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Drug Utilization Evaluation of Piperacillin and Tazobactum at a Tertiary Care Center in Hyderabad, India.

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ABSTRACT

Drug use evaluation is an ongoing, systematic, criteria-based program of medicine evaluations that will help ensure appropriate medicine use. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize pharmaceutical therapy. A DUE can be structured so that it will assess the actual process of administering or dispensing a medicine (i.e., appropriate indications, dose, and medicine interactions) or assess the outcomes. Empirical therapy forms the basis of treatment in India mostly and it is the responsibility of DTC (Drugs and therapeutics committee) to organize a DUE study and adopt suitable protocol for controlling irrational drug use. In our study we have developed a data collection form based upon WHO guidelines for conducting a DUE study on piperacillin and tazobactum use evaluation. To assess the usage of piperacillin and tazobactum at a tertiary care center Hyderabad compared to the indications for piperacillin and tazobactum use and standard treatment guidelines and provide recommendations to improve rational use of piperacillin and tazobactum at these hospitals and reduce the development of further antibiotic resistance, prevent ADRs associated with the drug, and to reduce the economic burden on the patient with inappropriate use. A retrospective evaluation of piperacillin and tazobactum usage patterns was carried out at a tertiary care hospital for the period of 3 months corresponding to the dates to 1-1-2018 to 31-3-2018. For conducting the evaluation process we had followed the standard guide lines formulated by WHO. The gender distributions of casesheets were male- 42, female- 23. Indication wise the distribution of case sheets were mostly treated for surgical prophylaxis, prophylaxis and infections. Out of 65 cases 65 (99%) has met the established criteria, they are as per STGs. Illness most frequently treated with piperacillin and tazobactum is ckd with acute deterioration (29.23%). The minimum number of days of treatment was 3 day and the maximum number of days of treatment was 14days. All patient folders evaluated with regards to HD, SEPTIC SHOCK, PNEMOMEDIATINM etc were found to meet the standard criteria appropriate for piperacillin and tazobactum use with respect to dose, and dose frequency. However, in the case of dose duration the evaluation was found to be largely inappropriate for all the justified indications. In addition, 33.84% of piperacillin and tazobactum use for unjustified indications was noted. This means that piperacillin and tazobactum has been deviated from standard treatment guidelines hence it facilitates the development of resistant strains to piperacillin and tazobactum and of no use in the near future, and it also effect the patient economically.

Keywords: DUE, piperacillin and tazobactum, WHO, tertiary care center, Hyderabad.

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INTRODUCTION

Drug use evaluation is an ongoing, systematic, criteria-based program of medicine evaluations that will help ensure appropriate medicine use. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize pharmaceutical therapy. A DUE can be structured so that it will assess the actual process of administering or dispensing a medicine (i.e., appropriate indications, dose, medicine interactions) or assess the outcomes. The following eight steps outline the basic information necessary to start and maintain a DUE Program.

Establish Responsibility:

Responsibility falls to the DTC or a subcommittee of the DTC that functions only to monitor DUEs In the hospital or clinic. The DTC should undertake this responsibility with considerable interest, because this process can solve many medicine use problems, as has proven to be the Case in many countries where this quality assurance function has been

fully utilized. The DTC or a subcommittee must establish procedures that will govern the committee in its activities concerning medicine use review and evaluation. As part of the responsibility of the DUE function, the DTC must establish a plan, outlining which medicines will be a part of the DUE process. This plan needs to be updated and evaluated each year.

Develop Scope of Activities

The DTC should assess and identify medicine use problems and using this information to develop a scope of activity for the DUE program. The scope can be extensive, or it can focus on a single aspect of pharmaceutical therapy. Methods to identify medicine use problems include and ABC or vital, essential, nonessential (VEN) analysis, defined daily dose analysis, ADR reports, medication error reports, antibiotic sensitivity results, procurement studies, hospital and primary care clinic indicator studies, patient complaints or feedback, and staff feedback. These screening mechanisms serve to provide the DTC with information concerning medicine use that would need further evaluation in a DUE.

