CHAPTER ONE
INTRODUCTION
Since the discovery of penicillin in 1928, which is the first chemical compound with antibiotic properties, many antimicrobials have become available for the treatment of infections. Antimicrobials play essential role in preventing spread of infectious disease and minimizing complications (Bahlas et al. 2016).

Ideally, good antimicrobials prescribing practice should reflect the use of the most effective, least toxic, and least costly antibiotic for the accurate duration of time needed to treat the infection. (Gandage et al. 2013)
Inappropriate antimicrobials, including improper choice of antimicrobials, insufficiency to complete treatment, reuse of leftover antimicrobials, skipping doses, wrong dose regimen, inappropriate combinations and too long period of drug usage can potentially expose patients to unwanted consequences (Ibrahim and Saber-Ayad 2012).

The inappropriateness in antimicrobials use is considered serious problem in the world, given that over 50% of antimicrobials use in hospitals may be inappropriate (Lim et al. 2015). Inappropriate use of antimicrobials create unnecessary costs, produce unwanted side effects, increase resistance toward antimicrobials, antibiotics toxicity, drug-drug interaction, catheter related infection associated with intravenous administration of antimicrobials, prolonged hospitalization, and increased mortality (Ibrahim and Saber-Ayad 2012, Bahlas et al. 2016).

Antimicrobials are one of the most commonly prescribed drugs in the hospital (nan et al. 2011). About half of inpatients receive the antimicrobials for at least one day during hospitalization (Scott Fridkin 2014). Antimicrobials are consumed commonly in surgical ward where 30% of surgery patients will develop post-operative surgical site infections (SSI) (Lim et al. 2015), Which is one of the most common type of nosocomial infections and also considered one of the most expensive nosocomial infections (Parulekar, Soman et al. 2009).

Inappropriate use of antibiotics is a main cause for the increase and spread of Antimicrobial resistance (Fukatsu et al. 1997), where the increase in Antimicrobials resistance is proportional to the use of antibiotic and increase morbidity and mortality (Scott Fridkin 2014).

Between 20 to 40% of the national health budget in developing countries is spent on pharmaceuticals, and more than 50% of those pharmaceuticals are used inappropriately (Who 2002). The total expenditure in Jordan on health in 2008 was 1,381,460,034 JOD, of which 496.4 million was spent on pharmaceuticals, that makes up 35.94% of the total health expenditure (Nuseirat 2015).

In order to decrease the inappropriate use of antimicrobials, several strategies were developed. These strategies include: antibiotics restriction policy, infection control program with focus an antimicrobials, complying with scientific based guidelines when prescribing antimicrobials, and antimicrobial stewardship program. (De Boer et al. 2011, Fernandez-Morato et al. 2016)

The role of pharmacist in the patronage of inpatients evolved over time with enlarged assurance on patient interaction and collaborative care, Nowadays, in countries such as the USA, Australia and UK, the effective participation of clinical pharmacists in the hospitals is usual practice. (De Boer et al. 2011, Kim et al. 2014) The effect of pharmacist delivered services has been reported for, asthma management (Saini et al. 2008), antithrombotic use (Bajorek et al. 2005), heart failure (Koshman et al. 2008), DM (Machado et al. 2007a), HTN (Machado et al. 2007b), on cost of drug therapy in intensive care unit and reducing medication errors. (Davey et al. 2013)

Clinical pharmacist participated in guideline development, formulary management, intravenous to oral conversions, evaluations outcomes of the program through monitoring usage of the drug, advise physicians, educate all healthcare provider, patient counseling, and participation on rounds, reconciliation, admission or discharge medication. (Weller and Jamieson 2004, Kaboli et al. 2006).

A clinical pharmacist is important member of the antimicrobial multidisciplinary group jointly with the infectious disease physician involved in patients' pharmacotherapy monitoring (Tonna et al. 2008). Several studies indicate that the clinical pharmacist cooperative with multidisciplinary teams have a considerable effect on improving the quality of drugs prescribing and costs, but few studies view the role of them in reducing inappropriate of therapeutic antimicrobials use on surgical wards (Kim et al. 2014).

Therefore we will try in this study to determine the role of pharmacists in reducing inappropriate therapeutic
antimicrobials use and consequently improving clinical outcome, patient safety and cost saving.

Aims and objectives
Our aims were twofold:
Firstly we observed and evaluated the appropriate use of therapeutic antimicrobials and its prescribing pattern on surgical wards.
Secondly we intended to determine the impact of clinical pharmacist intervention on the quality and costs of therapeutic antimicrobials use on surgical wards.

