation of essential medicines for the implementation of the sexual and reproductive health and rights (SRHR) guidelines in Iraq to provide a clear picture of the availability of these medicines and identifies gaps to be filled. The medicines were grouped into categories and subcategories and the assessment was begun after collecting information from the current national SRHR guidelines, global EML, national EML, registration index, and other relevant documents. The assessment included several points to be addressed about each medicine or group of medicines in the format of closed-ended questions to draw a clear picture on status of that medicine. The collected data organized in the form of informative tables and bar graphs showed that about 125 SRHR essential medicines are addressed in this study. Of these essentials medicines, 80 medicines (64%) are fairly covered in Iraq in terms of their clear recognition by the Iraqi healthcare system. The analysis also shows that only about 62% of the SRHR medicines were procured in 2019. The results suggest that more work needs to be done to provide better SRHR service in Iraq. This includes, but is not limited to, working on updating and publishing all the national management guidelines related to SRHR. It also includes revisiting the national EML and comprehensive list of medicines to provide better coverage of SRHR medicines. Finally, a robust strategy needs to be put together to harmonize the work of all the stakeholders to provide the necessary medicines when needed.

Keywords: Reproductive, Sexual, Essential medicines, Iraq, Enlisting, Procurement

Introduction

Availability of and access to essential medicines, medical supplies, and other health technology products constitute an important part of an effective and efficient health system that contributes towards achieving health-related sustainable development goals for ensuring healthy lives and promoting wellness for all at all ages [1-3].

Iraq had suffered many crises in the last four decades including humanitarian and health-related ones. Internal as well as external efforts are being made to help the country overcome

the consequences of these crises [4]. According to a report recently released by the Iraqi Ministry of Health and Environment (MoH), Iraq's total gross domestic product (GDP) has exceeded 111 billion US dollars in 2019; however, only 4.5% (about 5 billion US dollars) of the GDP is allocated for the healthcare and environmental sectors [5]. This percentage (4.5%) is considered the lowest among all the countries in the region that have a comparable economy. The report also indicated that only about 1.24 million US dollars were allocated for procuring medicines, medical appliances, and supplies by the state company for marketing drugs and medical appliances (KIMADIA), a company described in more details later in this section.

The Iraqi National Regulatory Authority (NRA) includes several directorates and departments that are parts of the Iraqi MoH, mainly the directorate of technical affairs (DOTA) [6]. The main functions of the Iraqi NRA are associated with ensuring safe, effective, and affordable medicinal products available in Iraq. These functions include, but are not limited to, granting marketing authorization, estimation of medicines quantities

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needed to be procured for the Iraqi healthcare institutions, laboratory quality control testing and batch release of medicines, inspection duties, granting pharmaceutical manufacturing licenses, and pharmacovigilance.

The Iraqi NRA is led by two supreme committees, the Medicines Policy Committee and the National Board for the Selection of Drugs (NBSD) [6]. The former committee is in charge of establishing the general outlines for medicines policy in the country. The NBSD is responsible for enlisting and authorizing medicines in Iraq. The NBSD categorizes medicines in Iraq under two lists which are the national essential medicine list (EML) and the comprehensive list. The national EML is further subdivided into three levels, L1, L2, and L3, as will be described later.

The state company for marketing drugs and medical appliances, or more widely known as “KIMADIA”, is the procurement arm of the Iraqi MoH. Its main responsibility is providing the government hospitals and healthcare centers with the necessary medicines (those enlisted in the Iraqi EML), vaccines, medical supplies, and equipment and materials for laboratories and hospitals [7]. The company has a flexible procurement system where it can use the tendering process with certain medicines and appliances or direct procurement with others. It is within KIMADIA regulations and procurement conditions that the product must be enlisted and registered in Iraq, especially when it comes to medicinal products. However, in certain circumstances, KIMADIA has the power to bypass these conditions to provide essential medicinal products for the country’s health institutions. It is also worth mentioning that KIMADIA is responsible for providing the public sector with the medicines enlisted in the L1 level of the national EML as well as providing other commodities to this sector. On the other hand, medicines enlisted in L2 and L3 levels of the national EML can be procured directly by the local health directorates and healthcare institutions when KIMADIA does not have enough funds to procure them [8].

The Iraqi MoH has been facing challenges to provide the necessary safe and effective medicines, especially those in the national EML, where part of them are essential for sexual and reproductive health and rights (SRHR) which are the focus of this paper [4]. The challenges are mainly monetary which might be alleviated by increasing the total expenditure on healthcare and procurement of medicines by the government. Other challenges have been related to a loose grip by the Iraqi MoH and other concerned departments within the Iraqi state in imposing the necessary rules and regulations that monitor the Iraqi pharmaceutical sector [5].

The availability of necessary SRHR medicines and other commodities in any country decides the effective implementation of the SRHR recommendations and guidelines of that country [9]. Countries develop and update their EMLs based on World Health Organization (WHO) global EML [10] and the changing epidemiology and requirements at the country level. Inclusion of all the necessary national SRHR-guidelines medicines in the national EMLs facilitates the availability of such medicines, though it is not necessarily ensuring their

availability. The inclusion of certain medicines in EMLs provides a strong background to create the initial stimulus for the availability of these medicines in countries. Furthermore, registration of medicines with local drug registration authorities and inclusion in public procurement lists are essential steps to ensure their availability [11, 12].

This study aims to sort out all the SRHR medicines required to implement national guidelines on preconception care, maternal care, family planning, safe and post-abortion care, and infertility in Iraq to identify the existing gaps in the availability of these medicines and advocate for registration and inclusion of missing ones in national EML.

Materials and Methods

A qualitative desk review assessment of the situation of availability of essential medicines that are required for national SRHR guidelines implementation was conducted through the direct communication of the researcher with the concerned MoH officials and employees to facilitate the process of conducting the assessment and collecting the available national SRHR guidelines. It is important to mention that most of the Iraqi SRHR guidelines are not available online; however, they had been printed and distributed to the Iraqi healthcare providers (HCPs) in the form of printed booklets and periodicals.

