3. LITERATURE REVIEW

3.1 Introduction to Prescription

Prescription order is an important transaction between the physician and the patient. It is an order for a scientific medication for a person at a particular time (37) It brings into focus the diagnostic acumen and therapeutic proficiency of the physician with instructions for palliation or restoration of the patient’s health (38) Prescription is a written document that engages the medical and legal responsibility not only of the physician but of all those subsequently involved in its execution (39).

Prescription writing used to be an art as well as a science. Unfortunately, times have changed. More often than not, we find incomplete and illegal prescriptions being handed over to patients, and, more unfortunately, honored at pharmacies. This has resulted in a disturbing trend of putting the patients safety at risk; and there is an urgent need to put things right (40). Nowadays the prescribing pattern is changing and it has become just an indication of medicine with some instructions of doses without considering its rationality. (37)

3.1.1 History

Early medicines were made up of multiple ingredients requiring complex preparation, and Latin was adopted as the standard language of the prescription to ensure understanding between physician and pharmacist and consistency in pharmaceutical composition. Latin no longer is the international language of medicine, but a number of commonly used abbreviations derive from old Latin usage. The symbol "Rx" is said to be an abbreviation for the Latin word *recipere*, meaning "take" or "take thus," as a direction to a pharmacist, preceding the physician's "recipe" for preparing a medication. The abbreviation "Sig" for the Latin *Signatura*, is used on the prescription to mark the directions for administration of the medication (41 ibid page no 1879).
3.1.2 Parts of the Prescription (42, 43).

The elementary requirements of a prescription are that it should state what is to be given to whom and by whom prescribed, and give instructions on how much should be taken how often, by what route and for how long or total quantity to be supplied.

1) Date
2) Address of doctor
3) Superscription {Symbol (R,)}
4) Inscription or the name and dose of medication prescribed
5) Subscription or Dispensing direction to Pharmacist
6) Signature or Instructions for Patient
7) Signature of doctor

1) Date: Prescriptions are dated at the time they are written and also when they are received and filled in the pharmacy. The date is important in creating the medication record of the patient. The Date is also important to pharmacist in filling prescription of controlled substances. No Prescription order of controlled drugs may be dispensed or renewed more than 6 months after the date prescribed.

2) Address of doctor: It is important to write physician’s name, address, telephone number and Drug Enforcement Agency (DEA) number or Medical council registration number in India on prescription pads.

3) Superscription {Symbol (R,)}: This is the symbol R generally is understood to be a contraction of the Latin verb recipe, meaning *take thou or you take*. The stroke after “R” is considered as an invocation to Jupiter. Jupiter is a god of healing. Sign of Jupiter employed as request for healing. Today, the symbol is representative of both the prescription and the pharmacy itself.

4) Inscription or the name and dose of medication prescribed: This is the body or principal part of the prescription order. It contains the name and quantities of the prescribed ingredients (41).

Today, majority of the prescriptions are written for medication already prepared or prefabricated into dosage forms by industrial manufacturers. The medications
may be prescribed under their trademarked or manufactures proprietary name or by their nonproprietary or generic names. Pharmacists are required to dispense the trademarked products when prescribed, unless substitution of an equivalent product is permitted by the prescribing physician or by the state law. Prescription orders requiring the pharmacist to mix ingredients are termed compounding prescriptions. Prescriptions requiring compounding contain the names and quantities of each ingredients required. The names of the ingredients generally are written using the nonproprietary names of the materials, although occasionally proprietary names may be employed. Quantities of ingredients to be used may be indicated in the metric or apothecary system of weights and measures; however, the use of the apothecary system is diminishing. In the metric system the decimal point is often replaced by vertical line that may be imprinted on the prescription blank or drawn by the prescriber(41).

5) **Subscription or Dispensing directions to Pharmacist:** This part of the prescription consists of directions to the pharmacists for preparing the prescription. In majority of prescriptions, the subscription serves merely to designate the dosage form (as tablets, capsules, etc) and the number of dosage units to be supplied. Examples of prescription directions to the pharmacist are "make a solution," "mix and place into 30 capsules," or "dispense 30 tablets (41).

