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The Use of Off-label and Unlicensed Drugs for Neonates: A Report from a Teaching Hospital in Baghdad

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Abstract

Background: Neonates who are admitted to hospitals will need various drugs. The use of unlicensed or off-label drugs without scientific evidence makes this exposure unsafe.

Aim of study: We aimed to assess the use of drugs for neonates based on the British National Formulary for Children and IBM Micromedex Neofax.

Patients and methods: This is a descriptive study which reviewed the clinical files of enrolled neonates who have stayed in the hospital for more than 24 hours and received at least one drug. It was conducted in the neonatal care unit of the Children Welfare Teaching Hospital/ Medical City Complex in Baghdad during the period from 1st of January to 30th of June/2018. The data was entered on a predesigned format and analyzed by using the appropriate statistical methods.

Results: A total number of 1079 neonates were admitted to the NCU during the study period, of whom 967 were included in the current study with 597 (61.7%) males and 370 (38.3%) females. There were 424 (43.8%) preterm, 496 (51.3%) term and post term neonates, and 47 (4.9%) neonates with unknown gestational age. Different classes of drugs were used with a total of 56 drugs, of which 33.9% were unlicensed and 66.1% were off-label. Accordingly, 42.5% of the neonates received unlicensed drugs and almost all patients received at least one off-label drug. Major risk factors for such use include mechanical ventilation, male sex and prolonged hospitalization.

Conclusions: In hospitalized neonates, drugs were more frequently prescribed as an off-label rather than unlicensed. Almost all neonates were exposed to off-label formulations.

Keywords: Off-label drug, unlicensed drugs, neonates, neonatal care unit, drug labeling

Introduction:

The World Health Organization definition of the rational use of drugs as "those patients who receive drugs according to their clinical needs and in doses that meet their own requirements for an adequate period of time at the lowest cost to them and to their community" (1). Since 1995 the American Academy of Pediatrics started to deal with drug use in neonates (2, 3). Due to the lack of scientific evidence about drug use in neonates, such use is still one of the important problems in practice (4). In neonatal care units (NCU), the number of drugs administered varies inversely with the gestational age and/or the birth weight (BW) of the newborn (5). Premature neonates, with a gestational age below 37 weeks and those with low birth weight (LBW) < 2500 grams are frequently affected by apnea of prematurity, neonatal encephalopathy, bronchopulmonary dysplasia, and systemic infections (6). Due to immaturity of various organ functions like kidneys and liver which affect drug metabolism and clearance, gastric motility which affects drug absorption in case of orally administered drugs, body compartments and hemodynamic factors which affect drug distribution (6), neonates may show Pharmaco-dynamic and pharmaco-kinetic variations making them more susceptible to adverse drug reactions (7, 8, 9). The Pharmaceutical researchers were reluctant to include children in clinical trials because of ethical issues, liability fear,s and small numbers of specialists in pediatric pharmacology departments (10, 11). Even in the presence of these complications, such drug use is not contraindicated and should be considered necessary when there is no other option, but it may be unlicensed or off-label in some NCUs (12). Off-label drugs were prescribed in a different manner to label recommendations in relation to dose, frequency, presentation, or indication (13), or more accurately is defined as "the prescription of a drug for a use not included in the summary of product characteristics (SPC), and is not listed in the product information, the uses outside the terms of their product license (approval) disclaimed in the SPC" (1). Unlicensed drugs on the other hand include one or more of the following situations: Modification of the drug dosage, the drug compounding, the direct use of chemically pure substance as a drug and the use of drugs that is not yet registered in the country but are available through importation (14). Off-label prescribing is a real challenge for any prescriber because the product information will not include advice about off label use and the drug companies