Once the current national SRHR guidelines were collected, reviewing and sorting out the necessary medicines to implement these guidelines was carried out. Mainly, tables were used to organize the information on each medicine or group of medicines with a focus on addressing the following questions; Is the medicine included in the national EML? Is the medicine included in the national comprehensive medicines list? Is the medicine registered by the drug regulatory authority of the country? if yes, how many products have been registered? Does Iraq have a pharmacovigilance system? if yes, is this medicine included in the pharmacovigilance system for quality control? Is the medicine included in the government procurement or tender lists? Has the medicine been procured in the past 24 months via recognized procurement agents that serve the public sector? Do the forecasting tools for medicines include this medicine?.

The prepared lists of medicines were mapped with the global EML [10], national EMLs [13], the comprehensive medicines list [14], and the list of registered medicines in Iraq [15] to identify the gaps. If gaps exist then remedies are to be identified to fortify the country’s ability to secure all the EML required to implement SRHR guidelines and ensure continuity of supply of these medicines in Iraq.

Results and Discussion

To present the large amount of data obtained in this study and to help a better understanding of the findings, the collected medicines from the available national SRHR guidelines and

documents were categorized into several categories and subcategories and listed in tables with proper color coding, as shown in the coming sections. The most prominent findings from each category and subcategory were explained under each of the corresponding results and discussion sections.

Situation of medicines and commodities for contraception

The collected information on medicines and commodities for contraception following the methodology of this study are summarized in **Table 1**. The most prominent findings that can be inferred from this table are explained here. Firstly, only

ethinylestradiol plus levonorgestrel (as tablets) are procured regularly by KIMADIA among all the medicines mentioned in the national guidelines, national EML and, global EML. Second, several medicines are enlisted in the global EML and are mentioned in the national SRHR guidelines but are not enlisted in the national EML, such as an etonogestrel-releasing implant, levonorgestrel tablet, estradiol cypionate plus medroxyprogesterone acetate injection, and ulipristal tablet. Finally, condoms and diaphragms are not enlisted in the national EML, instead, they are enlisted in the national list of commodities. Quantities needed were estimated by the Need Estimation Department in the DOTA but were not procured by KIMADIA in 2019.

Table 1. Situation of medicines and commodities for contraception

Name of the Medicine	Included in the global EML	Included in the national FP guidelines	Included in the national EML	If not included in the national EML, is it included in the comprehensive list?	Registered drug with the national drug control authority (number of products registered)	Amount procured in 2019	Included in the procurement list	Included in the forecasting tools for medicines	Included in the PV system
Oral hormonal contraceptives									
Ethinylestradiol + levonorgestrel. Tablet: 30 micrograms + 150 micrograms	Yes	Yes	Yes (L1)		Yes (1)	9991506	Yes	Yes (9991510)	No
Ethinylestradiol + norethisterone: Tablet: 35 micrograms + 1 mg.	Yes	Yes	Yes (L3)		No	np	No	No	No
Injectable hormonal contraceptives									
Estradiol cypionate + medroxyprogesterone acetate: Injection: 5 mg + 25 mg	Yes	No	No	No	No	np	No	No	No
Medroxyprogesterone acetate: Injection (intramuscular): 150 mg/mL in 1- mL vial. Injection (subcutaneous): 104 mg/0.65 mL in pre-filled syringe or single-dose injection delivery system	Yes	Yes	Yes (L1)		Yes (1)	np	No	No	No
Norethisterone enantate: Oily solution: 200 mg/mL in 1- mL ampoule	Yes	Yes	No	No	No	np	No	No	No
Intrauterine devices									
Copper-containing device	Yes	Yes	Yes (L3)		No	np	No	No	No
Levonorgestrel-releasing intrauterine: system with reservoir containing 52 mg of levonorestrel	Yes	Yes	Yes (L3)		Yes (1)	np	No	No	No
Barrier methods									
Diaphragms	Yes	Yes	Yes*		N/A	np	Yes	Yes (9905)	No
Condoms	Yes	Yes	Yes*		N/A	np	Yes	Yes (575549)	No
Implantable contraceptives									

Etonogestrel-releasing implant: Single-rod Etonogestrel-releasing implant, containing 68 mg of etonogestrel	Yes	Yes	No	Yes	No	np	No	No	No
Levonorgestrel-releasing implant: Two-rod Levonorgestrel-releasing implant, each rod containing 75 mg of levonorgestrel (150 mg total).	Yes	Yes	No	No	No	np	No	No	No
Intravaginal contraceptives									
Progesterone vaginal ring: Progesterone-releasing vaginal ring containing 2.074 g of micronized progesterone	Yes	Yes	No	No	No	np	No	No	No
Emergency contraceptives									
Levonorgestrel: Tablet: 30 micrograms; 750 micrograms (pack of two); 1.5 mg	Yes	Yes	No	Only 30 micrograms tab	No	np	No	No	No
Ulipristal Tablet: 30 mg (as acetate)	Yes	Yes	No	No	No	np	No	No	No
np: not procured	PV: pharmacovigilance			FP: family planning					
* enlisted in the National List of Commodities									

Situation of medicines related to antenatal care

The most prominent findings on medicines related to antenatal care are summarized in **Table 2**. Firstly, medicines for prevention and management of anemia, antacids, and medicines for the management of nausea and vomiting, and medicines for prevention and management of preeclampsia and eclampsia seem to be regularly estimated in the forecast and procured for the public sector. A reasonable number of these medicines have a valid registration status. Secondly, labetalol is not enlisted in the global EML but is available in Iraq; however, the situation is the opposite with bisoprolol. Thirdly, medicines for the management of diabetes complicating pregnancy seem to be regularly estimated in the forecast and procured for the public sector. A reasonable number of these medicines have a valid registration status.

All medicines for the prevention of mother-to-child transmission of the human immunodeficiency virus (HIV) and

other common infections that are mentioned in the available guidelines are enlisted in the national EML. Some of these medicines are procured and regularly estimated in the forecast every two or three years. However, **Table 2** shows many other HIV medicines are enlisted in the global EML but not enlisted in the national EML, such as atazanavir, darunavir, dolutegravir, tenofovir disoproxil fumarate, and raltegravir.