OBJECTIVES
1- To explore the appropriateness of therapeutic antimicrobials use in surgical hospitalized patients at University of Hospital in Jordan.
2- To identify the antimicrobial prescribing patterns in surgical hospitalized patients.
3- To assess the effect of clinical pharmacist on appropriate use of antimicrobials in surgical hospitalized patients.
4- To evaluate the impact of clinical pharmacist interventions on reducing the direct cost of antimicrobial use in surgical ward.
5- To determine of acceptance of clinical pharmacist intervention by health care provider team.
6- To determine the extent of antimicrobial resistance in surgical ward.

Literature review
1- Antimicrobials:
1-1- Definition.
An antimicrobial is any substance of natural, semi synthetic or synthetic origin that kills or inhibits the growth of microorganisms such as (bacteria, fungi, viruses and parasites) but causes little or no damage to the host, while antibiotics refers to substances produced by microorganisms that act against another microorganism, so All antibiotics are antimicrobials, but not all antimicrobials are antibiotics (Dictionary 2008).

1-2- Antimicrobials discovery and development.
In 1928, Alexander Fleming discovered penicillin which is one of the greatest achievements in medicine, later to be claimed as the miracle medication of the 20th century. However, the impact of this discovery has not been realized until the 1945 (Bahlas et al. 2016). In 1935, Gerhard Domagk discovered and developed the first sulfonamide, a synthetic red dye more popularly known by its trade name of Prontosil, the first commercially available antibacterial (Skld 2010).

Following discovery of these first two antimicrobials, penicillin and Prontosil, number of new antimicrobials was discovered, the time between the 1940s and 1960s was in fact the golden interval of discovery of new classes of antimicrobials (Chopra et al. 2002). The scientist produced more than 20 new classes of antimicrobials between 1930 and 1962. Since then, only two new antimicrobials classes have been marketed (Coates et al. 2011).

1-3- Mechanism of action of antimicrobials.
Antimicrobial agents exploit differences between animals’ cells and bacteria, protozoa, or fungi, to increase selective toxicity towards these microbes and decrease toxicity in humans. Antimicrobial agents act by interfering with cell wall synthesis, nucleic acid synthesis, cell membrane function, and action as antimetabolites (Hooper 2001).

A. Inhibition of Cell Wall Synthesis.
-Lactam antimicrobials interact with transpeptidases directly and inhibit cross-linking of peptidoglycan, Vancomycin and Teicoplanin bind to terminal D-ala-D-ala & prevent incorporation into growing peptidoglycan and inhibition of transglycosylation. Bacitracin inhibits dephosphorylation of phospholipid carrier in peptidoglycan structure, Cycloserine prevents incorporation of D-alanine into peptidoglycan.
(Hooper 2001)
B-Inhibition of Protein Synthesis. 
Macrolides, Chloramphenicol, Clindamycin Bind to 50S ribosomal subunit, Aminoglycosides and Tetracyclines Bind to 30S ribosomal subunit(Hooper 2001)

C-Inhibition of Nucleic acid synthesis 
Quinolones Inhibit DNA gyrase & Topoisomerase , Flucytosine and Griseofulvin Inhibit nucleic acid biosynthesis, Rifampin, Rifabutin, Rifapentine Inhibit of mRNA synthesis(Hooper 2001)

D-Alteration of Cell Membrane Function 
Imidazole antifungal Inhibit ergosterol biosynthesis, Polymyxins, Amphotericin B and Nystatin Bind to membrane sterols(Hooper 2001)

E-Alteration of Cell Metabolism 
Sulfonamides, Trimethoprim, Trimetrexate and Pyrimethamine Inhibit tetrahydrofolic acid production (cofactor for nucleotide synthesis), Isoniazid Inhibit mycolic acid biosynthesis, Metronidazole and Nitrofurantoin Bind to macromolecules(Hooper 2001)

1-4-Impact of antimicrobials on health care. 
Antimicrobials have rescued a large number of people from serious infectious disease and have played important role in surgery and medicine. they have cured or prevented infections that can occur in patients who are receiving chemotherapy drugs, who have chronic diseases such as diabetes, end-stage renal disease, or rheumatoid arthritis; or who have had complicated surgeries such as joint replacements, organ transplants, or cardiac surgery. In underdeveloped countries where hygiene is still bad, antimicrobial decrease the morbidity and mortality caused by food-borne and other poverty related infections.(Idsa 2011)

