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Original Research Article

Contribution of clinical pharmacy to the rational and safe use of medicines in the neonatology unit of the pediatric university hospital Charles de Gaulle of Ouagadougou, Burkina Faso

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ABSTRACT

Background: Newborns are exposed to drug therapeutic risks due to off-label prescribing and immaturity. The purpose of this study is to identify drug-related problems through the prescription and administration of drugs in the neonatology Unit and identify the need for pharmaceutical interventions.

Methods: To assess drug-related problems, a cross-sectional observational study was conducted over five days at the neonatology Unit of the Pediatric University Hospital Charles de Gaulle in Burkina Faso. The study population consisted of newborns receiving drug prescriptions and treatment for five days.

Results: Prematurity (50%) and early neonatal infection (53.3%) were the most common reasons for admission. A total of 380 prescription lines were recorded. Injectable and oral forms represented 72.1% and 26.3% respectively. Prescription lines in 16.8% were off-label medicines. An accuracy of drug dosages at 6.1% and an accuracy of prescribed doses at 52.7%, characterized therapeutic regimens. The prescribed drug administrations were performed in 80.0% with compliant doses and administration scheduled time 1 hour in 53.4 % and 54.6 %, respectively. Prescribers and nurses accepted 92.6% and 93.9% of proposed pharmaceutical interventions to solve drug-related problems.

Conclusion. Our study emphasizes the importance of a clinical pharmacist within the health care team for the safe and efficient prescription and administration of newborn medication.

Keywords: Neonatology, Drug-related problem, Medicines prescription and administration, Burkina Faso

INTRODUCTION

Health systems face the challenge of rational use of medicines. Rational use is "prescribing the most appropriate product, obtained on time and at an affordable price for all, dispensed correctly and administered at the appropriate dose and for the appropriate duration".¹ Nonrational use of medicines affects the quality of care, increases therapeutic risks, failure, and toxicity in patients, and increases household health expenditure. The

frequency of foreseeable, unpredictable adverse effects associated with misuse or abnormal conditions of use of medicines is an indicator of their proper, correct use. However, these adverse effects are under-reported in national or international healthcare centres.² Medication errors are among the most common causes of adverse events in hospitalized patients.^{3,4} They are three times more common in pediatric wards than in adult wards. In pediatrics, patients in intensive care and emergency units are more exposed to medication errors.⁵ Among these

errors, those related to prescribing and administration are more common. One in seven prescriptions contains at least one medication error.⁶ Neonates are particularly exposed to medication risks because of their prematurity, organ immaturity, and the high rate of off-label drug prescribing and dosing error due to continuous body weight change with growth.^{7,8} Human, technical, and procedural factors contribute to medication errors. Interventions to reduce medication errors have been proposed, including interception of errors, patient education, individual accountability, and secure cabinets.⁹ Computerizing medication prescriptions, using a single prescribing form, checklist medication monitoring, and the involvement of a clinical pharmacist as a care team member.¹⁰

The effectiveness of an intervention depends on the quality of the problem diagnosis and the adequacy of the proposed solutions. Optimal clinical pharmacy practice is crucial to the success of such an approach. The Pediatric University Hospital Charles de Gaulle of Ouagadougou is a national reference hospital for children from 0 to 14 years old. The neonatology Unit received its first patients in December 2019. The indoor pharmacy service, already experimented with solving medication-related problems, directly implanted the individual nominative dispensing of medicines close to patient beds. The medicine dispensing mode is associated with clinical pharmacy practices that promote the rational and safe use of medicines in newborns. Our study aims to analyse prescriptions, treatment preparations, and administrations to detect drug-related problems and propose pharmaceutical interventions to solve them.

METHODS

Study type

We conducted an observational descriptive and analytical study.

Study place

The study was conducted in the neonatology unit of the pediatric university hospital Charles de Gaulle, which is in Ouagadougou, the capital city of Burkina Faso. The neonatology Unit has a capacity of 40 beds and provides care to newborns under 28 days old. It comprises intensive care and hospitalization sections. The neonatology unit has hosted, at its creation in 2019, a pharmaceutical team for drug nominative and individual dispensing closed to inpatient beds.

Study duration

The study duration was from 4th to 8th January 2021.

Selection criteria of patients

The study included all patients hospitalized and receiving medication during the study period. The medication lines

listed in the patient records, medicine preparations and administrations by different teams of nurses were also included.