Medicines for the prevention and management of preterm births are covered within the national EML. Nifedipine is enlisted under L3 which means it can be procured at the healthcare institution level and not centrally through KIMADIA. Atosiban, even though this medicine is not enlisted in the global EML, it is included in the national guidelines and national EML. The results also show that albendazole is enlisted in L3 in the national EML and can be procured at the healthcare institution level, while mebendazole and adrenaline were not procured in 2019 even though they were regularly estimated in the forecast.

Table 2. Situation of medicines related to antenatal care

Name of the Medicine	Included in the global EML	Included in the national maternal care guidelines	Included in the national EML	If not included in the national EML, is it included in the comprehensive list?	Registered drug with the national drug control authority (number of products registered)	Amount procured in 2019	Included in the procurement list	Included in the forecasting tools for medicines (amount estimated)	Included in the PV system
Prevention and management of anemia									

Ferrous salt (Ferrous sulphate 200mg Tablet)	Yes	Yes	Yes (L1)		No	np	Yes	Yes (7150012)	No
Ferrous salt (Ferrous gluconate 400mg/15ml Syrup)	No	Yes	Yes (L1)		Yes (2)	456816	Yes	Yes (314187)	No
Ferrous salt + folic acid	Yes	Yes	Yes (L1)		Yes (8)	88148160	Yes	Yes (87646662)	No
Folic acid 5 mg tablet	Yes	Yes	Yes (L1)		Yes (8)	25773540	Yes	Yes (24445951)	No
Folic acid 400 microgram tablet	Yes	Yes	Yes (L1)		No	np	No	No	No
Vaccines									
Influenza vaccine	Yes	No	Yes (L1)		Yes (2)	~ 2200000	Yes	Yes (2200000)	No
Tetanus toxoid vaccine	Yes	yes	Yes (L1)		No	not specified	Yes	Under Study	No
Prevention and management of preeclampsia and eclampsia									
Calcium tablet	Yes	Yes	Yes (L1)		Yes (4)	3845900	Yes	Yes (3664639)	No
Acetylsalicylic acid (aspirin, 300 mg)	Yes	Yes	Yes (L1)		Yes (2)	524000	Yes	Yes (431325)	No
Magnesium sulfate	Yes	Yes	Yes (L1)		Yes (2)	50200	Yes	Yes (50210)	No
Hydralazine 20 mg ampule and 25 mg or 50 mg tablet	Yes	Yes	Yes (L1)		Yes (1)	37575	Yes	Yes (79922 inj)	No
Methyldopa tablet 250 mg	Yes	Yes	Yes (L1)		Yes (4)	2638670	Yes	Yes (1633675)	No
bisoprolol tablet 1.25 mg and 5 mg	Yes	No	No	Yes	Yes (14)	np	No	No	No
Labetalol injecion and tablet	No	Yes	Yes (L1)		Yes (1 for inj)	19490 inj.	Yes	Yes (19441 for inj) and (56719 for tab)	No
Prevention and management of preterm births									
Dexamethasone or betamethasone (IM)	Yes	Yes	Yes (L1)		Yes (2)	397463 (dexa)	Yes	Yes (7208189)	No
Nifedipine (a calcium channel blocker) 10 mg tablet	Yes	Yes	Yes (L3)		Yes (1)	np	No	No	No
Atosiban injection	No	Yes	Yes (L1)		Yes (1)	No need	Yes	Yes (2193)	No
Context specific medicines									
Preventive anthelmintic treatment: using single-dose albendazole (400 mg)	Yes	Yes	Yes (L3)		No	np	No	No	No
Preventive anthelmintic treatment: using mebendazole 500mg or 100 mg	Yes	Yes	Yes (L1)		Yes (1)	np	Yes	Yes (3014125)	No
Intermittent preventive treatment with sulfadoxine-pyrimethamine (IPTp-SP)	Yes	No	Yes (L3)		No	np	No	No	No
Azithromycin	Yes	Yes	Yes (L1)		Yes (17)	3395421	Yes	Yes (3415172)	No
Adrenaline	Yes	Yes	Yes (L1)		No	np	Yes	Yes (247414)	No
Co-trimoxazole prophylaxis for adults	Yes	Yes	Yes (L1)		Yes (8)	16805160 tablet 480 mg	Yes	Yes (14287048)	No
Ciprofloxacin 500 mg tab	Yes (250 mg)	Yes	Yes (L1)		Yes (25)	7152780	Yes	Yes (6989879)	No
np: not procured	PV: pharmacovigilance								

Situation of medicines required for intrapartum care

The situation of medicines required for implementing intrapartum care guidelines is summarized in **Table 3**. The table shows that antiseptics, including chlorhexidine solution and ethanol solution, are purchased at the healthcare institutions-level according to their needs. Only the povidone-iodine solution was decided to be procured by KIMADIA in Iraq. Povidone-iodine was not procured by KIMADIA in 2019 but was estimated in the forecast of the subsequent year (2020). A reasonable number of this product has a valid registration status.

IV fluids including normal saline and glucose solutions seem to be regularly estimated in the forecast and procured for the public sector. A reasonable number of these medicines have a valid registration status. For Induction of labor, misoprostol 25 µg vaginal tablet is not enlisted in the national EML in Iraq at any level (L1, L2, or L3) nor was procured by KIMADIA. Instead, a 200 µg-strength tablet is enlisted in the national EML under L1.

Under the section of pain relief, codeine is not enlisted in the national EML, but fentanyl, morphine, and pethidine are enlisted, even though pethidine is not enlisted in the global EML. Morphine injection was not procured in 2019; however, the quantity needed was projected in the forecast of the subsequent year (2020). On the other hand, medicines used in epidural analgesia are all enlisted in the national EML, procured, and regularly estimated. Lidocaine injection (1% and 2%) in vial or ampule were not procured in 2019 but was estimated in the forecast of the subsequent year (2020).

Regarding uterotonic, the combination of oxytocin and ergometrine (5 IU/500 µg) or oxytocin and ergometrine fixed-dose combination is not enlisted in the national EML nor mentioned in the guidelines. Ergometrine/ methylergometrine (200 µg, IM/IV), misoprostol (either 400 µg or 600 µg, orally), and tranexamic acid were not procured in 2019 but were estimated in the forecast of the subsequent year (2020). Oxytocin seems to be used as an alternative uterotonic to carbetocin in Iraq [16].

