

Evaluation of Gentamicin Use in Pediatric Patients in Chena Primary Hospital Southwest Ethiopia: A Retrospective Cross-Sectional Study

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Received: 19 Jul, 2022 | Accepted: 01 Aug, 2022 | Published: 08 Aug, 2022

Citation: Ejeta F, Mebratu G, Geto G (2022) Evaluation of Gentamicin Use in Pediatric Patients in Chena Primary Hospital Southwest Ethiopia: A Retrospective Cross-Sectional Study. *J Drug Res Dev* 8(2): dx.doi.org/10.16966/2470-1009.172

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Abstract

Introduction: Pharmaceuticals should be used appropriately, safely, and only when necessary. Irrational prescribing, dispensing, and patient usage of drugs can squander up to 50% of drug expenditure. Drug use assessment is a good tool for evaluating the rational use of drugs in health institutions, and it has increased performance. The goal of this study is to evaluate rational use of Gentamicin in Chena's primary hospital.

Methods: The research was carried out by evaluating the medical records of 106 Gentamicin patients using a retrospective systematic review. The study was conducted by reviewing the medication records of 106 patients who received Gentamicin during hospitalization at Chena's primary hospital from June 2020 to June 2021.

Results and conclusions: Most patients were dosed at 5mg/kg/day (67%). The duration of therapy was found to be high, in the range of 4-7 days (45.3%). Gentamicin was mainly used as a sepsis treatment (45.3%). With a frequency of 67.9%, Ampicillin was the most regularly co-administered medicine. Gentamicin was only appropriate in 43 cases (40.6%) for the justification of usage. The majority of inappropriate usage was observed in terms of duration during sepsis treatment, followed by frequency for severe acute malnutrition treatment. The prescriber's adherence to the national Standard Treatment Guideline (STG) was deemed to be insufficient. Prescribers should follow the national standard treatment guidelines to increase rational use and prevent the development of resistance. Short-term training intensification and antimicrobial control systems are two of the hospital's viable alternatives. Gentamicin therapy doesn't meet the current STG of Ethiopia.

Keywords: Drug use evaluation; Gentamicin; Chena hospital; Southwest ethiopia

Introduction

Antimicrobials are among the most commonly prescribed drugs in the worldwide. The development of bacterial resistance to antibiotics has become a major problem of its extensive use [1]. The rational uses of judiciously selected lowest cost drugs in accordance with a valid set of guideline for optimal clinical outcome bring not only success to health care but also it adds to socio-economic development [2].

In more clinical term Rational Drug Use (RDU) incorporates appropriate prescribing correct indication of the right drug for the right patient at the right dose and the right route, appropriate use of drug by patients and proper follow up of patients' adherence to come up with the intended targets of medical intervention [3]. Drug Use Evaluation (DUE) is an ongoing systematic process designed to maintain the appropriateness, safety and effectiveness of a medication to improve patient care. Optimizing medication has the potential to reduce the development of antimicrobial resistance and overall health care cost by providing cost effective treatments. It also corporate qualitative measures and emphasize on out comes including pharmaco-economic assessment [4]. DUE allows substantiating and

documenting the benefit of pharmacy intervention in improving therapeutic and economic profit of managed health care system which gives potential to increase quality of care [5]. It produces information that open ways to provide feedback for prescribers on their performance in implementing the treatment protocol and their compliance with present approved guidelines for use each medication [6]. Careful and well-focused use of antimicrobial drugs together with procedures to avoid the spread of infections may provide a chance of preserving the efficiency of antibiotics.