6) **Signature or Instructions for Patient:** The prescriber indicates the directions for the patient’s use of the medication in the portion of the prescription called signature. The word, usually abbreviated *signa* or *sig* means mark thou. The directions in the *signa* commonly are written using abbreviated forms of English or Latin terms or a combination of each (41). Examples are

*Tabs ii q4h* (Take two tablets every four hours)
*Caps I 4xd pc & hs* (Take one capsule four times a day after meals and at bedtime)
*Instill gtts ii od* (Instill two drops into the right eye)

The directions for use must be both drug-specific and patient-specific. The simpler the directions, the better; and the fewer the number of doses (and drugs) per day, the better. Many physicians continue to use Latin abbreviations; for example, "1 cap tid pc," will be interpreted by the pharmacist as "take one capsule three times daily after
meals.” However, the use of Latin abbreviations for these directions only mystifies the prescription and is discouraged. This can be a hindrance to proper patient-physician communication and is an otherwise unnecessary source of potential dispensing errors. Because the pharmacist always writes the label in English (or, as appropriate, in the language of the patient), the use of such abbreviations or symbols is unnecessary. Many serious dispensing errors can be traced to the use of abbreviations (44). Instructions to patients should be clear and preferably in English or vernacular language. 7) **Signature of the doctor:** It is the end of prescription.

![Figure 1: Sample Format of ideal Prescription](image)

**ABC Hospital**

Dr. A. B. Shah  
12, Modern Centre  
Anand, Gujarat

Name: ______________________ M/F  
Age: ________

Address: ______________________  
Wt: ________

**Losartan 50 milligram Tab, Dispense 30 tablets**

*Take one by Mouth daily in the morning*  
*For blood pressure control*

Refill ____________ times  
Signature ______________________

Generic Substitution ________  
Registration No.: ____________
The prescription must be carefully prepared to identify the patient and the medication to be dispensed, as well as the manner in which the drug is to be administered. Accuracy and legibility are essential. Use of abbreviations, particularly Latin, is discouraged, because it leads to dispensing errors. Inclusion of the therapeutic purpose in the subscription (e.g., "for control of blood pressure") can prevent errors in dispensing. For example, the use of losartan for the treatment of hypertension may require 100 mg/day (1.4 mg/kg/day), whereas treatment of congestive heart failure with this angiotensin II receptor antagonist generally should not exceed 50 mg/day. Including the therapeutic purpose of the prescription also can assist patients in organizing and understanding their medications. In addition, including the patient's weight on the prescription can be useful in avoiding dosing errors, particularly when drugs are administered to children. (41 ibid page no. 1880)

### 3.1.3 Introduction to Good Prescribing: What constitutes good prescribing? (45)

Barber stated that ‘Drugs are the stronghold of medical treatment, yet there are few reports on what constitutes “good prescribing” and the existing direction tends to imply that right answers exist, rather than recognizing the complex trade-offs that have to be made between conflicting aims’(45). There are four aims that a prescriber should try to achieve, both on first prescribing a drug and on subsequently monitoring it. They are: to maximize effectiveness, minimize risks, minimize costs, and respect the patient’s choices (45). This model of good prescribing brings together the traditional balancing of risks and benefits with the need to reduce costs and the right of the patient to make choices in treatment (45).

‘The four aims are shown as a diagram plotting their commonest conflicts, which may be used as an aid to discussion and decision making:’ (45)

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Maximize effectiveness

Minimize cost ← ----------------→  Respect patient sources

Minimize risk
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3.1.3.1 Assessing good prescribing
Barber said that “Whereas consensus may be gained within medicine on how to balance effectiveness, risk, and cost of drug treatment for a condition, including the patient makes judgments on the quality of prescribing difficult to conduct at a distance. In contrast, drug and therapeutics committees, pharmacists, medical advisers, and commissioning agencies are increasingly making judgments on the acceptability of prescribing. These approaches need not be mutually exclusive. The model of good prescribing proposed … can be integrated with the prescriptive, protocol driven approach currently gaining favors – for example, by setting a standard that 80 per cent of prescribing meets the protocol. The level at which the standard is set must come from debate among prescribers, patients, and commissioning agencies” (45).