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are unable to promote for these practices. (15) The food and drug administration (FDA) in the USA and the European medicines agency (EMA) in European countries are responsible for regulating drug registration. In many countries drug registration is based on data and information from internationally recognized regulatory agencies. (16) Saudi food and drug authority (SFDA) is a governmental agency that regulates licensing in the kingdom of Saudi Arabia, and has a Neonatal Dosage and Practical Guidelines Handbook (17, 18). In Iraq, there had been no drug regulating authority but a drug guide was published in 1990 and has never been revised or reprinted until 2016, when a new edition of the guide was updated according to the drugs approved by the National Board for Drug selection and Registration in Iraq. The Iraqi Medicines Guide describes each drug indications and doses for adults and children without specifying the neonatal age or weight. (19) The current study aimed to assess the use of drugs used for neonates based on the British National Formulary for Children and IBM Micromedex Neofax.

Patients and methods

This is a descriptive study which enrolled neonates who stayed for more than 24 hours in the NCU of the Children Welfare Teaching Hospital/ Medical City complex in Baghdad, and received at least one drug, from 1st of January to 30th of June 2018. This is an exclusively pediatric hospital with a NCU of a tertiary level. It has 60 beds and receives patients from the outpatient clinic and emergency room of the same hospital as well as those referred from other hospitals. A total of 1079 patients were admitted to the NCU during the study period, of whom 112 were excluded (39 with missing files and 73 not meeting the inclusion criteria). Inclusion criteria: Neonates who stayed in the NCU for more than 24 hours and received at least one drug. Exclusion criteria: Neonates who were admitted to the NCU for less than 24 hours, or have not received any drug other than intravenous fluids, electrolyte solutions, parenteral nutrition, blood and blood products (plasma, cryoprecipitate), local medications (for eyes or umbilicus), prophylactic vitamin K, phototherapy and O_2 . Data collection: The data collected from patients' files include: Gender, Gestational age (GA), body weight on admission (BW), mode of delivery and diagnosis. Prescribed drug data include: Number of prescribed drugs, active ingredients, indication, administration route, daily dose, duration of treatment and occurrence of adverse drug reactions (ADRs) and comparing it with the British National Formulary and IBM Micromedex Neofax (20, 21) in addition to the outcome (discharged, transferred or died). Statistical analysis: The data was entered to the statistical package for the social sciences 2. Simple data description was produced. For nominal variables, ANOVA and Pearson's Chi-square test were used, with a significance level of $p < 0.05$.

Results

Of the 967 neonates there were 597 (61.7%) males and 370 (38.3%) females. There were 424 (43.8%) preterm neonates, 496 (51.3%) term or post-term, while 47 (4.9%) were of unknown GA, with a range of 27 - 42 weeks. Those born with a low birthweight were 376 (38.9%), those with normal birthweight were 425 (43.9%), and those with an unknown birthweight were 166 (17.2%), with a range of 850 - 4300 grams. Spontaneous vaginal delivery (SVD) was the most frequent mode of delivery and represented 566 (58.5%), elective Cesarean Section (C/S) were 232 (24.0%) and emergency C/S were 169 (17.5%), table 1.

Table 1: Distribution of the study group by perinatal and neonatal characteristics

Variables	Categories	Number	%
Gender	Male	597	61.7
	Female	370	38.3
Gestational age (Weeks)	Unknown	47	4.9
	≤ 28	14	1.5
	29-33	78	8.1
	34-36	332	34.3
	≥37	496	51.3
Weight on admission (Grams)	Unknown	166	17.2
	< 1000	10	1.0
	1000-1500	75	7.8
	>1500- 2500	291	30.1
	>2500	425	43.9
Type of delivery	Spontaneous Vaginal Delivery	566	58.5
	Elective C/S	232	24.0
	Emergency C/S	169	17.5