Aminoglycoside antibiotics are frequently used as empirical antibiotics in critically ill patients against suspected gram-negative sepsis or in combination with others to cover some gram-positive species. They bind to ribosomal subunits within bacteria, preventing protein synthesis, but the exact mechanism of action remains unclear [7]. Gentamicin is a bactericidal antibiotic that works by binding the 30S subunit of the bacterial ribosome, interrupting protein synthesis. Gentamicin is an aminoglycoside antibiotic composed of a mixture of related Gentamicin components and fractions and is used to treat many types of bacterial infections, particularly those caused by

Gram-negative organisms [8]. However, Gentamicin is not used for *Neisseria gonorrhoea*, *Neisseria meningitidis* or *Legionella pneumophila*. Gentamicin is also ototoxic and nephrotoxic, with this toxicity remaining a major problem in clinical use. Like all Aminoglycoside, when Gentamicin is given orally, it is not systemically active. This is because it is not absorbed to any appreciable extent from the small intestine so, Gentamicin is administered intravenously, intramuscularly or topically to treat infections [9]. Evaluation of Gentamicin use is therefore critical to controlling the emergence of resistant strains as well as cutting down of unnecessary expenditures and also ensuring that patients derive maximum benefit from its use. Worldwide it is estimated that over 50% of all medicines are prescribed, dispensed or sold inappropriately [10]. However, inappropriate use of antimicrobial agents has been found to be common in various parts of the world, but there have been few studies in developing countries [11]. Antimicrobial agents are the most commonly used and misused of all the drugs [12].

The majority of hospitalized patients receive antibiotics for therapy or prophylaxis during their inpatient stay. It has been estimated that at least 50% of patients receive antibiotics without clear indication [13]. Compared to adult medicine, drug use in pediatrics is not extensively researched and the range of licensed drugs in appropriate dosage form is limited. Infants and children are among the most vulnerable population groups to contract illnesses. Because of this the use of antimicrobial agents, especially antibiotics has become a routine practice for pediatric illness [14].

Aminoglycoside antibiotics are frequently misused as empirical antibiotics in pediatric patients as mono therapy or in combination with other. Inappropriate and indiscriminate use of Gentamicin can potentially lead to a number of problems. These problems include rapid emergence of resistance, increased number adverse drug events, treatment failures, occurrence of preventable morbidity and mortality and increased drug-related costs [8].

The tool to reduce these problems is education, promotion of rational prescribing methods and drug use evaluations.

Irrational drug use in pediatrics could be due to lack of appropriate information on drugs, or treatment protocols or therapeutic guidelines for common clinical conditions. Furthermore, lack or shortage of drugs also predisposes to misuse of drugs. So, drug use evaluation for Gentamicin is important to minimize over and inappropriate use of antibiotics to promote rational drug use. Limited studies have been conducted on drug use evaluation in pediatric patients in Ethiopia, but as far as our knowledge concerned no research has been done on the Gentamicin use evaluation in Chena primary hospital. Thus, the aim of the present study was to evaluate the utilization pattern of Gentamicin in Chena primary hospital. Gentamicin was the aminoglycoside most widely used at this time, and the incidence of Gentamicin-resistant bacteria was 14%, while only 2.4% were resistant to Amikacin. For a period of 15 months Gentamicin use was restricted, and Amikacin was used almost exclusively [15]. The outcome of the study will provide useful information regarding Gentamicin use and the level of appropriateness among pediatric patients in the hospital. Moreover, the study will also generate tangible data about Gentamicin consumption in pediatrics ward for appropriate intervention and planning thereafter. It also will serve as useful information for further assessment of drug related problems in this group of patients. The designed study result will benefit pediatric patients, create awareness of health teams about the appropriate use of this drug and wake up the hospital to take measurements and apply policies to prevent drugs from misusing which result in ineffective therapy and drug resistance

besides economical wastage. This research is promised to fill the gap regarding the appropriateness of Gentamicin use in Chena primary hospital and gives clues all about the country.

Methods

Study area and period

Study area: The study was conducted at Chena primary hospital which was established in 2005. It is found in Chena town, Kaffa Zone, Southwest Ethiopia which is located 541 km far from Addis Ababa, the capital city of Ethiopia and it is the only hospital in Chena district. The hospital has been giving health services for the total population of 30,891 people in its catchment area with different four major departments including medical, pediatrics, surgical, and obstetrics, and gynecology. It also provides outpatient service, ophthalmology, emergency, Antiretroviral Therapy (ART) clinic, and ANC clinic. There were a total of 723 pregnant women who had attended ANC in 2020/21 and on average around 30-40 followers have been attended ANC clinic every day at Wacha primary hospital.