1-5-Antimicrobial use. 
The function of antimicrobials expanded from treating infectious disease to preventing surgical site infections, protecting immunocompromised and cancer patients, enhancing growth and preventing animals diseases. (Coates et al. 2011)

Antimicrobials are used for prophylaxis and treatment of infectious diseases, where 80% to 90% of antimicrobials are spent in outpatients and the remnant are spent to hospitalized patients.(Bisht et al. 2009)
In Jordan according(Al-Niemat et al. 2014) The percentage of prescriptions involving antibiotics was (85%) in study conducted in the outpatient pediatric emergency clinic at Queen Rania Al Abdullah II Children’s Hospital.

Antimicrobials are one of the most commonly prescribed drugs in the hospital. (��nan et al. 2011) about half of inpatients receive the antimicrobials for at least one day during hospitalization. (Scott Fridkin 2014)
antimicrobials are consumed commonly in surgical ward where 30% of surgery patients will develop post-operative surgical site infections, (SSI)(Lim et al. 2015) Which is one of the most common type of nosocomial infections and also considered one of the most expensive nosocomial infections . (Parulekar, Soman et al. 2009)

Prophylactic antibiotics are given in a timely manner to prevent post-operative surgical site infections (SSI) when a surgical procedure is expected to result in bacterial contamination of blood or sterile tissues. The aims are to avoid endogenous normal flora from causing disease in neighboring operated tissue, to avoid multiplication of endogenous bacteria that gain access to normally sterile areas, and to prevent exogenous organism infection. about 30-50% of antimicrobials use in hospital practice nowadays is for surgical prophylaxis.(Gandage et al. 2013)

1-6- Inappropriate use of Antimicrobials.
In inappropriate antimicrobials, including improper choice of antimicrobials, insufficiency to complete treatment, reuse of leftover antimicrobials, skipping doses, wrong dose regimen, inappropriate combinations and too long period of drug usage can potentially expose patients to unwanted consequences (Ibrahim and Saber-Ayad 2012).

The inappropriateness in antimicrobials use is considered serious problem in the world, given that over 50% of antimicrobials use in hospitals may be inappropriate (Lim et al. 2015). Inappropriate use of antimicrobials create unnecessary costs, produce unwanted side effects, increase resistance toward antimicrobials, antibiotics toxicity, drug-drug interaction, catheter related infection associated with intravenous administration of antimicrobials, prolonged hospitalization, and increased mortality (Ibrahim and Saber-Ayad 2012, Bahlas et al. 2016).
Antimicrobials consume a considerable portion of the total health care budget. In Jordan 35.94% of the total health expenditure was spent on pharmaceuticals in 2008.

According (Bugnon-Reber et al. 2004) In Switzerland, The proportion of patients on antibiotics was 22% in internal medicine wards and 26% in surgical wards and reported a higher rate of antibiotic misuse (58% vs. 34%) in surgical versus medical departments.

In other study in Switzerland, 75.4% of prescriptions antibiotic were for therapy and 24.6% for prophylaxis. The proportion of patients on antimicrobial treatment was 46.1% in the medical wards vs. 36.1% in the surgical wards and a total inappropriate use of antibiotic was 32% and Therapeutic antibiotic were more frequently inappropriate than prophylaxes antibiotic (37.0% versus 16.6%) (Cusini et al. 2010).

In Turkey (��nan et al. 2011) reported that inappropriate antimicrobial use rate was higher in hospitalized patient on surgical wards (29.3%) than on medical wards (13.3%), The proportion of patients on antibiotics was (40.5%) in internal medicine wards and (32.9%) in surgical wards and Antibiotics were used 70.8% patients for therapeutics and 29.1% for surgical prophylaxis.

According toLim et al. 2015 in study conducted in surgical wards In Malaysia,73.6% of inpatient in surgical wards received inappropriate antibiotic therapy and The spread of inappropriate antibiotic use was 55 42.0% and 66.3 for therapeutic and prophylactic purposes, respectively and The most common causes of inappropriate was choice of antibiotics 42.1% and inappropriate indication 40.7%.

In Australian hospitals even with the rollout of antimicrobial stewardship (AMS) programs, about 50% of hospital inpatients in Australia will receive an microbial and 22.9% of these antimicrobials were used inappropriately (Broom et al. 2015).