The prescription lines of medical devices, eye drops, local antiseptics, and milk were not considered. The preparations and administrations made outside of our presence were not considered.

Procedure

The study consisted of a prescription review and participative observation of medicine preparation and administration to hospitalized patients.

Data were collected from medical records, admission registry, supplementary and external prescriptions forms, returned drug sheets, patient medicine delivery plans, pharmaceutical care, and drug dispensing records, and patient-packed medicines labels. Prescribers, nurses, and patient companions also provided data, which were processed using previously validated collection sheets.

For the observational study data collection, we were present during the morning, permanence, and guard drug preparations and administrations. We evaluated each team's drug preparation and administration to patients. We typed all observed or potential drug inquiries or errors and recorded them as a need for pharmaceutical intervention. We noticed the risk of error and the error finding, and we took measures to prevent or correct them as much as possible.

Ethical Approval

The Medical Commission authorized the study, with permission from the Head of the Hospital, with N° 2020-02346 DG. Patient parents and nursing teams were informed about the research and gave oral consent. Data were collected on an anonymous sheet. Risks of error and observed errors were prevented or corrected before considering their shortcomings.

Statistical analysis

The collected data was entered into a database designed on Epi-info® version 7.2.2.6, which was transported to the Excel® 2019 spreadsheet.

The pharmaceutical analysis of drug prescriptions was made using references such as the neonatology guidelines, the hospital's list of drugs, the recommendations from pediatric societies, and the summary of licensed product characteristics. Also, Vidal® 2019, the Clinical and Therapeutic Pharmacy Guide 5th edition of the French Society of Clinical Pharmacy, the Nelson Textbook of Pediatrics 20th edition, Merenstein and Garners's Handbook of Neonatal Intensive Care, and the Clinical Pharmacy and Therapeutics by Whittlesea, 6th edition 11–13 were used.

The medication errors carried out at different stages of this cross-sectional study were classified using the Taxonomy of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).¹⁴ For the presentation of the results, continuous variables were expressed in classes. Qualitative variables were expressed proportionally or in compliance rate. The pharmaceutical validation of the prescription consisted of verifying the adequacy of the indication of the drug according to the age and patient background, the dose, the frequency, the flow rate, and the drug's administration route.

The adequacy of the quantitative parameters (dose, volume, flow rate) was assessed with a margin of tolerance of $\pm 10\%$. The time of administration of the drugs was found to be consistent with a tolerance of ± 1 hour from the indicated time.¹⁵ A prescription has been considered complete if the drug's name, dosage, dosage form, dose, route of administration, and frequency are specified. The compliance with the WHO criteria for rational use has been clarified.¹⁶

RESULTS

Patients' characteristics

The study enrolled 30 patients with a median birth weight of 1800 g, and 1st and 3rd quartiles at 1025 g and 750g, respectively. The weights below 2500 g accounted for 63.3%. The newborns' gestational age of <37 weeks accounted for 50% of cases.

Sixty-two (62) pathologies or vulnerabilities were diagnosed in patients with an average of 2.07 per patient. Bacterial infections, prematurity, and congenital malformations were the most common, with proportions of 27.4%, 25.8%, and 24.2%, respectively. The anthropometric and clinical characteristics of patients are reported in Table 1.

Prescription data

The patients received a total of 380 lines of prescribed drugs. The average number of prescription lines per patient and daily was 4.16, with extremes of 1.5 and 8. The prescribed drugs belong to different ATC classes. The most prescribed drugs were from the blood and hematopoietic organs (B) group with 31.1%, followed by systemic antibiotics (J), 24.2% digestive tract and metabolism drugs (A), 18.9%. Injectable and oral forms accounted for 72.1% and 26.3% of prescription lines, respectively. The off-label prescription represented 16.84%. The ATC classes, galenic forms, and off-label drug characteristics are given in Table 2.

Compliance with drug prescription lines

The prescribed drug lines were available at the indoor pharmacy in 72.9%. The drugs in 85.3% were written in international non-proprietary names (Table 3).

The galenic form dosages were well-indicated in 6.1% of cases out of 380 prescription lines. The medication regimen data, such as the dose and administration schedule, were noticed for 376 and 190 drug lines with an accuracy of 52.7 and 62.6, respectively (Table 4).