Study design: A hospital based retrospective cross-sectional study was conducted to evaluate Gentamicin use in Chena primary hospital from June 2020 to June 2021.

Population

Source population: The medical records of pediatric patients in Chena primary hospital June 2020 to June 2021.

Study population: The medication records of pediatric patients who are in pediatric age group and received Gentamicin during hospitalization.

Inclusion and exclusion criteria

Inclusion criteria: All medication records of hospitalized pediatrics patients who are less than 18 years old and took Gentamicin from June 2020 to June 2021.

Exclusion criteria: Patient Medical Records (PMR) which had incomplete patient data (age, sex, drugs prescribed).

Sample size and sampling technique

The study included all pediatrics patients' medical charts containing Gentamicin at Chena primary hospital from June 2020 to June 2021 that only fulfill the inclusion criteria (so, 106 patient medical records reviewed were taken). Convenient sampling technique was used as per data collection period and inclusion criteria, a type of non-probability sampling in which people are sampled simply because they are "convenient" sources of data for researchers.

Study variables

Independent variables: Age, Sex, Diagnosis, Weight of children.

Dependent variables: Indications, Dosage regimen (dose, frequency and duration) and clinically significant potential drug-drug interaction.

Data collection techniques and instrument

Data collection from pediatric patient's medical records containing Gentamicin by using structured format. The format contains patient information (sex, age, weight, and card number), clinical information and pattern of Gentamicin use. The data was collected by trained nurses. Data collectors were closely assisted and supervised by principal investigators. The card numbers of the patients who took Gentamicin were found from records of total card number log book of pediatric

patients who were admitted in the last year. Data collection format was adopted from WHO drug use evaluation. A pretest was carried out on randomly selected 7 medical records at Mizan-Tepi university Teaching hospital to make sure that whether the study was feasible in this way and to see if the data collection format is appropriate and consistent with the patient medical record when gathering the intended information. After finalizing the data collection tool and obtaining permission from the hospital chief executive officer to conduct the research; data was collected by using the data collection format.

Data quality assurance, analysis and interpretation

The collected data were coded, cleared and checked for completeness and entered into Epi data version 4.0.2 and then exported to SPSS version 21.0 for analysis. A descriptive analysis was performed on the demographic and clinical data, including sex, age, diagnosis, variables for prescribing Gentamicin, such as dose, duration of treatment. Frequencies and percentages were used to describe variable. The appropriateness of Gentamicin was evaluated using the set criteria for drug use evaluation from the national STG of Ethiopia for general hospitals, and pediatrics guidelines for the management of common illnesses in children. Potential drug interaction with Gentamicin and other co-prescribed drugs was detected by micromedxsolutions.com and reported as frequency and percentages by SPSS of aforementioned version.

Ethical Clearance

The study was conducted after ethical clearance was received from research and ethics review committee of pharmacy department of Mizan-Tepi University. Moreover, permission was sought from medical records the hospital. All the responsible officials were informed about purpose and aim of the study and permission was obtained. The confidentiality of data collected was maintained. Name and address of patient and prescriber was omitted from the data collection format.

Operational Definition

- **Appropriate use:** right usage of medications in terms of dose, frequency, duration, and indication in lining with the Ethiopian Standard Treatment Guideline (STG) for general hospitals.
- **Appropriate duration:** recommended length of therapy based on Ethiopian Standard Treatment Guideline (STG) for General Hospital.
- **Appropriate frequency:** frequency of medication per day which is in line with the Ethiopian STG for general hospitals.
- **Completeness;** full of data recorded on the medical chart of the patient.
- **Inappropriate use:** use of medications, which deviate from the Ethiopian STG for general hospitals in terms: dose, frequency, duration, route of administration or indication.
- **In appropriate indication:** drug indications which deviate from the Ethiopian STG for general hospitals from the specific diagnosis.
- **Incompleteness:** missed information from the medical records which is required for the study.
- **Medical record:** can be defined as a record that contains patient information, medical condition, drug prescribed, laboratory values, nursing notes.
- **Pediatric age group:** age group less than 18.