Finally, the plasma substituents dextran 70 is not enlisted in the national EML. However, human albumin use in Iraq might provide an alternative to this product [17].

Table 3. Situation of medicines required for intrapartum care.

Name of the Medicine	Included in the global EML	Included in the national intrapartum care guidelines	Included in the national EML	If not included in the national EML, is it included in the comprehensive list?	Registered drug with the national drug control authority (number of products registered)	Amount procured in 2019	Included in the procurement list	Included in the forecasting tools for medicines	Included in the PV system
Antiseptic									
Chlorhexidine Solution: 5% (digluconate)	Yes	Yes	Yes (L3)		No	np	No	No	No
Ethanol Solution: 70% (denatured)	Yes	Yes	Yes (L3)		No	np	No	No	No
Povidone iodine solution: 10% (equivalent to 1% available iodine)	Yes	Yes	Yes (L1)		Yes (5)	np	Yes	Yes (654758)	No
I.V. fluids									
Saline solution	Yes	Yes	Yes (L1)		Yes (6)	9583175	Yes	Yes (9527198)	No
Glucose solution	Yes	Yes	Yes (L1)		Yes (4)	7686725	Yes	Yes (4803048)	No
Induction of labour									
Misoprostol 25 µg vaginal tablet	Yes	Yes	No	No	No	np	No	No	No
Oxytocin injection	Yes	Yes	Yes (L1)		Yes (6)	1913425	Yes	Yes (2882012)	No
Pain relief									
Codeine 30 mg tab (phosphate)	Yes	No	No	Yes	No	np	No	No	No
Fentanyl	Yes	No	Yes (L1)		Yes (2)	214210	Yes	Yes (154783 inj)	No
Morphine injection	Yes	No	Yes (L1)		Yes (3)	np	Yes	Yes (76114 inj)	No
Pethidine	No	No	Yes (L1)		Yes (1)	11290	Yes	Yes (142283 inj)	No
Epidural analgesia									
Bupivacaine Injection: 0.25%; 0.5% (hydrochloride)	Yes	Yes	Yes (L1)		yes (1)	114980	Yes	Yes (139699)	No
Lidocaine Injection: 1%, 2% (hydrochloride) in vial	Yes	Yes	Yes (L1)		Yes (3)	np	Yes	Yes (243018)	No
Ephedrine Injection: 30 mg (hydrochloride)/ mL in 1- mL ampoule. (For use in spinal anaesthesia	Yes	Yes	Yes (L1)		No	179750	Yes	Yes (104657)	No

during delivery, to prevent hypotension)									
Uterotonics									
Oxytocin injection	Yes	Yes	Yes (L1)		Yes (6)	1913425	Yes	Yes (2882012)	No
Carbetocin (100 µg, IM/IV)	Yes	No	Yes (L3)		Yes (1)	np	No	No	No
Ergometrine/ methylethergometrine (200 µg, IM/IV)	Yes	Yes	Yes (L1)		Yes (1)	np	Yes	Yes (1118398)	No
Misoprostol (either 400 µg or 600 µg, PO)	Yes	Yes	Yes (L1)		Yes (1)	Yes	Yes	Yes (468717)	No
Combination of oxytocin plus ergometrine (5 IU/500 µg) oxytocin and ergometrine fixed-dose combination	Yes	No	No	No	No	np	No	No	No
Tranexamic acid (TXA) 1 g in 10 mL (100 mg/mL)	Yes	Yes	Yes (L1)		Yes (1)	np	Yes	Yes (189107)	No
Blood components									
Coagulation factor VIII (500 IU/vial)	Yes	No	Yes (L1)		Yes (4)	150525	Yes	Yes (155260)	No
Coagulation factor IX (500-1000 IU/vial)	Yes	No	Yes (L1)		Yes (3)	42077	Yes	Yes (39090)	No
Plasma substitutes									
Dextran 70	Yes	No	No	Yes	No	np	No	No	No
np: not procured		PV: pharmacovigilance							

Situation of medicines required for postpartum care

The most prominent findings from the situation of medicines required for postpartum care are summarized in **Table 4** (part1) and can be described as following. Medicines for postpartum care seem to be regularly estimated in the forecast and procured for the public sector. A reasonable number of these medicines have a valid registration status. Anti-D immunoglobulin was not procured in 2019, but it was found that 54983 injections were procured by KIMADIA in December

2018. In addition to that, this product is included in the forecast for 2020.

The situation for enoxaparin 4000 IU is the same as for anti-D immunoglobulin above, where this product was not procured in 2019, but it was found that 762312 prefilled syringes were procured by KIMADIA in June 2018. In addition to that, this product is included in the forecast for 2020.

Finally, erythromycin (tablets, capsules, or injections), ampicillin injections, and clindamycin injections or capsules were enlisted under either level 2 or 3 of the national EML.

Table 4. Situation of medicines required for postpartum care and comprehensive abortion care

Name of the Medicine	Included in the global EML	Included in the national guidelines	Included in the national EML	Registered drug with the national drug control authority (number of products registered)	Amount procured in 2019	Included in the procurement list	Included in the forecasting tools for medicines	Included in the PV system
Part 1: Postpartum care section								
Iron and folic acid supplementation	Yes	Yes	Yes (L1)	Yes (8)	88148160	Yes	87646662	No
Anti-D immunoglobulin Injection: 250 micrograms in single-dose vial	Yes	Yes	Yes (L1)	Yes (2)	80903 (300 microgram PFS)	Yes	Yes (64855)	No
Erythromycin tablet, capsule, or injection	Yes	Yes	Yes (L3) only tab or cap	Yes (3)	np	No	No	No
Amoxicillin and clavulanic acid ("co-amoxiclav")	Yes	Yes	Yes (L1)	Yes (30 for tab) and (25 for susp)	29749280 (tab), 2476728 (susp)	Yes	Yes (1434639 for susp) and ongoing for tab	No
Ampicillin injection	Yes	Yes	Yes (L2)	Yes (3)	np	No	No	No
Gentamicin injection	Yes	Yes	Yes (L1)	Yes (9)	906980	Yes	Yes (3248298)	No
Clindamycin	Yes	Yes	Yes (L3)	Yes (3 for inj) and (2 for cap)	np	No	No	No
Enoxaparin 4000 IU	Yes	Yes	Yes (L1)	Yes (1)	np	Yes	Yes (1015566)	No