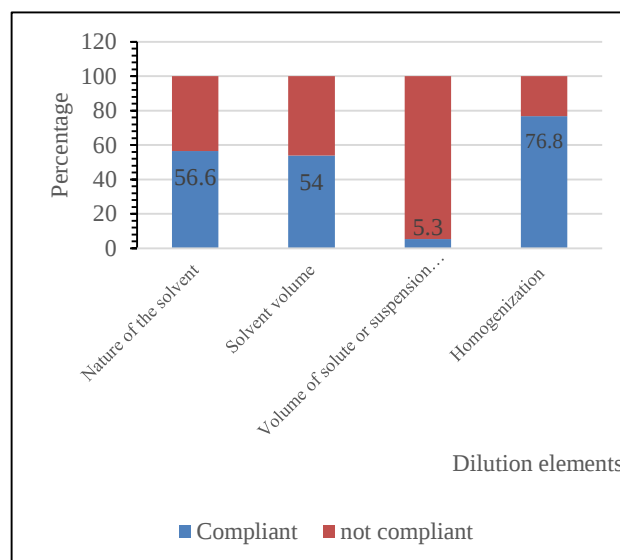
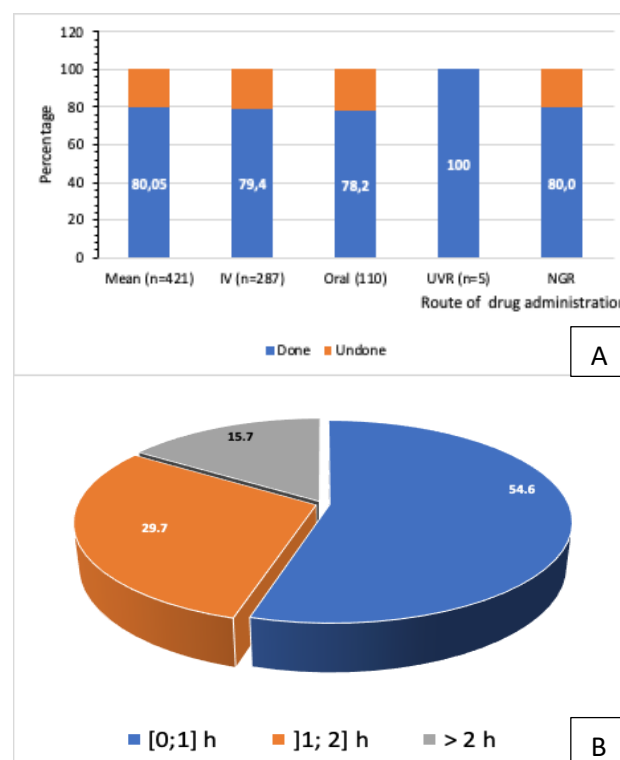


Figure 1: Compliance with drug dilution acts realized by nurses.



IV=intravenous, UVR=umbilical venous route, NGR=Nasogastric route.

Figure 2: Status drug administration (A) accomplishment level according to route, (B) The gap time between planned and realized drug administration.

Compliance with drug preparations

The observational study noticed that 574 dose preparations were expected. The effectively prepared doses were 79.09% of cases. The Drug preparation consisted of reconstitution with or without dilution. The observed reconstitutions involved two oral drugs and three injectable drugs. The frequencies and storage modalities are given in Table 5.

The reconstitution of vancomycin did not respect storage requirements. For drug dilution, the type and volume of the solvent used were exact at 56.6% and 54.0%, respectively. Compliance with dilutions is illustrated in Figure 1.

Compliance with drug administrations

The observational study found that 421 administrations were expected and 337 (80.04%) were completed. Table 6 illustrates the best practices of drug administration. The recording of drug administration procedures in patients'

medical records was 96.1%, with an accuracy rate of 1%. The accuracy of doses was 72.1%, and the timely administration of drugs was effective at 32.0%. Figure 2 shows the gap between planned and effective time for drug administrations. The drug administrations were completed on time ($\pm$ one hour) at 54.6%. The gap was more than 2 hours in 15.7% of cases.

Oral route administration of drugs to newborns often implies mixed with milk in 65 out of 110. Table 7 details the potential risk of reduction of drug resorption due to drug-drug or drug-milk interactions.

Drug-related problems solving

One hundred nine pharmaceutical interventions were formulated following the analysis of the newborn medication process (Table 8). The acceptance rate of suggested pharmaceutical interventions was 92.6% and 93.9% by physicians and nurses respectively.

Table 1: Anthropometric and clinical characteristics of patients.