As for the treatment outcome, 653 (67.5%) of the neonates improved and were discharged home, 161 (16.7%) were discharged on their families' responsibility before completing treatment, 38 (3.9%) were transferred to other hospitals for further medical treatment like assisted ventilation with mechanical ventilation or continuous positive airway pressure (CPAP) or for surgical interventions, while 115 (11.9%) died (15 of the total deaths were surgical cases). According to the reported diagnosis on patients' files, respiratory diseases including respiratory distress syndrome (RDS), transient tachypnea of the newborn (TTN), bronchiolitis and pneumonia were the most frequent causes of admissions to the NCU representing 369 (38.2%) of all admissions. The second cause was sepsis 225 (23.3%), neonatal jaundice was 185 (19.1%) followed by CNS in 82 (8.5%) then renal diseases and surgical cases as 28 (2.9%) cases for each, GIT and LBW with prematurity was 20 (2.1%) for each, and hemorrhagic diseases of newborn 10 (1.0%), table 2.

Table 2: Distribution of the study group by diagnosis

Category	No.	%
Respiratory	369	38.2
Sepsis	225	23.3
Jaundice	185	19.1
Central nervous System (CNS)	82	8.5
Renal	28	2.9
Surgical	28	2.9
Gastro-intestinal (GIT)	20	2.1
LBW, prematurity	20	2.1
Hemorrhagic diseases of newborn	10	1.0
Total	967	100

The drugs prescribed in the NCU were classified according to their indications, where antibiotics were the mostly prescribed category 19 (33.9%), followed by respiratory drugs 9 (16.1%), CNS drugs 6 (10.7%), GIT and minerals with vitamins were 5 (8.9%) for each, cardiac drugs and blood derivatives 3 (5.4%), diuretics 2 (3.6%) and a miscellaneous group 4 (7.1%), table 3.

Table 3: Distribution of the drug categories used in the management of the neonates

Class of drug	No.	%
Antibiotics	19	33.9
Respiratory	9	16.1
Central nervous System (CNS)	6	10.7
Gastro-intestinal (GIT)	5	8.9
Minerals and vitamins	5	8.9
Cardiac	3	5.4
Hematology	3	5.4
Diuretics	2	3.6
Miscellaneous	4	7.1
Total	56	100

The duration of hospitalization of the neonates ranged from 2 - 48 days, and accordingly, their exposure to drugs differed from 1 - 6 drugs. All prescribed drugs used in NCU were found in IBM Micromedex Neofax with all information related to GA, BW, dose, route of administration and indication, except for 11 drugs which were not found in this reference guide:

Neofax comparing to BNFC which showed that 19/56 (33.9%) of these drugs are unlicensed to be used in neonates. According to SPC only 14 (25%) of the used drugs were on-label and had been used in neonates, while the other 42 (75%) were off-label, table 4. There are certain drugs which affect the results of laboratory tests which include meropenem and imipenem (givea positive coomb's test) while tazobactam and flucloxacilline (give a false positive urinary glucose). Mechanically ventilated newborns, male sex and those who required prolonged hospitalization were more likely to be exposed to off-label or unlicensed use respectively, (P values 0.006, 0.016 and 0.03, and OR 1.91, 0.23 and 1.57 respectively), while BW and GA were not associated factors (P values of 0.94 and 0.2 and OR of 0.94 and 1.27 respectively).

Table 4: Unlicensed and off label drugs

Unlicensed		Off- label drugs	
BNF (35.85%)	Micromedex (19.64%)	SPC (75%)	
Imipenem	Bromhexine	Meropenem	Metoclopramide
Meropenem	Budesonide	Imipenem	Domperidone
Tazobactam	Carbamazepine	Azithromycin	Ursodeoxycholic acid
Ciprofloxacin	Clonazepam	Amoxicillin	Zinc sulfate
Budesonide	Flucloxacilline	Ciprofloxacin	Folic acid
Nystatin	Immunoglobuline	Amikacin	Ferrous sulfate
Omeprazole	Levocarnitine	Nystatin	Thiamine
Ranitidine	Oxcarbazepam	Cefotaxime	Furosemide
Domperidone	Prednisolone	Tazobactam	Spironolactone
Metoclopramide	Thiamine	Cefepime	Tranexamic acid
Ursodeoxycholic acid	Zinc sulfate	Floxacilline	Carnitine
Ferrous sulfate		Amphotericin	I.V.I.G
Cholecalciferol		Fluconazole	Vit-K-
Thiamine		Salbutamol	Albumin
Zinc sulfate		Budesonide	Phenobarbital
Sildenafil		Dexamethasone	Phenytoin
Paracetamol		Hydrocortisone	Levetiracetum
Tranexamic acid		Aminophylline	Carbamazepine
Clonazepam		Prednisolone	Oxcarbazepine
		Bromhexine	Clonazepam
		Ranitidine	
		Omeprazole	