In Jordan, inappropriate antibiotic use have established in many studies, according (Al-Momany et al. 2009) in her study the commitment to all antibiotic prophylaxis guidelines was not attain for any study patients and 97.0% of patients received an needless midnight dose of antibiotic the night before surgery.

1-7- Antimicrobial resistance
Antimicrobials resistance occurs when microorganisms (such as bacteria, fungi, viruses, and parasites) change in one method or another that remove or diminish the efficacy of antimicrobial drugs (such as antibiotics, antifungals, antivirals, antimalarials, and anthelmintics). Resistance occurs when the usually systemic antimicrobials concentration cannot slow down or stop microorganism growth with normal dosage schedule, and/ or fall in the minimum inhibitory concentration ranges of antimicrobials. The resistance to two or more antimicrobials or antimicrobials classes is defined as the multiple drug resistance, whilst the cross resistance is defined as resistance to particular antimicrobial that often results in resistance to other antimicrobials (Who 2016).

1-8-Mechanisms of Antibiotic Resistance.
Resistance to b-lactams is usually due to the hydrolysis of the antibiotic by a b-lactamase or the alteration of Penicillin-binding proteins PBPs or cellular permeability. and the presence of an efflux pump (Hawkey 1998)

Resistance in sulfonamides is commonly mediated by genes encoding alternative drug-resistance variants of the dihydropteroate synthesis (DHPS) (Skold 2000)

Three different mechanisms of acquired Macrolide resistance have been found. These include Post-transcriptional modifications of the 23S rRNA by the adenine-N6. Efflux proteins, which pump these antibiotics out of the cell or the cellular membrane and Hydrolytic enzymes.(Vester and Douthwaite 2001)

Resistance to Tetracycline, Doxycycline, Minocycline, and Oxtetracycline occurs mainly through three mechanisms, efflux of the antibiotics, Ribosome protection, and Modification of the antibiotic.(Speer et al. 1992)

Resistance to Chloramphenicol is generally due to inactivation of the antibiotic by a Chloramphenicol acetyltransferase Sometimes decreased outer membrane permeability or active efflux is responsible for the resistance in gram-negative bacteria.(Fernandez et al. 2011)

Mechanisms of bacterial resistance to quinolones fall into two principal categories: alterations in drug target enzymes and alterations that limit the permeability of the drug to the target.(Hooper 2001)

Resistance to Aminoglycosides such as Amikacin,Gentamicin, Tobramycin, and Streptomycin is common, Aminoglycosides modified at amino groups by AAC enzymes or at hydroxyl groups by ANT or APH enzymes lose their ribosome-binding ability and thus no longer inhibit protein synthesis. Besides Aminoglycoside-modifying enzymes, efflux systems and rRNA mutations .(Ramirez and Tolmasky 2010)

Amphotericin-B (Am-B) resistant occurs after alterations in the lipid composition of fungal cell membranes. AmB resistant cells reduce or increase ergosterol content.(Brajtburg et al. 1990)

1-9-Why is antimicrobial resistance a global concern?. The problem is that inappropriate use of antibiotics is a main cause for the increase and spread of Antimicrobial resistance (Fukatsu et al. 1997),Ibrahim and Saber-Ayad 2012, where the increase in Antimicrobials resistance is proportional to the use of antibiotic and increase morbidity and mortality (Scott Fridkin 2014).

Antimicrobial Resistance affects adversely both cost and therapeutic outcomes, such as lack of success of treatment so this need toxic and/or expensive alternative antimicrobials, extending durations of hospitalization and the need for changes in empirical therapy. Now, the greatest challenge to the successful treatment of infectious disease is Spread of Antimicrobial resistance. (Hangoma (2014.).)
According(Bisht et al. 2009) now, about 70 % of the bacteria in hospitals are resistant to one of the antibacterial agents at least. Some microbes are resistant to all accepted antibacterial and can be treated only with potentially toxic antibacterial.

1-10-Financial affect.
Between 20 to 40% of the national health budget in developing countries is spent on pharmaceuticals, and more than 50% of those pharmaceuticals are used inappropriately (Who 2002). The total expenditure In Jordan on health in 2008 was 1,381,460,034 JOD, of which 496.4 million was spent on pharmaceuticals, that makes up 35.94 % of the total health expenditure. (Nuseirat 2015)
Antimicrobials account more than one-third of a hospital’s pharmacy budget (Parulekar et al. 2009) In Turkey, the most prescribed medications are antimicrobials (19.9% of all medications) and the total
medication and antimicrobials cost annually per person was calculated as $130 and $26 respectively (Cusini et al. 2010) (nan et al. 2011). So the antimicrobial cost is an important matter, but only few studies have investigated the economic impact of the contribution of pharmacists to the clinical process (De Boer et al. 2011).