Establish Criteria, Define and Establish Thresholds

Criteria are statements that define correct medicine use. Establishing criteria is the single most important procedure in a DUE. Criteria for the use of any medicine should be established by the DTC using relevant evidence based literature sources and recognized international and local experts. The criteria for any DUE should reflect what is in the country's STGs (assuming that they have been developed correctly) and any medicine-use protocols that exist. Credibility of the DUE relies on criteria that are based on evidence-based medicine. Criteria must be developed with and accepted by the medical staff for the process to be credible. Criteria should be developed for three to five of the most important indicators for each aspect of medicine use. Reviewing larger numbers of indicators will make for a more difficult DUE process and may significantly impair the outcomes of the review. This is not to say that more extensive use of indicators should not be reviewed, only that results are more easily obtained and possibly more meaningful when the scope is narrowed to include only the most important aspects of care. After developing criteria, the DTC must establish a threshold or standard (benchmark) against which the criteria will be judged. A threshold refers to the percentage of charts or records that will meet or exceed the established criteria for the medicine. Ideally, this threshold will be 100 percent, but realistically, a smaller percentage will be more appropriate to account for exceptions to routine medicine prescribing. Therefore, a threshold of 90 to 95 percent is typically used for many criteria, but each instance must be carefully analyzed before reaching a conclusion.

Collect Data and Organize Results.

DUEs can be accomplished as prospective evaluations, or they can be performed retrospectively. A prospective analysis involves the collection of data as the medicine is being prepared or dispensed to the patient. Retrospective analysis is done using chart reviews or other data sources to review medicine use according to indicators and criteria prepared in advance. The advantage of a prospective review is that the pharmacist (or other reviewer) can intervene at the time the medicine is dispensed to prevent errors in, for example, dosage, indications, or interactions. Retrospective evaluation, which may involve more of the reviewer's time or require access to medical records, is best accomplished when the reviewer has time away from the patient care areas and distractions.

Analyze Data

Data are collected, tabulated, and analyzed to see if criteria and thresholds are met. The following important steps should be completed when analyzing data—

- Tabulate results for each indicator
- Analyze results to see if the criteria are met and the thresholds are not exceeded
- Determine why thresholds are not met
- Analyze data quarterly or more frequently

If a threshold is not met, it may indicate a medicine use problem that requires the attention of the DTC.

Develop Recommendations and Action Plan

After completing the data analysis, information is presented to the DTC and a decision is made as to the appropriateness of the information in the DUE. The DTC also must decide on whether to continue, discontinue, or expand the functions of the DUE in question. All medicines that do not meet the thresholds must be evaluated carefully and plans must be made to improve the use of the medicine relative to the criteria.

Recommendations should be prepared for the DTC to address the following—

- Inappropriate medicine use
- Unacceptable patient outcomes
- Methods to resolve any medicine use problem

Recommendations should include specific steps to correct any medicine use problem that is evident from performing the DUE. For example, if a specific medicine is being prescribed at a high dose, then the recommendations need to reflect this and how the DTC might improve the dosing of this medicine. Interventions to improve medicine use might include—

- Education, including letters to practitioners, in-service education, workshops, newsletters, and face to-face discussions
- Implementation of medicine order forms
- Prescribing restrictions
- Formulary manual changes
- Change (or better enforcement) of the STGs.

Conduct DUE Follow-up

Follow-up in every DUE is critical to ensure resolution of any unresolved medicine use problems. The DUE may have identified new problems that need to be resolved within the health care system. If the problems are not resolved, then the DUE will have little usefulness to the health care system. As a part of a follow-up plan, the DTC must assess the need to continue, modify, or stop the DUE activity depending on the results of each specific medicine review. A DUE should be an ongoing process in which medicine related problems are regularly addressed. Medicine review should be considered a long-term program, one that is continuously updated and revised to reflect current situations and needs within the health care institution. All programs within the DTC should be evaluated yearly. This complete evaluation is necessary to

look comprehensively at the entire program and analyze its merits and its utility in improving medicine use. Programs that do not have a significant impact on medicine use should be redesigned so that they can provide measurable improvements. Without improvements in medicine use and patient outcomes, the time spent on DUE will be of no value. It must be stressed that indicators and criteria for a DUE can be highly individualized depending on the specific needs of the health care facility.[1,2]

Piperacillin and tazobactam for injection:

Piperacillin sodium exerts bactericidal activity by inhibiting septum formation and cell wall synthesis of susceptible bacteria. In vitro, piperacillin is active against a variety of gram-positive and gram-negative aerobic and anaerobic bacteria. Tazobactam sodium has little clinically relevant in vitro activity against bacteria due to its reduced affinity to penicillin-binding proteins. It is, however, a β-lactamase inhibitor of the Richmond-Sykes class III (Bush class 2b & 2b') penicillinases and cephalosporinases. It varies in its ability to inhibit class II and IV (2a & 4) penicillinases. Tazobactam does not induce chromosomally-mediated β-lactamases at tazobactam concentrations achieved with the recommended dosage regimen.

Piperacillin and Tazobactam for injection, USP) is indicated for the treatment of patients with moderate to severe infections caused by piperacillin-resistant, piperacillin/tazobactamsusceptible, β-lactamase producing strains of the designated microorganisms in the specified conditions- Appendicitis (complicated by rupture or abscess) and peritonitis caused by piperacillin-resistant, β-lactamase producing strains of Escherichia coli or the following members of the Bacteroides fragilis group: B. fragilis, B. ovatus, B. thetaiotaomicron, or B. vulgatus. The individual members of this group were studied in less than 10 cases.

Uncomplicated and complicated skin and skin structure infections, including cellulitis, cutaneous abscesses, and ischemic/diabetic foot infections caused by piperacillin-resistant, β-lactamase producing strains of Staphylococcus aureus. Postpartum endometritis or pelvic inflammatory disease caused by piperacillin-resistant, βlactamase producing strains of Escherichia coli. Community-acquired pneumonia (moderate severity only) caused by piperacillin-resistant, βlactamase producing strains of Haemophilus influenzae. Nosocomial pneumonia (moderate to severe) caused by piperacillin-resistant, β-lactamase producing strains of Staphylococcus aureus and by piperacillin/tazobactam-susceptible Acinetobacter baumanii, Haemophilus influenzae, Klebsiella pneumoniae, and Pseudomonas aeruginosa (Nosocomial pneumonia caused by P. aeruginosa should be treated in combination with an aminoglycoside). Piperacillin and Tazobactam for injection is indicated only for the specified conditions listed above. Infections caused by piperacillin-susceptible organisms, for which piperacillin has been shown to be effective, are also amenable to Piperacillin and Tazobactum treatment due to its piperacillin content. The tazobactam component of this combination product does not decrease the activity of the piperacillin component against piperacillin-susceptible organisms. Therefore, the treatment of mixed infections caused by piperacillin-susceptible organisms and piperacillin resistant, β-lactamase producing organisms susceptible to piperacillin and Tazobactun should not require the addition of another antibiotic. Piperacillin and Tazobactum is useful as presumptive therapy in the indicated conditions prior to the identification of causative organisms because of its broad spectrum of bactericidal activity against gram-positive and gram-negative aerobic and anaerobic organisms. Appropriate cultures should usually be performed before initiating antimicrobial treatment in order to isolate and identify the organisms causing infection and to determine their susceptibility to Piperacillin and Tazobactum. Antimicrobial therapy should be adjusted, if appropriate, once the results of culture(s) and antimicrobial susceptibility testing are known. To reduce the development of drug-resistant bacteria and maintain the effectiveness of piperacillin and tazobactam injection and other antibacterial drugs, piperacillin and tazobactam should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.[3]

Aim:

To assess the usage of piperacillin and tazobactum at a tertiary care center in Hyderabad compared to the indications for piperacillin and tazobactum use and standard treatment guidelines and provide recommendations to improve rational use of piperacillin and tazobactum at these hospitals and reduce the development of further antibiotic resistance, prevent ADRs associated with the drug, and to reduce the economic burden on the patient with inappropriate use.

Objective:

- To analyse the pattern of piperacillin and tazobactum use among patient categories identified by age.
- To identify the illnesses most frequently treated with piperacillin and tazobactum.
- To determine whether piperacillin and tazobactum was appropriately prescribed in respect of dose, dose frequency, and dose duration.
- To identify areas in which further information and education was needed by health care provider.
- To evaluate reason for stopping (discontinue) the drug is based on guide line or not.
- To assess whether the indication of piperacillin and tazobactum is on par with standard guidelines or not.
- To assess the frequency of ADRs associated with the drug use.
- To assess the potential and actual Drug-Drug interactions associated with piperacillin and tazobactum.