Bromhexine, Levocarnitine, Carbamazepine, Oxcarbazepam, Clonazepam, Prednisolone, Budesonide, Flucloxacilline, Thiamine, Zinc sulfate and Immunoglobulin. The British National Formulary for Children (BNFC) is another referenced guide which described all drugs except for three which were not found: Cefepime, Bromhexine, and Surfactant. All drugs were considered licensed according to IBM Micromedex

Discussion:

Mechanical ventilation is one of the major risk factors for off-label and unlicensed drug use in NCUs as reported by Kumar et al and Mazhar (22, 17). Another major risk factor is male gender, which disagrees with the findings of Warrier et al in the USA (23). The current study has reached similar findings to other studies conducted in NCUs in

Brazil by Calvalho et al (24), Estonia by Lass et al (25), and Ireland by Keiran et al (26) regarding conditions that led to hospitalization among which are RDS, sepsis and

jaundice.. The current study has reached similar results regarding the length of hospital stay and the number of drugs used to those found by studies in India and the Netherlands (2010) (27, 28), which reported 7.4 days and 2.8 drugs/ patient respectively, but lower than a US study (13 days and 11.8 drugs/ patient) (7). Both low birth weight and prematurity were considered as minor risk factors for such drugs use, which is consistent with a study conducted in a children's hospital in Michigan (23). The number of drugs per prescription should always be kept low as it can lead to higher possibility drug interaction, increased risk of adverse drug reactions and antibiotic resistance (27). Systemic antibiotics were the most frequently prescribed group of drugs and its use varies according to the physician's clinical experience, hospital policies and the time needed while waiting for the results of culture and sensitivity, which was also suggested by Lime et al (28). We should consider the toxic potential of vitamins and minerals when there is another source of supplementation. (29) The findings of the current study in relation to unlicensed drugs (33.9%) and off-label drugs (66.1%) are consistent with two previous studies where off-label use was (64.8%, 66%) but are different in relation to unlicensed drug use (5.9%, 0.7%), which is mostly because many countries have governmental regulatory authorities which is not the case in Iraq (30, 18). Almost all drug groups have drugs which are off-label and nearly all newborns were exposed to at least one off-label drug, which is consistent with an Australia study (31). Exposure to unlicensed drugs in this study was (33.9%) in agreement with a Saudi study (40%) (17), but disagrees with another study which showed a wide range (23-60%) of neonates exposed to unlicensed drugs (32). This may be related to variations in the definitions of unlicensed drugs. Table 5 shows a simple comparison between the current and previous studies (33).

Table 5: Comparison between previous studies and the current study (33)

Number of Patients in the study	Off-label drugs (%)	Unlicensed drugs (%)	Country, year, Reference
293	44	28	Holland, 2001 (T' Jong GW et al, 2001)
97	47	11	Australia, 2002 (O'Donnell et al, 2002)
35	51	12	Italy, 2007 (Dell' Aera et al, 2007)
108	7	11	Finland, 2009 (Lindell-Osuagwu et al,
490	65	22	2009)
110	39	19	Estonia, 2011(Lass et al, 2011)
218	52.7	4.4	Ireland, 2014 (Kieran et al, 2014)
967	66.1	33.9	Portugal, 2015 (Silva et al, 2015)
			Iraq, 2019 (current study)

Conclusions:

In hospitalized neonates, Drugs were more frequently prescribed as an off-label rather than unlicensed. Almost all neonates were exposed to off-label formulations.