3.2 Types of Prescribing (10)
There are two types of prescribing based on approach of prescriber, one is Rational (Appropriate) and another approach is irrational (Inappropriate) prescribing.

3.2.1 Rational (Appropriate) prescribing: (9, 10)

- **Rational prescribing**
  - The process whereby prescribing decisions are made
  - follows guidelines

- **Appropriate prescribing**
  - Rational prescribing + tailored to patients needs and characteristic
  - need not be appropriate!

The terms "appropriate" and "rational" use of drugs will be used interchangeable (46). Laing R stated “What is rational use of drugs? What does rational mean? People may have different perceptions and meanings regarding rational use of drugs or more specifically regarding rational prescribing” (46). However, the Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization in Nairobi in 1985, defined rational use as follows:
Rational use, and thus rational prescribing of drugs, requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (46).

Rational use of medicines refers to the correct, proper and appropriate use of medicines. Rational use requires that patients receive the appropriate medicine, in the proper dose, for an adequate period of time, and at the lowest cost to them and their community (46).

The requirements for rational use will be fulfilled if the process of prescribing is appropriately followed. This process includes steps in defining a patient’s problems (or diagnosis); in defining effective and safe treatments (drugs and nondrug); in selecting appropriate drugs, dosage, and duration; in writing a prescription; in giving patients adequate information; and in planning to evaluate treatment responses (46).

The definition implies that rational use of drugs, especially rational prescribing, should meet certain criteria as follows: (46)

- **Appropriate indication.** The decision to prescribe drug(s) is entirely based on medical rationale plus safety and effectiveness of drug therapy.

- **Appropriate drug.** It depends on efficacy, safety, suitability, and cost of drug.

- **Appropriate patient.** No contraindications exist, with minimum adverse reactions and acceptable to the patient.

- **Appropriate patient information.** Patients are provided with relevant, accurate, important and clear information regarding their conditions and for the prescribed medication(s).

- **Appropriate evaluation.** Appropriately monitored and interpret unexpected effects of medications.

### 3.2.2 Irrational (Inappropriate) Prescribing: (47)
Vance MA reported that “Medically inappropriate, ineffective and economically inefficient use of pharmaceuticals is commonly observed in health care systems throughout the world, including developing countries” (47). However, various forms of inappropriate prescribing often remain unnoticed by those who are involved in health sector decision making or delivery of health services (47). This problem will usually come to the attention of health decision makers or managers when there is an acute shortage of pharmaceutical budget that requires action for cost-efficiency (47).

Promoting appropriate use of drugs in the health care system is needed not only because of the financial reasons with which policy makers and managers are usually most concerned. Appropriate use of drugs is also one essential element in achieving quality of health and medical care for patients and the community. Obviously, quality of care is of concern to practitioners. Actions or intervention programs to promote the appropriate use of drugs should, therefore, be continuously implemented and systematically incorporated as an integral part of the health care system (48).

Unfortunately, in the real world, prescribing patterns do not always conform to these criteria and can be classified as inappropriate or irrational prescribing. Irrational prescribing may be regarded as "pathological" prescribing when the above-mentioned criteria are not fulfilled. Common patterns of irrational prescribing may, therefore, be manifested in the following forms: (49-51)

- Use of drugs when no drug therapy is indicated, e.g., antibiotics for viral upper respiratory infections
- Use of the wrong drug for a specific condition requiring drug therapy, e.g., tetracycline in childhood diarrhea requiring ORS
- Use of drugs with doubtful or unproven efficacy, e.g., the use of antimotility agents in acute diarrhea
- Use of drugs of uncertain safety status, e.g., use of dipyridamole (Baralgan, etc.)
- Failure to provide available, safe, and effective drugs, e.g., failure to vaccinate against measles or tetanus, or failure to prescribe ORS for acute diarrhea
• Use of correct drugs with incorrect administration, dosages, and duration, e.g., the use of IV metronidazole when suppositories or oral formulations would be appropriate