MATERIALS AND METHODS

Study Design: Retrospective Drug Utilization Evaluation Study.

Study Site: A tertiary Care Center at Hyderabad, India.

Study Duration: 3 months.

Source of Data: A Data-collection form was developed based on WHO Guidelines.

Sample Size: 65.

Study Procedure: Since it is a retrospective study, we have collected all the case records from the medical record department from 1-01-2018 to 31-3-2018 that contained

piperacillin and tazobactum in the prescription. A total of 65 case records were obtained containing piperacillin and tazobactum as a drug in the prescription. During the process of evaluation, the prescriptions were analyzed for correct indication, correct dose, frequency, ADRs, Drug-Drug interactions, and contra-indications. The criterion established was adopted from standard treatment guidelines as formulated by FDA. The Threshold was developed by taking into consideration, the prescribing habits (KAP) of the doctors at these centers, the indicators are assigned with a threshold of 90-100%.

Statistical analysis: Descriptive statistical analysis has been carried out in the present study where ever necessary.

RESULTS

A total of 65 case sheets were obtained that contained piperacillin and tazobactum as one of the drug in the treatment plan during the course of their stay at hospital. The 65number of cases were obtained from the following dates: 1-1-18 to 31-3-18. Month wise the number of case sheets that contained piperacillin and tazobactum are as follows:

months	nephrology	gynecology	pediatrics	gastroenterology	pulmonology	total
Jan	24	2	3	3	1	33
feb	13	2	2	1	2	20
march	8	1	2	1	0	12

Percentage of Piperacillin and Tazobactum usage in each department:

Department:

Nephrology -45
Paediatrics-7
Gastroenterology-5
Gynecology-5
Pulmonology -3

Total overall cases reviewed are 65 case sheets.

Age wise the number of case sheets that contain piperacillin and tazobactum are as follows:

AGE GROUP	No. OF CASES
0-10	4
11-20	4
21-30	7
31-40	14
41-50	8
51-60	21
61-70	5
71-80	0
81-90	2
91-100	0

Gender wise the number of case sheets that contain piperacillin and tazobactum are as follows:

Males = 42

Female = 23

Indication wise number of case sheets that contain piperacillin and tazobactum areas follows:

Nephrology indications:

Hemodialysis – 12

PCN -1

Obstructive uropathy – 3

Ckd – acute deterioration – 19

AKI – 10

Pediatrics:

Blunt injury with pneunomediastinum – 1

Endotracheal tube – 1

Preoperative prophylaxis, of biliary tree surgery – 1

Central venous catheter with fever – recent abdominal surgery -1

Tracheitis -1

Nasocomial pneumonia -1

Post operative purulent wounds -1

Gynecology:

Pelvic peritonitis -1

Bartollins abscess -1

Abdominal hysterectomy -1

UTI -1

Acute salpingitis -1

Gastroenterology:

Foleys catheter -1

EVL -1

Biliary Stent Removed, Hilar Stricture -1

Post adjunct chemotherapy -1

Acute cholangitis -1

Pulmonology:

Rt – synpneumonic effusion, CAP, kochs -2

Pulmonary hypertension -1

Age v/s duration of piperacillin and tazobactum therapy is as follows:

Age	Min(days)	Max(days)
0-10	1	7
11-20	1	19
21-30	3	14
31-40	1	19
41-50	3	19
51-60	1	15
61-70	3	18
71-80	0	0
81-90	4	5
91-100	0	0

Dose per Day:

The minimum dose used per day is 1.5 g and maximum dose used per day is 5 g.