Part 2: Comprehensive abortion care									
Mifepristone	Yes	No	Yes (L3)	No	np	No	No	No	No
The combination regimen (mifepristone and misoprostol)	Yes	No	No	No	np	No	No	No	No
Ibuprofen (400–800 mg) tablet	Yes	No	Yes (L1)	Yes (18)	57531200 (200 mg tab.)	Yes	Yes (45171807)	No	No
Diazepam 5–10 mg tablet	Yes	No	Yes (L1)	Yes (10)	5169000	Yes	Yes (3556904)	No	No
Opioid analgesia for pain relief									
Codeine tablet 30mg (phosphate)	Yes	No	No	No	np	No	No	No	No
Fentanyl	Yes	No	Yes (L1)	Yes (2)	214210	Yes	Yes (154783 inj)	No	No
Morphine injection	Yes	No	Yes (L1)	Yes (3)	np	Yes	Yes (76114 inj)	No	No
Pethidine injection	No	No	Yes (L1)	Yes (1)	11290	Yes	Yes (142283 inj)	No	No
Epidural analgesia/anesthesia									
Bupivacaine Injection: 0.25%, 0.5% (hydrochloride)	Yes	No	Yes (L1)	Yes (1)	114980	Yes	Yes (139699)	No	No
Lidocaine Injection: 1%, 2% (hydrochloride) in vial. Injection	Yes	No	Yes (L1)	Yes (3)	np	yes	Yes (243018)	No	No
Ephedrine Injection: 30 mg (hydrochloride)/ mL in 1- mL ampule (for use in spinal anaesthesia during delivery, to prevent hypotension)	Yes	No	Yes (L1)	No	179750	Yes	Yes (104657)	No	No
np: not procured PV: pharmacovigilance									

Situation of medicines required for comprehensive abortion care

The situation of medicines required for comprehensive abortion care is summarized in **Table 4** (part 2). It is important to mention that there are no national comprehensive guidelines dedicated to abortion care in Iraq. However, some of these medicines are included in the basic health services package for Iraq (2009) which covers this section. The table shows that mifepristone is enlisted only under L3 of the national EML. Mifepristone in combination with misoprostol is not enlisted in the national EML or the comprehensive list of medicine. The non-steroidal anti-inflammatory drug (NSAID) Ibuprofen 200 mg tablet was procured for the public health sector in 2019. A reasonable number of this medicine (generic products) have valid registration status. Diazepam seems to be regularly estimated in the forecast and procured for the public sector. A reasonable number of this medicine has a valid registration status. Morphine injection was not procured by KIMADIA in 2019; however, it is included in the 2020 forecast. Finally, for epidural analgesia, every medicine seems to be covered in Iraq except for the lack of procurement of lidocaine injection in 2019 and the lack of registered products for ephedrine injection.

Situation of medicines required for preconception and fertility care

There are no national comprehensive guidelines dedicated to preconception care in Iraq. However, some of **Table 5** (part 1) medicines are included in the basic health services package for Iraq (2009). The situation indicates no ferrous sulphate tablet products are registered or have valid registration status in Iraq. This medicine was not procured in Iraq in 2019 but was included in the 2020 forecast. On the other hand, ferrous gluconate syrup is included in the national guidelines (the basic health services package for Iraq, 2009), included in the national EML, registered, and procured regularly by KIMADIA. However, the ferrous gluconate syrup dosage form is not enlisted in the global EML.

Folic acid preparations (alone or in combination) are included in the national guidelines and enlisted under L1 of the national EML. A significant number of these products have been registered and procured in 2019.

Regarding the vaccines, the table shows that influenza vaccines were not procured in 2019. Two influenza vaccine products are registered and 2200000 doses are estimated for 2020. On the other hand, the human papillomavirus vaccine (HPV) is not yet part of the Iraqi immunization schedule. All other vaccines seem to be regularly estimated in the forecast and procured by KIMADIA. However, most of these vaccines were not registered in Iraq.

Finally, clomiphene citrate tablets were not procured for the public sector in 2019 but are included in the 2020 forecast. Two products are registered and this medicine is enlisted under L1 of the national EML.

Table 5. Situation of medicines required for preconception and fertility care, and newborn care