• Use of unnecessarily expensive drugs, e.g. the use of a third generation, broad-spectrum antimicrobial when a first-line, narrow spectrum agent is indicated

Some examples of commonly encountered inappropriate prescribing practices in many health care settings include— overuse of antibiotics and antidiarrheals for nonspecific childhood diarrhea, indiscriminate use of injections, e.g., in malaria treatment, multiple or over-prescription, excessive use of antibiotics for treating minor acute respiratory infection, multivitamins and tonics for malnutrition and unnecessary use of expensive anti-hypertensive.

The drug use system is complex and varies from country to country. Drugs may be imported or manufactured locally. The drugs may be used in hospitals or health centers, by private practitioners and often in a pharmacy or drug shop where over the counter preparations are sold. In some countries all drugs are available over the counter as in India. Finally, the public includes a very wide range of people with differing knowledge, beliefs, and attitudes about medicines. Consumers may have a very different perspective of what is rational (49-51).

3.2.3 Factors contributing to inappropriate use of medicines (52)

Various different factors have an effect on the irrational use of drugs. In addition, different cultures view drugs in different ways, and this can affect the way drugs are used.

• Lack of skills and knowledge. Diagnostic uncertainty, lack of prescriber knowledge of optimal diagnostic approaches, lack of independent information such as clinical guidelines, lack of opportunity for patient follow-up, or fear of possible litigation, lead to inappropriate prescription and dispensing of medicines.

• Inappropriate unethical promotion of medicines by pharmaceutical companies. Most prescribers get medicine information from pharmaceutical companies rather than independent sources such as clinical guidelines. This can often lead to overuse.
Some countries allow direct-to-consumer advertising of prescription medicines, which may lead to patients pressuring doctors for unnecessary medicines.

- **Profits from selling medicines.** In many countries, drug retailers prescribe and sell medicines over-the-counter. Extra income can be generated by more sale and generate more income leading to overuse of medicines, particularly the more expensive medicines.

- **Unrestricted availability of medicines.** In many countries including India, prescription medicines such as antibiotics, are freely available over-the-counter. This leads to overuse, inappropriate self-medication and non-adherence to dosing regimes. This creates drug resistance.

- **Overworked health personnel.** Many prescribers have too little time with each patient, which can result in poor diagnosis and treatment. In such conditions prescribers rely on prescribing pattern as they do not have the time to update their knowledge of medicines.

- **Unaffordable medicines.** Where medicines are too costly, people may not purchase a full course of treatment or may not purchase the medicine at all. Instead they may seek alternatives, such as medicines of non-assured quality from the Internet or other sources, or medicines prescribed to family or friends.

- **Lack of coordinated national pharmaceutical policy.** Less than half of all countries implement the basic policies recommended by World Health Organization (WHO) to ensure the appropriate use of medicine. These include appropriate measures and infrastructure for monitoring and regulation of medicine use, and training and supervision of prescribing health workers.

The major forces can be categorized as those deriving from patients, prescribers, the workplace, the supply system including industry influences, regulation, drug information and misinformation, and combinations of these factors (52).
Table 1: Factors contributing to inappropriate use of drugs

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<tr>
<td><strong>Patients</strong></td>
<td>- drug misinformation</td>
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<td></td>
<td>- misleading beliefs</td>
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<tr>
<td></td>
<td>- patient demands/expectations</td>
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<tr>
<td><strong>Prescribers</strong></td>
<td>- lack of education and training</td>
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<td></td>
<td>- inappropriate role models</td>
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<td></td>
<td>- lack of objective drug information</td>
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<td></td>
<td>- generalization of limited experience</td>
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<td></td>
<td>- misleading beliefs about drugs efficacy</td>
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<tr>
<td><strong>Workplace</strong></td>
<td>- heavy patient load</td>
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<td></td>
<td>- pressure to prescribe</td>
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<td></td>
<td>- lack of adequate lab facility</td>
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<td></td>
<td>- insufficient staffing</td>
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<td><strong>Drug Supply System</strong></td>
<td>- unreliable suppliers</td>
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<td></td>
<td>- drug shortages</td>
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<td>- expired drugs supplied</td>
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<tr>
<td><strong>Drug Regulation</strong></td>
<td>- nonessential drugs available</td>
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<td></td>
<td>- informal prescribers</td>
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<td></td>
<td>- lack of regulation enforcement</td>
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<tr>
<td><strong>Industry</strong></td>
<td>- promotional activities</td>
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<td></td>
<td>- misleading claims</td>
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All of these factors are affected by changes in national and global practices (46, 47, 48).