DISCUSSION

Piperacillin/tazobactam, sold under the brand names piptaz among others, is a combination medication containing the antibiotic piperacillin and the β-lactamase inhibitor tazobactam. The combination has activity against many Gram-positive and Gram-negative bacteria including Pseudomonas aeruginosa.The development of resistance by microorganisms is of global concern. This is because microorganisms that were susceptible to some anti-infective agents have now become resistant. Unfortunately, irrational prescribing is a global problem. Studies on medicine prescribing in India have concluded that much of it is irrational. Making a prescribing decision is vital in the prevention of morbidity and mortality. The physician's prescribing decision is the result of input from patients, commercial sources, professional colleagues, academic literature, and government regulations. Ineffective use of these sources of information can result in a wide variety of prescribing errors. Medicine utilization review is the most common and structured approach used to examine patterns of medicine use and to determine levels of appropriateness in prescribing. Medicine usage reviews are essential to establish the extent of rational and irrational prescribing and to deliver better healthcare services. Antimicrobials, like any other medicines, may be used inappropriately. A prescriber may choose an inappropriate type of antimicrobial, taking into account the clinical condition, resistance patterns and cost. Continuing antimicrobial misuse leads not only to poor patient outcome, unnecessary adverse reactions and wasted resources, but also to emerging resistance of bacteria to antimicrobials. Antimicrobials can also be very expensive, and in most facilities, they constitute a major portion of the drug budget. The phenomenon of resistance is seen not only in bacteria and mycobacterium (multidrug resistant TB, for example), but also in protozoal infections (resistance to chloroquine as an antimalarial) and viral infections (HIV and antiretroviral).This study provides the data on the use of piperacillin and tazobacum at a tertiary care centre in hyderabad. The considered parameters are age, gender, indication, dose, frequency, duration of therapy, contraindications and drug interacting with piperacillin and tazobactum.

1. Drug utilization pattern according to gender:

A total of 65 cases of piperacillin and tazobactum use were identified between the period from 1/1/18 - 31/3/18 patient. The distribution of cases on gender basis is males (35.38%) and females (64.61%).

2. Drug utilization pattern according to age:

The age range was between 5yrs to 85yrs. The usage pattern of piperacillin and tazobactum among various age groups are as follows: of 0-10 (6.15%), 11-20 (6.15%), 21-30yrs (10.76%) and 31-40 (21.53%), 41-50 (12.30%), 51-60 (32.30%), 61-70 (7.69%), 71-80 (0%), 81-90 (3.07%) and 91-100 (0%). As per STGs, the percentage of piperacillin and tazobactum used among the age group 0-10 years hasn't met the established criteria, and the rest met the criteria.

3. Drug utilization pattern according to indication:

In our study, the percentage of piperacillin and tazobactum indicated in the conditions are:-

Nephrology indications:

Hemodialysis – 12(18.46%)

- PCN -1(1.53%)
- Obstructive uropathy – 3(4.61%)
- Ckd – acute deterioration – 19(29.23%)
- AKI – 10(15.38%)

Pediatrics:

- Blunt injury with pneunomediastinum – 1(1.53%)
- Endotracheal tube – 1(1.53%)
- Preoperative prophylaxis, of biliary tree surgery – 1(1.53%)
- Centralvenous catheter with fever – recent abdominal surgery -1(1.53%)
- Tracheitis -1(1.53%)
- Nasocomial pneumonia -1(1.53%)
- Post operative purulent wounds -1(1.53%)

Gynecology:

- Pelvic peritonitis -1(1.53%)
- Bartollins abscess -1(1.53%)
- Abdominal hysterectomy -1(1.53%)
- UTI -1(1.53%)
- Acute salpingitis -1(1.53%)

Gastroenterology:

- Foleys catheter -1(1.53%)
- EVL -1(1.53%)
- Biliary Stent Removed, Hilar Stricture -1(1.53%)
- Post adjunct chemotherapy -1(1.53%)
- Acute cholangitis -1(1.53%)

Pulmonology:

- RT – synpneumonic effusion, CAP, kochs -2(1.53%)
- Pulmonary hypertension -1(1.53%)

Out of 65 cases 65 (99%) has met the established criteria, they are as per STGs. Illness most frequently treated with piperacillin and tazobactum is ckd with acute deterioration (29.23%) **Drug utilization pattern according to dose, ROA, Frequency, and the potential for interaction Drug utilization pattern according to dose, ROA, Frequency, and the potential for interaction** In this research, the criteria of appropriateness of piperacillin and tazobactum use at the dose, dose frequency, dose duration were

The **dose** of piperacillin and tazobactum based on indication and duration given was in all the indications studied, they met the benchmark requirement of 95%. Therefore piperacillin and tazobactum was used appropriately so far as dose was concerned.