Results

A total of 106 patient's medical records were reviewed and analyzed for the use of Gentamicin in Chena primary hospital. Among 106 patients, 55 (51.9%) were males and 51 (48.1%) were females. Majority of patients 86 (81.1%) were in the age group less than 5 years of age as shown in table 1.

The most common cause of hospitalization in this study for which Gentamicin was prescribed include sepsis and sever acute malnutrition each accounting for 47 (44.3%) and 33 (31%) respectively (Table 2) followed by severe pneumonia (11.3%) and meningitis (6.6%).

Evaluation of appropriateness of Gentamicin use

Gentamicin use was evaluated as per the Ethiopian standard treatment guideline, which states Gentamicin 3-5mg/kg IV QD in divided doses for 10-14 days for pediatrics [16]. Among the 106 evaluated prescriptions 43 (40.6%) were found to be appropriate while the rest 63 (59.4%) were inappropriate as depicted in figure 1.

This study showed that most common causes of inappropriate Gentamicin use include inappropriate duration of treatment, dose and frequency of therapy. In 106 prescriptions 100 (94.3%) indications were appropriate and 6 (5.7%) were inappropriate as described in figure 1.

The appropriate Gentamicin dose administration was 78 (73.6%) while 28 (26.4%) was inappropriate as it is evident from table 3.

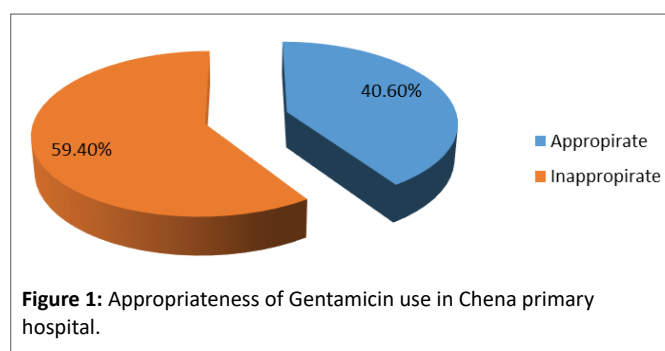
Table 1: Age and sex distribution of patient in Chena primary hospital.

Age group	Sex	
	Male	Female
	Frequency/percentage	Frequency/percentage
<5	47/86 (54.65)	39/86 (45.35)
6-16	5/13 (38.46)	8/13 (61.54)
>16-18	3/7 (42.86)	4/7 (57.14)
Total	55/106 (51.9)	51/106 (48.1)

Table 2: Admission diagnosis distribution of pediatric patients in Chena primary hospital.

Diagnosis	Frequency/percentage
Sepsis	47/106 (44.3)
SAM	33/106 (31.1)
Sever pneumonia	12/106 (11.3)
Meningitis	7/106 (6.6)
Bacterial conjunctivitis	7/106 (6.6)
Total	106 (100.0)

SAM: Sever Acute Malnutrition



On the other hand, the daily Gentamicin dose distribution of 5mg/kg comprises of 67% of the study population followed by 3mg/kg (8.5%) and 7.5mg/kg (5.7%) as shown in table 4.

Frequency of administration was appropriate in 99 (93.4%) of the population and was inappropriate in 7 (6.6%) as shown in table 3.

Out of 106 Gentamicin prescriptions, the appropriate duration of administration was 50 (47.2%) while 56 (52.8%) was inappropriate as shown in tables 3, and 5.

Combination of therapy is common pediatric population. Our findings also showed that in table 6 below Gentamicin was commonly co-administered with Ampicillin (67.9%); and Cloxacillin plus Ampicillin (3.8%).

Discussion

This study showed that Gentamicin was utilized inappropriately. This is in line with retrospective study done on pattern of drug prescription in pediatrics ward of university of Gondar specialized hospital, Gondar Ethiopia which showed that Gentamicin was the highly prescribed individual drug (10.8%). However, it was prescribed inappropriately in most cases [17].