3.2.4 Impact of Inappropriate Use of Drugs

The impact of irrational use of drugs can be seen in many ways:

- Reduction in the quality of drug therapy leading to increased morbidity and mortality
- Waste of resources leading to reduced availability of other vital drugs and increased costs
- Increased risk of unwanted effects such as adverse drug reactions and the emergence of drug resistance, e.g., malaria or multiple drug resistant tuberculosis

- Psychosocial impacts, e.g. when patients come to believe that there is “a pill for every ill.” This may cause an apparent increased demand for drugs (51).
3.3 Current Scenario of Prescribing

Indian markets are flooded with over 70,000 formulations, compared to roughly 350 preparations listed on the WHO Essential Drugs List (53). There are thousands of drug companies, and several companies manufacture generic preparations using different brand names. In addition, thousands of formulations of vitamins, tonics, and multi-drug combinations that are unique to the Indian market are manufactured and marketed regularly.

A visit to the physician has come to necessarily mean a prescription comprising of a broad-spectrum combination of antibiotics — one or more, an anti pyretic or frequently an unnecessary combination of the two drugs, a multivitamin tonic, and a cough syrup. Intravenous, rehydration, and parenteral medication are also used frequently (54).

Worldwide, more than half of all medicines are prescribed, dispensed, or sold unacceptably, and 50% of patients take them wrongly. Moreover, about one third of the world’s population lacks access to essential medicines (55). A survey conducted in 8 hospitals in southern Ethiopia that investigated their prescription patterns concluded that irrational prescribing, as evidenced by high average number of drugs prescribed per encounter, high percentage of injections, and high percentage of antibiotic use, was prevalent in the studied region (56). It is obvious that irrational prescribing is a global problem. Bad prescribing habits lead to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient, and higher costs. Irrational prescribing patterns are perpetuated through patient pressure, bad example of colleagues, and high-powered salesmanship by drug company representatives. In teaching hospitals, new graduates will copy from seniors, completing the vicious circle. Changing existing practice of prescribing habits becomes very difficult (57). Assessment of drug use patterns with the WHO drug use indicators is becoming increasingly necessary to promote rational drug use in developing countries (48, 58). Physician prescribing is the most frequent medical intervention with a highest impact on healthcare costs and outcomes. Therefore improving and promoting rational prescribing is of great interest. In a study a four-arm randomized trial with economic evaluation was conducted in Tehran. Three interventions (routine feedback, revised feedback, and printed educational material)
and a no intervention control arm were compared. Physicians working in outpatient practices were randomly allocated to one of the four arms using stratified randomized sampling. The interventions were developed based on a review of literature, physician interviews, and current experiences in Iran and with theoretical insights from the Theory of Planned Behavior. Effects of the interventions on improving antibiotic and corticosteroid prescribing were assessed using regression analyses. Cost data was assessed from a health care provider’s perspective and an incremental cost-effectiveness ratio was calculated (58). The another study by Soleymani et al determined the effectiveness and cost-effectiveness of three interventions and determined the most effective interventions in improving prescribing pattern. Study concluded that if the interventions are cost effective, they would likely to be applied nationwide (59).