2-Role of pharmacist

Historically, role of pharmacists centered about dispensing prescription medicines, ensuring that different treatments are appropriate for the patients. Checking dosage and ensuring that medicines are correctly and safely supplied and labeled.

The role of pharmacist in the patronage of inpatients evolved over time with enlarged assurance on patient interaction and collaborative care. Nowadays, in countries such as the USA, Australia and UK, the effective participation of clinical pharmacists in the hospitals is usual practice. (De Boer et al. 2011, Kim et al. 2014)

In contrast, in developing countries, because lack of awareness of the role of clinical pharmacists, clinical activities of clinical pharmacists are not as encouraged as USA, Australia and UK. (Nissen 2009).

The effect of pharmacist delivered services has been reported for, asthma management (Saini et al. 2008), antithrombotic use (Bajorek et al. 2005), heart failure (Koshman et al. 2008), DM (Machado et al. 2007a), HTN (Machado et al. 2007b), on cost of drug therapy in intensive care unit and reducing medication errors. (Davey et al. 2013)

Clinical pharmacist participated in guideline development, formulary management, intravenous to oral conversions, evaluations outcomes of the program through monitoring usage of the drug, advise physicians, educate all healthcare provider, patient counseling, and participation on rounds, reconciliation, admission or discharge medication. (Weller and Jamieson 2004, Kaboli et al. 2006)

(Mialon et al. 2004) reported an 80% decrease in prescription errors after implementation of emergency department clinical pharmacy services and a projected cost saving of over $800,000 annually, at an emergency department of Children’s Medical Center in Dallas, Texas.

In other study was conducted at Henry Ford Hospital in Detroit researcher reported The rate of preventable adverse drug events (ADEs) was reduced by 78%, after Participation of a clinical pharmacist in the daily rounds of a general medicine unit. (Kucukarslan et al. 2003)

In order to decrease the inappropriate use of antimicrobials, several strategies were developed. These strategies include: antibiotics restriction policy, infection control program with focus an antimicrobials, complying with scientific based guidelines when prescribing antimicrobials, and antimicrobial stewardship program. (De Boer et al. 2011, Fernandez-Morato et al. 2016)

A clinical pharmacist is important member of the antimicrobial multidisciplinary group jointly with the infectious disease physician involved in patients’ pharmacotherapy monitoring (Tonna et al. 2008).

Several studies indicate that the clinical pharmacist cooperative with multidisciplinary teams have a considerable effect on improving the quality of drugs prescribing and costs, (Fernandez-Morato et al. 2016) reported a significant reduction in the number of days of antimicrobial therapy and length of stay, with no significant differences in mortality after implementing an antimicrobial stewardship program in two surgical wards at a tertiary care.

According to (Murray et al. 2013) in a prospective before-and-after intervention study conducted from November 2011 to December 2012,

The intervention resulted in a reduction in the duration of antimicrobial treatment from 8.3 to 6.8 days, the rate of antimicrobial-related adverse effects reduced from 31% to 19%, and there was no increase in mortality or length of stay.

In other study conducted in a cardiothoracic ward at a tertiary teaching hospital in Suzhou, China the researcher found significant decrease of SSI rate, cost of prophylactic antibiotic, length of stay and the rates of antibiotic resistant, also the proportion of antibiotic prophylaxis, rational antibiotic selection, prophylactic antibiotic duration and suitable timing of administration of the first preoperative dose was significantly
increased. (Saokaew et al. 2009) reported that a pharmacist’s interventions in intensive care unit had a positive potential impact on overall drug cost, cost saving, and cost avoidance and were well accepted by the team. (Bond et al. 2000) found associations between clinical pharmacy services and total cost of care. Clinical pharmacy services were associated with a cost saving per hospital per year of 5-8 million USD. The addition of clinical pharmacist services in the care of inpatients generally resulted in improved care, with no evidence of harm (Kaboli et al. 2006)

despite presence of many published studies exploring role of pharmacist in reducing inappropriate antimicrobials use in different wards of hospital and role of pharmacist in surgical ward, few studies view the role of them in reducing inappropriate of therapeutic antimicrobials use on surgical wards (Kim et al. 2014).

Primary Sources
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