Appropriateness on indication of Gentamicin

In our study more than half the Gentamicin prescription was inappropriate i.e., prescribed for wrong indication. This is similar to a retrospective drug use evaluation that has conducted on Gentamicin use in Ambo Hospital (AH), west Shewa Ethiopia by Gelaw BK, et al., showed that from 400 patients 30 (7.5%) was prescribed

Table 3: Evaluation of the appropriateness of Gentamicin dose, frequency of administration and duration of Gentamicin therapy appropriateness in Chena primary hospital.

Evaluation of Gentamicin Therapy		
Appropriateness of Gentamicin dose	Status	Frequency/percentage
Appropriateness of Gentamicin dose	Appropriate	78/106 (73.6)
	Inappropriate	28/106 (26.4)
Appropriateness of Gentamicin frequency of administration	Appropriate	99/106 (93.4)
	In appropriate	7/106 (6.6)
Appropriateness of duration of Gentamicin therapy	Appropriate	50/106 (47.2)
	Inappropriate	56/106 (52.8)

Table 4: Gentamicin daily dosing distribution in Chena primary hospital.

Daily dosage distribution	Frequency/percentage
3mg/kg	9/106 (8.5)
4mg/kg	5/106 (4.7)
5mg/kg	71/106 (67)
6mg/kg	5/106 (4.7)
7.5mg/kg	6/106 (5.7)
2 drop	5/106 (4.7)
Others	5/106 (4.7)
Total	106 (100)

Others: 2mg/kg, 8mg/kg, 1 drop

Table 5: Evaluation of duration of Gentamicin therapy in Chena primary hospital.

Duration (days)	Frequency/percentage
1-3	32/106 (30.2)
4-7	48/106 (45.3)
8-14	21/106 (19.8)
>14	5/106 (4.7)
Total	106 (100)

Table 6: Co-administered drugs with Gentamicin in Chena primary hospital.

Co-administered drugs	Frequency/percentage
Ampicillin	72/106 (67.9)
Cloxacillin+Ampicillin	4/106 (3.8)
Folic Acid+Ampicillin+Albendazole	2/106 (1.9)
Ampicillin+Folic Acid	1/106 (0.9)
No co-administered medication	8/106 (7.5)
Phenobarbital+Ampicillin	3/106 (2.8)
Ampicillin+Paracetamol	5/106 (4.7)
Vitamin A+Ampicillin	5/106 (4.7)
Ampicillin+Ceftriaxone	1/106 (0.9)
Ampicillin+Salbutamol Puff	2/106 (1.9)
Ampicillin+Erytromycin+ Tetracycline	1/106 (0.9)
Metronidazol+Ampicillin	1/106 (0.9)
Ampicillin+Zinc+Folic Acid+Vitamin A	1/106 (0.9)
Total	106 (100)

inappropriately on indication and 370 (92.5%) was prescribed appropriately on indication [18]. But this study contradicts with retrospective drug use evaluation of Gentamicin study conducted in pediatric ward in India which showed that from 100 patients 29 (29%) was prescribed inappropriately on indication and 71 (71%) was prescribed appropriately on indication [19]. Compared to another retrospective drug use evaluation that has conducted on Gentamicin use in Goba Hospital, Bale zone, Oromia Region, Ethiopia by Mama M, et al., which showed that from 62 patients 62 (100%) was prescribed appropriately on indication [20] the indication of Gentamicin for this study is low. This might be due to difference in study setting and health care professional level of experience and difference in sample size.