Before activities to promote rational drug use are started, an effort should be made to describe and quantify the situation. Several well-established survey methods are available for this purpose. One assessment method is a prescribing and patient care survey using the WHO health facility drug use indicators. These quantitative indicators are now widely accepted as a global standard for problem identification and have been used in over 30 developing countries (60). Prescribing patterns need to be evaluated periodically to increase the therapeutic efficacy, decrease adverse effects and provide feedback to prescribers (61).

3.3.1 The problem of irrational use

Irrational use is the use of medicines in a way that is not compliant with rational use as defined earlier. Worldwide more than 50% of all drugs are prescribed, dispensed, or sold inappropriately, while 50% of patients take them incorrectly. Moreover, about one-third of the world’s population does not have access to essential medicines. This incorrect use of medicine may take the form of overuse, underuse and misuse of prescription or non-prescription drugs. In developing countries, the proportion of patients managed as per clinical guidelines for common diseases in primary care is less than 40% in the public sector as well as 30% in the private sector. Common types of irrational medicine use are: the use of more than two medicines per patient (polypharmacy), inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections, over-use of injections when oral formulations would be more
appropriate, failure to prescribe in accordance with clinical guidelines and inappropriate use of self-medications (61). Finally, irrational over-use of medicines can stimulate inappropriate patient demand, and lead to reduced access and attendance rates due to medicine stock-outs and loss of patient confidence in the health system (62).

3.3.1.1 Consequences of incorrect use of medicines

Incorrect use of medicines occurs in all countries, causing harm to people and wasting resources. Consequences include:

a) *Antimicrobial resistance*. Overuse of antibiotics increases antimicrobial resistance and the number of medicines that are no longer effective against infectious disease. Many surgical procedures and cancer therapies are not possible without antibiotics to fight infection. Resistance prolongs illnesses and hospital stays, and can even cause death, leading to costs of US$ 4–5 billion per year in the United States of America (63) and €9 billion per year in Europe (64).

b) *Adverse drug reactions and medication errors*. Harmful reactions to medicines caused by wrong use, or allergic reactions to medicines can lead to increased illness, suffering and death. Adverse drug reactions have been estimated to cost millions of dollars each year (65,66).

c) *Lost resources*. Between 10–40% of national health budgets are spent on medicines. Out-of-pocket purchases of medicines can cause severe financial hardship to individuals and their families. If medicines are not prescribed and used properly, billions of dollars of public and personal funds are wasted.

d) *Eroded patient confidence*. Exacerbated by the overuse of limited medicines, drugs may often go out of stock or be available at unaffordable prices and as a result, erode patient confidence. Poor or negative health outcomes due to inappropriate use of medicines may also reduce confidence (66).
3.4 Measures to Improve Rational Use of Medicines

Rational use of drugs is multifaceted. Its medical, social, and economic aspects are well reflected in the World Health Organization (WHO) definition: “Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community” (47, 53).

A major step towards rational use of medicines was taken in 1977, when WHO established the 1st Model List of Essential Medicines to assist countries in formulating their own national lists. The present definition of rational use was agreed at an international conference in Kenya in 1985. In 1989, the International Network for the Rational Use of Drugs (INRUD) was formed to conduct multi-disciplinary intervention research projects to promote more rational use of medicines. Following this, the WHO/INRUD indicators to investigate drug use in primary health care facilities were developed and many intervention studies conducted. A review of all the published intervention studies with adequate study design was presented at the 1st International Conference for Improving the Use of Medicines (ICIUM) in Thailand in 1997 (47).

The effect varied with intervention type, printed materials alone having little impact compared to the greater effects associated with supervision, audit, and group process and community case management. Furthermore, the effects of training were variable and often unsustained, possibly due to differences in training quality and the presence or absence of follow-up and supervision (47).

3.4.1 Training courses related to the rational use of medicines (66)

- Promoting the rational use of drugs (medicines), in collaboration with the International Network for the Rational Use of Drugs (INRUD) coordinated by Management Sciences for Health, USA. This course teaches the investigation of medicine use in primary health care and how to promote rational use of medicines by providers.
• **Promoting rational drug (medicine) use in the community**, in collaboration with the University of Amsterdam, The Netherlands. This course teaches the investigation of medicine use in the community, and how to promote rational use of medicines by consumers. The National Health Policy 2002 of India also emphasizes on the rational use of drugs within the modern medicine system, along with increased access to systems of traditional medicine (67).