Characteristics	Number/Frequency	%
Gestational age (weeks)	30	100
<32	4	13.4
32-37	11	36.6
≥ 37	15	50
Weight (g)	30	100
<1000	6	20
1000-1500	9	30
1500-2500	4	13.3
≥ 2500	11	36.7
Pathologies	62	100
Bacterial infections	17	27.4
Prematurity	16	25.8
Congenital malformations	15	24.2
Respiratory distress	8	12.9
Metabolic diseases and intoxication	6	9.7

Table 2: ATC classification, pharmaceutical forms, and off-label drugs prescribed to patients.

Drug characteristics	Prescription lines	Frequency (%)
ATC class	380	100
B: Blood and hematopoietic organs	118	31.1
J: General anti-infectives for systemic use	92	24.2
A: Digestive tract and metabolism	72	18.9
N: Nervous system	64	16.8
D: Dermatological drugs	17	4.5
C: Cardiovascular system	16	4.2
H: Systemic hormones, Sex hormones	1	0.3
Pharmaceutical forms	380	100
Solution for infusion	107	28.2
Solution for injection in ampoule	86	22.6
Powder for reconstitution	81	21.3

Continued.

Drug characteristics	Prescription lines	Frequency (%)
Syrup	64	16.8
Tablets	21	5.5
Powder for oral suspension	15	3.9
Cream/ ointment	6	1.6
Off-label*	64	100
Phenobarbital inj.	21	32.8
Clonazepam tablet	5	7.8
Etamsylate inj	11	17.2
Cefixime susp.	7	10.9
Molsidomine tablet	5	7.8
Captopril tablet	6	9.4
Cyclopiroxolamine cream	5	7.8
Zinc tablet	4	6.3

*Represented 16.8% of total prescription lines

Table 3: Indicators of rational use of medicines prescribed to patients (n=380).

Parameters	Prescription lines	%
Prescription in INN	324	85.3
Antibiotic prescription	112	29.5
At least one injectable	279	73.4
At least one oral product	113	29.7
Prescribed drug lines delivered by indoor pharmacy (availability)	277	72.9

INN=international nonproprietary name

Table 4: Accuracy of galenic form dosages prescribed and treatment regimens.

Elements	Prescription lines	Accuracy
Pharmaceutical forms		23 (6.1)
Powder for injection	81	1 (0.3)
Solution for injection	86	2 (0.5)
Syrup	64	0 (0.0)
Oral suspension	15	1 (0.3)
Solution for infusion	107	6 (1.6)
Tablets	21	13 (3.4)
Cream/ointment	6	0 (0)
Elements of the treatments' regimen		
Galenic form dosage	59	33 (55.9)
Route of administration	71	54 (76.1)
Dose	376	198 (52.7)
Administration technique	38	10 (26.3)
Infusion rate	113	109 (96.5)
Administration schedule	190	119 (62.6)
Treatment lasting	63	63 (100)

Table 5: Compliance of 116 drug reconstitutions.

Form	Drugs	Compliance of solvent			Compliance of storage	
		Nature	Volume	Conditions	Duration	Labelling
Oral powder	Amoxicillin + clavulanic acid	7	7	7	7	0
	Cefixime	2	2	2	2	0
Injectable powder	Cefotaxime	81	81	81	81	0
	Omeprazole	13	13	13	13	0
	Vancomycin	13	13	0	0	0
Total		116	116	103	103	0

Table 6: Compliance of drug administrations by nurses.

Administration related Act	Frequency		Number of observations
	Number	Proportion	
Verification of the concordance of dispensation labels and identity of the patient	0	0	30
Verification of the expiry date	0	0	421
Highlighting dispensing errors	10	2.6	421
Compliance with the aseptic procedure	0	0	337
Compliance with the prescribed time of administration	109	32.0	421
Dose accuracy	243	72.1	337
Compliance with the administration technique/administration throughput	13	3.8	337
Mentioned in patient' records	420	96.1	421
Accuracy of the recording	4	1	421

Table 7: Assessment of the risk of drug-drug, and drug-milk interaction.

No. of drugs	Frequency	Mixtures of medicines and milk	Risk
1	5	Iron	Decreased absorption
2	9	Iron+Nystatin	Iron chelation and decreased absorption
3	39	Iron+Nystatin+Pinkoo®+Uvesterol®+Iron+Astym in C ®Nystatin+Uvesterol®+Astymin®	Iron chelation and decreased absorption
5	12	Iron+Amoxicillin-clavulanic acid+Nystatin+Captopril+Molsidomine	Reduction of Captopril absorption by 35% Iron chelation

Table 8: Outcomes of pharmaceutical Interventions suggested by pharmacists to prescribers and nurses to solve drug-related problems.