Appropriateness on dosage regimen

Dose, frequency and duration of treatment of Gentamicin are essential components of appropriate dosage regimen. Our study showed that Gentamicin was utilized for inappropriate duration of therapy. This study is in line with a retrospective drug use evaluation of Gentamicin conducted in pediatric ward of the in India showed that from 100 patients, 9 (9%) patients was prescribed inappropriate duration [19] and; a retrospective drug use evaluation that has conducted on Gentamicin by Mama M, et al. which showed that from 62 patients 3 (4.8%) patients was prescribed inappropriate dose and 3 (4.8%) patients was prescribed inappropriate duration [20,21]. But contradicts with a study conducted on drug use evaluation on Gentamicin use by Gelaw BK, et al., which showed that from 400 patients 40 (10%) patients was prescribed inappropriate dose, 47 (11.75%) patients was prescribed inappropriate frequency and 94 (23.5%) patients was prescribed inappropriate duration (23%). This might due to attributed to difference in sample size [22].

Gentamicin use against indications (contraindications to Gentamicin use)

In our study utilization against indication is high. This is in line with the study conducted by Mama M, et al., which showed that from 62 patients (11.03%) patients were contraindicated to Gentamicin [20].

Potential drug interactions to Gentamicin

In this study the potential drug interaction with Gentamicin is higher in Ampicillin followed by Cloxacillin plus Ampicillin as shown in table 7. This study is in line study conducted by Mama M, et al. which showed that from 62 patients (87%) Gentamicin contained one or more potentially interaction drug [20]. But contradicts with the study conducted on Gentamicin use in Ambo Hospital (AH), by Gelaw BK, et al., which showed that from 400 patient's drug-drug interaction not occurred at all [18,23]. This might be due difference in sample size and experience of healthcare professionals.

Conclusion

The optimal prescribing practice is manipulated by evaluating the Gentamicin use in terms of indication, duration of therapy, and frequency of administration. According to WHO guidelines, prescribers in Chena primary hospital were not following Ethiopian national STG. The majority of inadequacies were found in the duration of therapy, indication, daily dosing, frequency, and the high possible drug interactions. The current study's findings revealed a high rate of inappropriate Gentamicin use, paving the way for the emergence of bacterial strains resistant to the available antimicrobial drug, resulting in increased therapy costs and treatment failure.

Recommendations

The following recommendations were made to improve the proper use of Gentamicin in Chena primary hospital:

- In a few cases, an improper dose and frequency must be provided, so the prescriber in Chena primary hospital should take close care when prescribing Gentamicin.
- Easy access of the national STG to all health professionals setting continuous drug use evaluation programs.
- A drug therapeutic committee (DTC) should be established in the hospital so that proper prescriptions can be made.

Table 7: Potential drug interactions with Gentamicin.

Potential Drug Interaction	Frequency/percentage
Ampicillin+Gentamicin	72/106 (67.9)
Cloxacillin+Ampicillin+Gentamicin	4/106 (3.8)
Folic Acid+Ampicillin+Albendazole+Gentamicin	2/106 (1.9)
Ampicillin+Folic Acid+Gentamicin	1/106 (0.9)
Gentamicin	8/106 (7.5)
Phenobarbital+Ampicillin+Gentamicin	3/106 (2.8)
Ampicillin+Paracetamol+Gentamicin	5/106 (4.7)
Vitamin A+Ampicillin+Gentamicin	5/106 (4.7)
Ampicillin+Ceftriaxone+Gentamicin	1/106 (0.9)
Ampicillin+Salbutamol Puff+Gentamicin	2/106 (1.9)
Ampicillin+Erythromycin+Tetracycline+Gentamicin	1/106 (0.9)
Metronidazole+Ampicillin+Gentamicin	1/106 (0.9)
Ampicillin+Zinc+Folic Acid+Vitamin A+Gentamicin	1/106 (0.9)
Total	106

Limitation of Study

This is a retrospective chart review study and a single-centered study; the result may not also be generalized to all hospitals. Thus, we suggest further prospective and multi-centered studies to be done.

- An inability to generalize the results of the survey to the population as a whole.
- The possibility of under- or over-representation of the population.
- Biased results, due to the reasons why some people choose to take part and some do not.

Acknowledgment

We would like to extend our gratitude to Mizan-Tepi University for allowing us to conduct this study. We are also extended our gratitude to all individuals who involved in data collection.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Competing Interests

The authors declare that they have no competing interests.

Funding Source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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