• **Drugs and therapeutics committees**, in collaboration with the Rational Pharmaceutical Programme coordinated by Management Sciences for Health, USA. This course teaches methods for evaluating medicine utilization and how to promote rational use of medicines in hospitals and districts.

• **Problem-based pharmacotherapy teaching**, in collaboration with Groningen University, The Netherlands, the University of Cape Town, South Africa, the University of La Plata, Argentina (in Spanish) and the National Centre for Pharmacovigilance, Ministry of Health, Algiers, Algeria (in French). This course teaches a problem-based approach to rational prescribing based on WHO’s Guide to Good Prescribing (68).

• **Pharmacoeconomics**, This course teaches how to do economic evaluation in medicine selection.

• **Drug (medicine) policy issues for developing countries**, in collaboration with Boston University, USA. This course teaches about general medicines policy including aspects relating to promoting more rational use of medicines.

• **ATC/DDD methodology for medicine consumption**, in collaboration with the WHO Collaborating Centre for Drug Statistics Methodology. This course provides an introduction to the application of ATC/DDD methodology in measuring medicine consumption (69) International Network for the Rational Use of Drugs (51).

• **Electronic Prescribing**- The era of e-prescribing has begun. Its implementation is still expensive, but the subsequent benefits to patients and savings in personnel costs, along with its integration with electronic medical records, drug inventory control, and billing, point to the wide use of e-prescribing in the future. Computerized prescription ordering eliminates some of the subjective features of prescribing. Thus, if the proper information is entered correctly in the electronic system, medication errors due to illegible
handwriting, incorrect dose, incorrect medication for medical condition, and
drug interactions can be reduced, because each prescription can be linked to
high-quality drug databases that check that the information on the prescription
is appropriate for the patient (e.g., age, weight, gender, condition, lab values,
disease being treated, concurrent medications) and that known warnings and
potential problems are brought to the attention of the physician, pharmacist,
and patient. Such systems must not be used as a substitute for personal
attention to the individual patient by healthcare workers but, rather, as an
adjunct measure that ensures safe, high-quality, efficient care (70).
Saeed et al have highlighted that there was high incidence of irrational
prescribing practices that increased with the total number of drugs per
prescription. Irrational therapy needs to be identified and weeded out. The
results of study call for interventional strategies to promote rational drug
therapy (70).

3.4.2 WHO activities to improve rational use of medicine (71)

To improve rational medicine use, WHO:

- monitors global medicine use and pharmaceutical policy;
- provides policy guidance and support to countries in monitoring medicine use
  and to develop, implement and evaluate national strategies to promote rational
  use of medicines;
- develops and delivers training programmers’ to national health professionals
  on how to monitor and improve medicines use at all levels of the health
  system (55).

3.4.3 Core policies to promote more rational use of medicines

Although many gaps remain in our knowledge, a summary of what is known
concerning core policies, strategies and interventions to promote more rational use of
medicines are as below:

Twelve core interventions to promote more rational use of medicines (55)
1. A mandated multi-disciplinary national body to coordinate medicine use policies

Many societal and health system factors, as well as professionals and many others, contribute to how medicines are used. Therefore, a multi-disciplinary approach is needed to develop, implement and evaluate interventions to promote more rational use of medicines. A national regulatory authority (RA) is the agency that develops and implements most of the legislation and regulation on pharmaceuticals. Ensuring rational use will require many additional activities which will need coordination with many stakeholders. Thus a national body is needed to coordinate policy and strategies at national level, in both the public and private sectors. The form this body takes may vary with the country, but in all cases it should involve government (ministry of health), the health professions, academia, the RA, pharmaceutical industry, consumer groups and non-governmental organizations involved in health care. The impact on medicine use is better if many interventions are implemented together in a coordinated way, single interventions often having little impact.