Drug related problems	Frequency	Acceptance
Prescribers	27	25 (92.6 %)
Inappropriate dose	11	9
Dose distribution	1	1
Confused terminology	1	1
Transcription error	1	1
Adequate suggestions	13	13
Nurses	82	77 (93.9 %)
Dose schedule reminder	27	27
Solvent	2	2
Dilution	5	5
Dose	25	25
Administration modalities	10	10
Traceability	2	0
Treatment monitoring	7	5
Drug storage	1	1
Infusion rate	2	1
Product confusion	1	1

DISCUSSION

Our study evaluated the quality of the acts performed by the actors involved in the newborn medication process in the Neonatology Unit of the Pediatric University Hospital Charles de Gaulle of Ouagadougou in Burkina Faso. It

highlighted the need for clinical pharmacist assistance in newborn care units where patients are characterized by prematurity, low birth weight, and earlier neonatal infections. In our context, a high rate of prematurity is expected in neonatology units. Malaria infection during pregnancy is one of the leading causes. In Burkina Faso,

Nagalo et al have reported 24.4% of congenital malaria in private neonatology units.¹⁷ The prematurity and low birth weight were associated with several pathologies which complicate the management of newborns.¹⁸ This requires competent, experienced staff aware of pharmacological and pharmaceutical properties in the context of the needs of off-label medicines.

Newborn prescription characteristics

Our study revealed that newborn medication accounts for at least 50% of neonatal infections and/or prematurity. The effectiveness and safety of treatments are to be sought by the therapeutic quality of prescriptions and a follow-up with prevention or reduction of drug iatrogenesis. One must consider the evolution of body weight and renal excretion capacities in newborns for dose adjustments.¹⁹ WHO has edited criteria to promote the rational use of drugs. The prescription in INN form is 100 % of prescription lines and is limited to 2 medicines per prescription. These are not respected in our study. The university hospital center of Vaudois in Lausanne reported an average of six prescription lines per day in the neonatology unit. The prescription in INN remains an effort required by our prescribers in general as prescribing generics is economical and avoids errors of drug confusion in the hospital. The drug retained for prescription at least 90% must belong to the hospital's list of medicines whose availability is insured by the pharmacy. Antibiotic rational use constitutes a challenge with the emergence of microbe resistance. At least one antibiotic is retrieved in 29.24% of prescriptions, and that is aligned with the WHO recommendation of 20-30%.²⁰⁻²²

We found that 73.42% of prescription lines are injectable forms. The WHO's recommendation of less than two injectable forms per prescription is difficult to fulfil as in a third-level hospital, the cases are severe and require rapid and effective medicines. In sum, beyond the economic aspect, polypharmacy, in general, exposes patients to a risk of severe side effects by increasing drug interactions. Also, drug iatrogenesis is favoured in the context of off-label medication.²³

Adequacy of prescribed drugs

The Blood and hematopoietic organs (B) (32.36%), systemic antibiotics (J) (24.21%), and nervous system (N) (16.84%) of ATC classes of medicines were the more prescribed drugs. Off-label prescription accounted for 16.8% of prescription (Table 2). In intensive neonatal care services in Belgium, a predominance of antibiotic prescriptions followed by medications for Blood and Hematopoietic Organs and the nervous system was reported. The off-label medication represented 23%. The premature and pathological condition justifies the high prescription of class B. The parenteral nutrition and blood substitutes cover daily needs, compensate for water restriction, and stop bleeding. Also, group J drugs, such as antibiotics, are necessary to face early neonatal infections

as their prevalence was 53.3% among inpatients. The Group N medicines are essential to manage convulsions and fever accompanying neonatal infections, respiratory distress, nuclear jaundice, and prematurity. This could justify the high combination of prescriptions for these three classes of drugs.²⁴ The mention of the dosage of drugs was noticed in 6.1% of the prescription lines, which is a source of medication error during drug dispensing or administration. Also, the use of antibiotics requires bacteriological documentation. Anticipated use of antibiotics must be sustained by continuous surveys of the epidemiology of isolated microbes concerning standard-operated protocols. Compliance with good practices reduces the emergence of multi-resistant strains of bacteria in healthcare settings.²⁵

Compliance with drug preparation and administration

The drug preparation consisted of reconstitution and/or dilution of the therapeutic unit preceding administration. All processes have to be done according to good preparation and administration practices.²⁶ The drug preparations by nurse teams were observed, and deficiencies were pointed out regarding labeling and preservation. These are sources of error, confusion, and deterioration of drug-active ingredients, which in turn can cause harm to the patient.