Name of the Medicine	Included in the global EML	Included in the national guidelines	Included in the national EML	If not included in the national EML, is it included in the comprehensive list?	Registered drug with the national drug control authority (number of products registered)	Amount procured in 2019	Included in the procurement list	Included in the forecasting tools for medicines	Included in the PV system
Part 1: Preconception and fertility care									
Ferrous salt (Ferrous sulphate 200mg Tablet)	Yes	No	Yes (L1)		No	np	Yes	Yes (7150012)	No
Ferrous salt (Ferrous gluconate 400mg/15ml Syrup)	No	No	Yes (L1)		Yes (2)	456816	Yes	Yes (314187)	No
Ferrous salt + folic acid	Yes	No	Yes (L1)		Yes (8)	88148160	Yes	Yes (87646662)	No
Folic acid 5 mg tablet	Yes	No	Yes (L1)		Yes (8)	25773540	Yes	Yes (24445951)	No
Influenza vaccine	Yes	No	Yes (L1)		Yes (2)	np	Yes	Yes (2200000)	No
HPV vaccine	Yes	No	No	Yes	No	np	No	No	No
Rubella vaccine	Yes	No	Yes (L1)		Yes (1)	Procured	Yes	Yes (4103235)	No
Tetanus vaccine	Yes	No	Yes (L1)		No	Procured	Yes	Yes (56037 for DT vaccine) and (3034016 for D.T.P)	No
Infertility		No							
Clomifene Tablet: 50 mg (citrate)	Yes	No	Yes (L1)		Yes (2)	np	Yes	Yes (539241)	No
Part 2: Newborn care									
Chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine)	Yes	Yes	Yes (L3)		No	np	No	No	No
Surfactant	Yes	Yes	Yes (L1)		Yes (1)	13028	Yes	Yes (71614)	No
Oxygen therapy	Yes	Yes	Yes		NA	np	NA	NA	No
Vitamin K1	Yes	Yes	Yes (L1)		Yes (1)	np	Yes	Yes (146355)	No
Tetracycline hydrochloride 1% eye ointment	Yes	Yes	Yes (L1)		Yes (2)	np	No	No	No
Erythromycin 0.5% eye ointment	Yes	No	No		No	np	No	No	No
Povidone iodine	Yes	Yes	Yes (L1)		Yes (5)	np	Yes	Yes (654758)	No
Chloramphenicol 1% eye ointment	No	No	Yes (L1)		Yes (3)	202800	Yes	Yes (721045)	No
Phenobarbital ampule	Yes	Yes	Yes (L1)		No	186830	Yes	186783	No
Midazolam injection	Yes	Yes	Yes (L1)		Yes (3)	np	Yes	Yes (206518)	No
Lidocaine injection	Yes	Yes	Yes (L1)		Yes (3)	np	yes	Yes (243018)	No
Aqueous benzyl penicillin 100000–150000 U Procaine penicillin 50000 U	Yes	Yes	No	Yes	No	np	No	No	No
Hepatitis B vaccine	Yes	Yes	Yes (L1)		Yes (1)	621000	Yes	Yes (1992831)	No
Oral polio vaccine	Yes	Yes	Yes (L1)		No	21000000	Yes	Yes (22601828)	No
BCG vaccine	Yes	Yes	Yes (L1)		No	Procured	Yes	in process	No
Cloxacillin	Yes	Yes	No	No	No	np	No	No	No
Ceftriaxone 1g vial I.V. injection	Yes	Yes	Yes (L1)		Yes (7)	6161458	Yes	6051458	No
Spectinomycin 25 mg/kg	Yes	No	No	No	No	np	No	No	No

Situation of medicines required for newborn care

The situation of medicines required for newborn care is summarized in **Table 5** (part 2). The most prominent findings are described as following. Chlorhexidine is enlisted under L3 of the national EML. Surfactants seem to be regularly estimated in the forecast and procured for the public sector, where two of these medicines have a valid registration status. Vitamin K is enlisted under L1 of the national EML with one product that has a valid registration status. Vitamin K is included in the 2020 forecast but was not procured by KIMADIA in 2019. Tetracycline eye ointment is included in the guidelines and enlisted under L2 of the national EML but erythromycin eye ointment seems to be absent from the national guidelines, national EML, registration, procurement, and forecast. Phenobarbital ampules seem to be regularly estimated in the forecast and procured by KIMADIA. However, no product has a valid registration status. Midazolam and lidocaine injections were not procured in 2019. These two products however are included in the 2020 forecast. Aqueous benzylpenicillin 100000–150000 U, procaine penicillin 50000 U, and cloxacillin seem to be no longer part of the national EML. Vaccines for newborns are adequately covered by the Iraqi MoH. Spectinomycin is not enlisted under any level of the national EML, no product has a valid registration status, and lastly, this medicine has not been procured or enlisted in the forecast.

Putting all the data from **Tables 1, 2, 3, 4, and 5** together can provide a global look at the situation of essential medicine required for the implementation of national SRHR guidelines in Iraq. The number of SRHR medicines grouped under different categories is shown in **Figure 1**, where one can see that about 64% of the SRHR medicines enlisted in the global EML are fairly covered in Iraq. The meaning of fairly covered is that the SRHR medicine (only enlisted ones in the global EML) is well recognized by the Iraqi regulatory authority and healthcare system through enlisting in the national EML, comprehensive list, procured, and/or forecasted to be procured. The figure also clearly shows the number of SRHR medicines that are not included in the guidelines (32 out of 125), not enlisted in the national EML or comprehensive list (19 out of 125), not registered but in the national EML (26 out of 125), not procured in 2019 but enlisted in national EML-L1 (23 out of 125), and finally not included in the forecast but enlisted in national EML-L1 (3 out of 125).

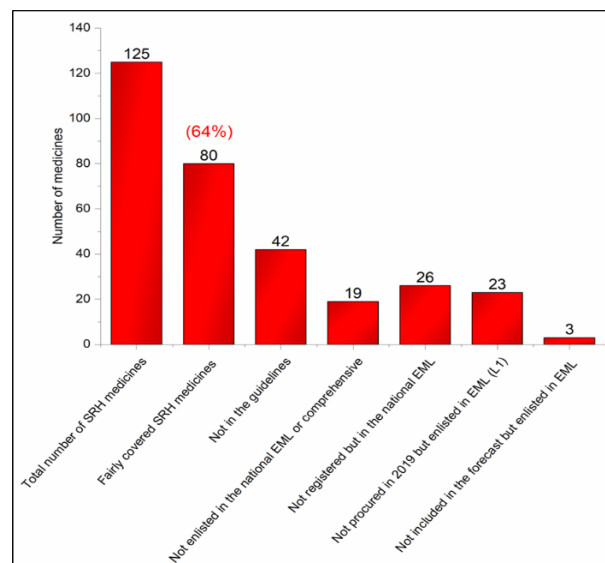
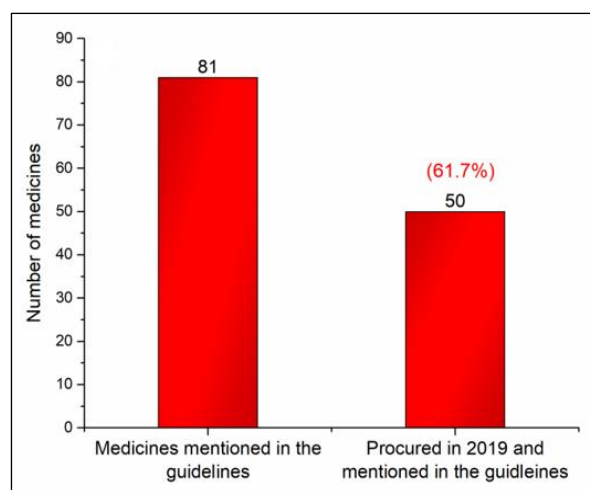