Out of 65 cases, **dose frequencies** were eight hours and 24 hours in 6cases (9.23%) and 59cases (90.76%) respectively.

Dose durations were mostly inappropriate for all the justified indications studied. According to STGs for

hemodialysis patients average duration of therapy is 7 to 14 days, results showed minimum of three days and maximum of fourteen days were given, on an average the results are appropriately meeting the STGs (100%). As per standards, the duration of piperacillin and tazobactum in hemodialysis is given for nineteen days hence duration of therapy fails to meet the standards. There would be a lot of carriers in the system and the disease would continue to be transmitted from person to person. Hence, it facilitates the development of resistant strains to piperacillin and tazobactum.

Drug interactions The potential for piperacillin and tazobactum interaction with microlide antibiotics .Out of 65cases (100%), cases (87.69%) are reported without any potential interaction and cases (9.93%) reported with interaction.

Drugs interacting with piperacillin/tazobactam are:

no interactions	**87.69%**
doxycycline	**3.01%**
azithromycin	**3.46%**
clarithromycin	**3.46%**

Culture sensitivity test:

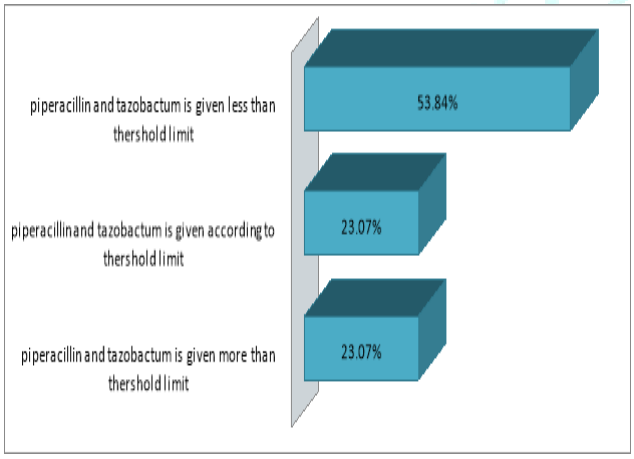
Nephrology	**1case**
Pulmonolgy	**2cases**
Gastroenterology	**3cases**
Gynecology	**1case**
Paediatrics	**0**
without culture test	**58cases**

Drug utilization pattern according to contraindication:

In our study, out of 65 cases, all cases met the threshold of 100% as per STG's.

Outcomes: 89% drug is given without culture test. Dose, duration as per STG's.patients improved symptomatically and infection resolved almost cases. 33.84% are non indicated.

Piperacillin and tazobactum duration of therapy thresholds measured:



CONCLUSIONS AND RECOMMENDATION

CONCLUSION

All patient folders evaluated with regards to HD, SEPTIC SHOCK, PNEMOMEDIATINM etc were found to meet the standard criteria appropriate for piperacillin and tazobactum use with respect to dose, and dose frequency. However, in the case of dose duration the evaluation was found to be largely inappropriate for all the justified indications. In addition, 33.84% of piperacillin and tazobactum use for unjustified indications was noted. This means that piperacillin and tazobactum has been deviated from standard treatment guidelines hence it facilitates the development of resistant strains to piperacillin and tazobactum and of no use in the near future, and it also effect the patient economically.

RECOMMENDATION: Health care providers must be periodically updated with the national standard treatment guidelines. It is further recommended that the hospital's management attention be drawn to the draw backs observed regarding the inappropriate use and duration of piperacillin and tazobactum, so that specific interventions could be initiated to improve its use for excellent outcomes. Following the implementation of the interventions, another DUE should be conducted to determine the level of adherence to the acceptable standards and its impact on patient outcomes.

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We would like to express our gratitude to everyone who was instrumental in this study.

ABBREVIATIONS USED

DTC – Drug therapeutic committee

DUE – Drug utilization evaluation

DUR – Drug utilization Review

FDA – Food drug administration

DDD – Defined daily dose

ADR– Adverse drug reactions

PCN- Percutaneous nephrotomy

CKD- chronic kidney disease

AKI- Acute kidney injury

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