The rate of execution of preparation (79.09%) denoted some prepared drugs were shared between patients. Dilutions were required to allow the administration of the prescribed doses. The functions of drug dilution are either to reduce the concentration of the active ingredient to improve tissue tolerance to corrosion or to allow dose splitting in the case of drugs with a narrow therapeutic index. Apart from these cases, dilution is a need for dose adjustment due to the lack of pharmaceutical forms adapted to the newborn. Dilution is a source of medication error when it is not controlled.²⁷ An exact calculation is needed to determine the precise volumes of solvent. A total of 421 dose administrations were planned, of which 337 were effective. The non-administration of doses was due to the non-availability of the venous route or the medicines at the indoor pharmacy. The procurement had to be obtained in town pharmacy stores, delaying patient treatments. Time gaps were observed between the scheduled time and the real-time treatment administration.

That situation fluctuates the plasma concentration of the drug. Some authors have reported such drug misadministration.²⁸ Failure to comply with administration hours could be due to late medical visits and time-out of the actions to be taken. The consequences of misadministration are underdosing and overdosing, leading to therapeutic failure or toxicity. Non-compliance with drug delivery rates accounts for 73.3% of administrations, with very rapid administration in 76.9% of cases. Zribi et al, reported 64% of non-compliance with infusion rates in Tunisia.²⁹ Too rapid administration of the drug exposes to the income of hypotension or an increase in the risk of

death from shock. Aseptic procedures were in cause in 100% of cases as reported elsewhere. These shortcomings could be due to insufficient planning or overwork. Indeed, the diet, the change of layers, and the milk preparation are provided by one team for a period. Feeding premature babies was done every 2 hours, and newborns at term every 3 hours most of the time. Also, more than monitoring of drug infusions was required. Gravity infusion did not allow proper regulation of the infusion rate. Disposal of flow controllers, electric syringe pushers, or “smart pumps” with training on appropriate use could reduce infusion flow errors.^{30,31} Furthermore, the poor traceability of nurse acts in inpatient nursing records handicaps the continuity of care by the counterpart teams. Compliance with the prescription, drug preparation, and administration according to good practices is a critique of the quality and safety of patient care.

Pharmaceutical interventions and dispensing

All prescriptions in our study were analysed. Implementing the drug individual nominative dispensing requires the continuous presence of a pharmacist in the neonatology unit. All the shortcomings or non-conformities observed were subject to pharmaceutical interventions during the five-day observational audit. Each medication error was qualified as a need for intervention. The practice of individual nominative dispensing and the presence of pharmacists on the staff improved the quality of care for patients. The clinical impact of our intervention was not scored. In Côte d'Ivoire, Abrogoua et al, reported that 63.63% of pharmaceutical interventions had significant clinical impacts, and 31.81% had a very significant clinical impact on the quality of patient care.³²

The acceptance rates of pharmaceutical interventions by physicians (92.6%) and nurses (93.9%) on prescriptions and administrations denote good cooperation between pharmacists and the medical and nursing staff. A high acceptance rate of interventions reflects the recognition of the pharmacist as a trusted actor to secure and improve patient care.³³ It is worth pharmacists' making their intervention visible by setting up patient pharmaceutical records, the data of which can be used by medical and nursing teams. Achieving therapeutic objectives requires a focus on respecting SOPs and good patient treatment practices. The involvement of all stakeholders, including parents, in the medication process could improve the safety and quality of patient care.³⁴

Several limitations must be considered when interpreting our results. Our study was only conducted in the neonatal unit and for only 5 days. Extrapolation of the results to the whole country must be done with caution. The clinical impact of medication errors on patients were not assessed.

CONCLUSION

Our study evaluated the prescribing, preparation, and administration of drugs to newborns at the CHUP-CDG. It

highlighted areas for improvement in the newborn medication process, such as prescription, preparation, and administration of treatments. Solving the detected medication errors or misuses is possible and accepted by nurses and physicians through pharmaceutical interventions. We have pointed out the need for nurse capacity-building in drug preparation and administration. It is also necessary for pharmacists to set up patient pharmaceutical records to mitigate therapeutic risk and make visible their contribution to improving the quality of care at Charles de Gaulle Pediatric University Hospital.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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