Figure 1. Number of SRHR medicines grouped under different categories (as labeled inside the figure)

Furthermore, the calculations show that about 61.7% of the medicines mentioned in the national SRHR guidelines were procured in 2019 (50 medicines out of 81 medicines), as shown in **Figure 2a**, assuming that is the contracted medicines were supplied to KIMADIA smoothly and no contract was rescinded. However, the analysis also shows a higher percentage (71.4%) of procurement when comparing the number of medicines enlisted in national EML (L1) to the number of these medicines procured in 2019 (**Figure 2b**).



a)

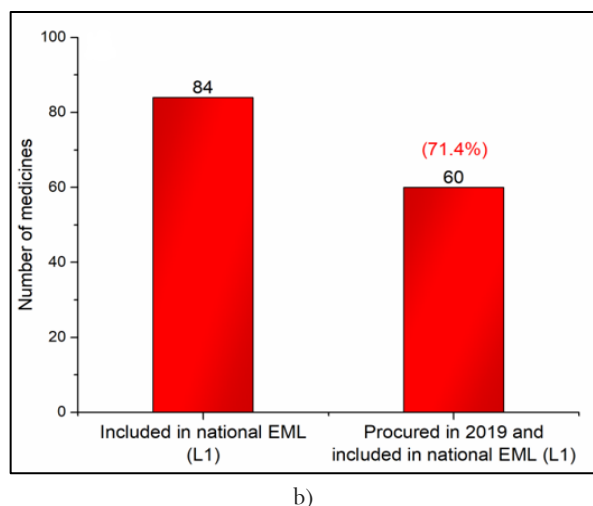


Figure 2. (a) Number of SRHR medicines mentioned in the national guidelines compared to a number of these medicines procured in 2019. (b) Number of SRHR medicines included in the national EML (L1) compared to the number of these medicines procured in 2019.

The most prominent findings from the results section can be discussed following the same categorization of the SRHR medicines used in the previous section and as below:

Situation of medicines and commodities for contraception

It seems that the Iraqi MoH supplies its healthcare institutions through KIMADIA with only ethinylestradiol plus levonorgestrel tablets for family planning. As it can be seen from the registered drug column, there are two more products (medroxyprogesterone acetate I.M. injection and levonorgestrel-releasing intrauterine system) having a valid registration status and can provide alternatives in the private sector and/or procured at the healthcare institution level (enlisted under L3 level). Many other means of family planning medicines are enlisted in the global EML and are mentioned in the national SRHR guidelines but not enlisted in the national EML. Therefore, these medicines need to be considered by NBSD as additional or alternative medicines to the national EML enlisted family planning medicines [18]. To our knowledge, emergency contraceptives mentioned in **Table 1** are available in the private sector and might need to be registered by the Iraqi MoH to ensure a safe and effective medicine for the public.

Finally, condoms and diaphragms were not procured by KIMADIA due to the lack of cost estimation of these two commodities. Cost estimation is supposed to be provided to KIMADIA by DOTA for the tender announcement. Therefore, work needs to be accelerated by the division of cost estimation units within the DOTA to facilitate the procurement of these two sexual commodities.

Situation of medicines related to antenatal care

It seems that even when a medicine is not registered nor has no valid registration status, it can still be procured by KIMADIA, if necessary (an example is ferrous sulphate 200 mg tablet) [8]. However, it is worth mentioning that every batch of medicine procured by KIMADIA has to be tested in the national quality control (QC) laboratories for release purposes to ensure a minimum level of safety and efficacy of the unregistered medicine. Bisoprolol is not enlisted in the national EML but there seems to be a good alternative beta-blocker medicine, which is labetalol. However, the use of labetalol might need to be validated by specialized healthcare professionals if it can serve the purpose here [19]. Ranitidine was not procured by KIMADIA in 2019 probably because of the n-nitrosodimethylamine (NDMA) impurities of the medicine [20], but it might also be because of the available stock balance (590270 ampules were procured in September of 2018). Alternative injectable antiulcer medicines were found to be enlisted recently by NBSD, such as omeprazole and esomprazole vials. Based on the NDMA issue, the global EML might need to be revised where the removal of ranitidine from the list and finding other alternative, beside injectable omeprazole, need to be considered by the WHO [21]. The National EML contains only the lyophilisates dosage form of ondansetron tablet. Conventional tablet dosage form of this drug enlisted in the global EML might also need to be proposed to the NBSD for possible cost-saving and widening the basket of alternatives to this medicine in Iraq, even though the orally disintegrating tablets offer a more elegant choice [22]. For HIV medicines, the analyses show many other HIV medicines that are enlisted in the global EML but not enlisted in the national EML such as atazanavir, darunavir, dolutegravir, tenofovir disoproxil fumarate, and raltegravir. These medicines can be proposed for enlisting in the national EML, if necessary, depending on the prevalence of HIV infection in Iraq [23]. Finally, atosiban is included in the national guidelines (management of preterm labor) and is included in the forecast but was not procured in 2019, when checked across KIMADIA procurement lists, suggesting the need to urge KIMADIA to make it available at least for healthcare institutions or procuring the alternative medicine, nifedipine [24, 25].

Situation of medicines required for intrapartum care

Even though misoprostol 25 µg vaginal tablet has been recommended in the national guidelines for induction of labor, it was not included in the national EML probably due to the presence of the alternative oxytocin, lack of reliable suppliers of this vaginal tablets, and/or the extra cautions implied by the WHO statement in using this medicine for induction of labor, where the global EML stipulated the following in using this medicine: "Misoprostol vaginal tablet 25 micrograms can only be used for induction of labor where appropriate facilities are available" [10, 26].

Codeine phosphate is enlisted only in the comprehensive list. However, no product has been registered yet. Registration of this product might need to be encouraged to take this medicine at least available in the private market. Also, registering ephedrine injection used in epidural analgesia should be encouraged by the Iraqi MoH to ensure an acceptable quality, safety, and efficacy of such product when procured by KIMADIA.