Authors' declaration:

Conflicts of Interest: None.-

We hereby confirm that all the Figures and Tables in the manuscript are mine/ ours. Besides, the Figures and images, which are not mine /ours, have been given permission for re-publication attached with the manuscript.-Authors sign on ethical consideration's approval-Ethical Clearance: The project was approved by the local ethical committee in Children Welfare Teaching hospital, Medical City. according to **the code number (35.3.12.2017).**

Authors` contribution: NNH contribute in Concept and design of study, Drafting the article or revising it critically for important intellectual content; and Final approval of the version to be published and submissions. **SKA** contribute in acquisition of data or analysis and interpretation of data; Drafting the article or revising it critically for important intellectual content; and Final approval of the version to be published.

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استخدام الأدوية غير المصرح بها لحديثي الولادة: تقرير من مستشفى تعليمي في بغداد

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الخلاصة

الخلفية: يتعرض الأطفال حديثو الولادة الراقدون في وحدة العناية المركزة إلى عدد كبير من الأدوية وبدون أية معلومات عن كفاءة أو سلامة تلك الأدوية المتزامن مع قلة الأدلة العلمية لاستخدام الأدوية للأطفال حديثي الولادة فإن مثل هذا التعرض يعتبرغير مرخص حسب كتب الأدوية العلمية أو غير مذكور للاستخدام في النشرة المرفقة بكل دواء.

الهدف: تهدف هذه الدراسة إلى تقييم إستخدام الأدوية غير المرخصة في وحدة العناية بالأطفال حديثي الولادة ولمقارنة هذا الإستخدام حسب كتب الأدوية والنشرة المرفقة.

المرضى والمنهجية: تعتبر دراستنا الحالية دراسة وصفية أجريت في مستشفى حماية الأطفال/وحدة العناية بالاطفال حديثي الولادة، وشملت الدراسة المرضى الراقدين في العناية لمدة 24 ساعة أو أكثر وإستلموا على الأقل دواءاً واحداً أو أكثر، خلال فترة ستة أشهر (الأول من كانون الثاني ولغاية الثلاثين من حزيران\2018). تم جمع المعلومات من السجلات السريرية للمرضى الراقدين وسجلت في إستمارة خاصة بالدراسة وشملت معلومات عن المريض وعن الأدوية الموصوفة وتم تحليل هذه المعلومات بإستخدام طرق إحصائية تحليلية وتمثيلها بشكل نسب مئوية في جداول معينة.

النتائج: لقد كان العدد الإجمالي للمرضى الراقدين في وحدة الخدج خلال فترة الدراسة هو 1079، تم أستثناء 112 مريضا لتشمل الدراسة 967 مريض فقط. بلغت نسبة الذكور 61.7% والأناث 38.3% ومن بينهم 43.8% أعمارهم الجنينية أقل من 37 إسبوع. تم إستخدام 56 نوع مختلف من الأدوية خلال فترة الدراسة وكانت نسبة الأدوية غير المرخصة هي 33.9% بينما بلغت نسبة الأدوية غير المذكورة 66.1%، وبالتالي تعرض 42.5% من المرضى الراقدين للأدوية غير المرخصة وتقريبا تعرض جميع المرضى على الأقل لدواء واحد غير مذكور الإستخدام في نشرته المرفقة.

الإستنتاج: في الاطفال حديثي الولادة الراقدين في المستشفى، تم وصف الأدوية بشكل متكرر على أنها خارج التسمية بدلا من كونها غير مرخصة وقد تعرض جميع الاطفال حديثي الولادة تقريبا لتركيبات خارج التسمية.

الكلمات المفتاحية: دواء خارج التسمية, الأدوية غير المرخصة ، حديثي الولادة ، وحدة رعاية الأطفال حديثي الولادة ، توسيم الأدوية.