Lastly, the combination of oxytocin and ergometrine (5 IU/500 µg) or oxytocin and ergometrine fixed-dose combination can be proposed to the NBSD if there is a significant advantage of using these products as uterotonics and when doing so, the intrapartum guidelines can be updated accordingly.

Situation of medicines required for postpartum care

There seems to be only one enoxaparin product registered in Iraq and that is the brand product (Clexane®). Biosimilar products to enoxaparin sodium have become widely available. It is highly recommended that the Iraqi MoH consider some biosimilar enoxaparin products to improve access to enoxaparin and ensure the continuity of the supply chain of this medicine [27].

Additionally, erythromycin (tablet, capsule, or injection), ampicillin injection, and clindamycin were not procured by KIMADIA because these products are enlisted under either level 2 or 3 of the national EML and are supposed to be procured by the healthcare institutions directly. There are reasonable numbers of registered products of these medicines which can enable the healthcare institutions to directly procure them.

Situation of medicines required for comprehensive abortion care

The results show that mifepristone alone or in combination with misoprostol has not been considered for comprehensive abortion care. However, misoprostol seems to be regularly estimated in the forecast and procured for the public sector and can provide a good alternative [28]. The necessity of mifepristone alone or in combination medicines might need to be proposed to the NBSD by the concerned MoH department(s).

Opioid analgesia is not included in the guidelines column of **Table 5** due to the absence of national comprehensive guidelines dedicated to abortion care in Iraq. However, most of these analgesics are enlisted in the national EML, regularly estimated in the forecast, and procured for the public sector. Pethidine and fentanyl can provide an alternative to morphine injection enlisted in the global EML [29]. Regarding epidural analgesia, even though no ephedrine injection is registered, but as was mentioned before, KIMADIA can still procure the medicine when it is needed [8]. Registration of ephedrine injection should be encouraged in Iraq to assure appropriate quality for such medicines. Lidocaine injection needs to be

procured, as estimated per 2020 and subsequent years forecast, to avoid any shortage of this essential medicine since this medicine was not procured in 2019. However, it is worth mentioning that this medicine was procured twice in 2018 (106780 injections in June and 238380 injections in September) which means that the country stockpile of this medicine is adequate for the Iraqi MoH needs.

Situation of medicines required for preconception and fertility care

Instead of using ferrous sulphate syrup for anemia as per the global EML, ferrous gluconate syrup has been used in Iraq. It is known that ferrous gluconate has a low stability profile and is more prone to oxidation and conversion to the less absorbable ferric ion than the sulphate salt of iron [30]. Therefore, the removal of ferrous gluconate syrup from the national EML and replacement with ferrous sulphate syrup is a necessity.

The results collected from the available resources also show that influenza vaccines are needed to be procured yearly since the expiration date of these products is typically one year based on the possible changes in the vaccine virus strains. The vaccine is included in the forecast for 2020. Even though the perception of this vaccine by the general public is still weak, it might need to be at least provided for high-risk people and encourage people to take it, especially with possible benefits of the vaccine in reducing COVID-19 complications [31].

Also, HPV needs to be proposed to the NBSD and related parties within the Iraqi MoH to be included in the Iraqi routine immunization schedule, as per WHO recommendations for routine immunization, to help reduce cervical cancer in female individuals [32, 33]. A study by the concerned MoH department(s) is recommended to decide accordingly.

Vaccines registration should be encouraged in Iraq to ensure a safe and effective vaccine reaches the general public. Even though the majority of vaccines are not registered in Iraq but they can still be procured by KIMADIA only when they are prequalified by WHO. It is also worth mentioning that every vaccine batch procured by KIMADIA has to be tested in the national QC laboratories for release purposes to ensure a minimum level of safety and efficacy of the unregistered vaccine.

Situation of medicines required for newborn care

Aqueous benzylpenicillin 100000–150000 U, procaine penicillin 50000 U, and cloxacillin are no longer part of the national EML mainly due to suspected bacterial resistance to these antibiotics in Iraq. Flucloxacillin 500 mg vial is enlisted under L3 of the national EML and a suggestion to move it to L1 might need to be pursued in Iraq.

When looking at the totality of data collected in **Tables 1, 2, 3, 4, 5, 6, and 7** one can note that none of the SRHR medicines are included in the Iraqi pharmacovigilance system for quality control. Even though Iraq has a spontaneous pharmacovigilance

reporting system, active (mandatory) pharmacovigilance is lagging [34]. Such a gap would need to be filled and a swift and urgent collaboration between the Iraqi Pharmacovigilance Center and the SRHR-specialized healthcare institutions should be pursued to ultimately ensure an effective and safe medicine at the same time.

The overall situation of SRHR medicines looks better for 2019 compared to previous years, especially in 2018, where only 12% of all medicines enlisted in the national EML were procured in that year [5]. However, several other actions can be taken as discussed above to make the situation even much better and provide a possible improvement in the sexual and reproductive health in the country and ultimately reach 100% coverage for SRHR medicines in Iraq.

Conclusion

This comprehensive assessment of the situation of essential medicines required for the implementation of national SRHR guidelines in Iraq can provide a solid basis for all the stakeholders involved in providing better SRHR services based on the current ground and by taking into account the data and suggestions reported in this study. The work also suggests the necessity of developing national guidelines for safe and post-abortion care, preconception, and infertility by Iraqi MoH concerned programs' managers and technical experts. It is also important to update the national SRHR guidelines and makes them available online continuously, taking into consideration the most recent scientific achievements, to make sure that they are providing the best treatment practice in Iraq and better wellness.

Furthermore, more work is required for enlisting all essential medicines that are reported in the national guidelines and classify these medicines according to the available budget to one of the priority levels (i.e. L1, L2, or L3) assigned by the NBSD. Work is also needed to enhance the communication & coordination among healthcare programs managers, need estimation, and KIMADIA to ensure regular procurement for the L1 medicines, and to avoid any gaps in these essential medicines. On the other hand, improving the accessibility and affordability of quality and safe medicines in the local market by encouraging the registration of more medicines, vaccines, and pharmaceutical companies according to solid registration criteria becomes a necessity. Finally, more work is also needed to attain an adequate level of pharmacovigilance control over SRHR medicines to ensure their safety.

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