2. Clinical guidelines

Clinical guidelines (standard treatment guidelines, prescribing policies) consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. Evidence-based clinical guidelines are critical to promoting rational use of medicines. Firstly, they provide a benchmark of satisfactory diagnosis and treatment against which comparison of actual treatments can be made. Secondly, they are a proven way to promote more rational use of medicines provided they are: (1) developed in a participatory way involving end-users; (2) easy to read; (3) introduced with an official launch, training and wide dissemination; and (4) reinforced by prescription audit and feedback. Guidelines should be developed for each level of care (ranging from paramedical staff in primary health care clinics to specialist doctors in tertiary referral hospitals), based on prevalent clinical conditions and the skills of available prescribers. Evidence-based treatment recommendations and regular updating help to ensure credibility and acceptance of the guidelines by practitioners.

3. Essential Medicines List based on treatments of choice

Essential medicines are those that satisfy the priority health care needs of the population. Using an essential medicines list (EML) makes medicine management
easier in all respects; procurement, storage and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals if they have to know about fewer items. A national EML should be based upon national clinical guidelines. Medicine selection should be done by a central committee with an agreed membership and using explicit, previously agreed criteria, based on efficacy, safety, quality, cost (which will vary locally) and cost-effectiveness. EMLs should be regularly updated and their introduction accompanied by an official launch, training and dissemination. Public sector procurement and distribution of medicines should be limited primarily to those medicines on the EML, and it must be ensured that only those health workers approved to use certain medicines are actually supplied with them. Government activities in the pharmaceutical sector (e.g. quality assurance, insurance reimbursement policies and training), should focus on the EML. The WHO Model List of Essential Medicines can provide a starting point for countries to develop their own national EML. The latest edition of WHO EDL is October, 2013 (72) and Current National Essential drug list available in India is 2011(73).

4. Drugs and therapeutics committees in districts and hospitals

A drugs and therapeutics committee (DTC), also called a pharmacy and therapeutics committee, is a committee designated to ensure the safe and effective use of medicines in the facility or area under its jurisdiction. Such committees are well-established in industrial countries as a successful way of promoting more rational, cost effective use of medicines in hospitals. Governments may encourage hospitals to have DTCs by making it an accreditation requirement to various professional societies. DTC members should represent all the major specialties and the administration; they should also be independent and declare any conflict of interest. A senior doctor would usually be the chairperson and the chief pharmacist, the secretary. Factors critical to success include: clear objectives; a firm mandate; support by the senior hospital management; transparency; wide representation; technical competence; a multidisciplinary approach; and sufficient resources to implement the DTC’s decisions.

The operation of Drug and therapeutics committee (DTC) in health establishments has become a norm to ensure good management and rational use of drugs. The availability
of functional DTC in hospitals is a prerequisite for accreditation in the USA, and almost all hospitals in Australia and United Kingdom have DTCs.

5. Problem-based training in pharmacotherapy in undergraduate curricula

The quality of basic training in pharmacotherapy for undergraduate medical and paramedical students can significantly influence future prescribing. Rational pharmacotherapy training, linked to clinical guidelines and essential medicines lists, can help to establish good prescribing habits. Training is more successful if it is problem-based, concentrates on common clinical conditions, takes into account students’ knowledge, attitudes and skills, and is targeted to the students’ future prescribing requirements. The Guide to Good Prescribing is a publication that describes the problem-based approach, which has been adopted in a number of medical schools.

Clinical pharmacology and therapeutics (CPT) envisages undergraduate (UG) medical students being able to plan, select, communicate, and guide patients throughout their illness to use medicines and other devices. The main objective of CPT is to impart knowledge, skills, and attitudes so that a student is able to check risk benefit ratio of treatment along with cost-effectiveness, understand the sources of variability in responses to medicine, best prescribing decisions on sound evidence, and monitor medicine effects appropriately (74).

It develops the premise that a thorough understanding of basic principles translates into good prescribing, and lists essential attributes for prescribers under three headings concerning the use of drugs: knowledge, understanding, skills, and attitudes. This curriculum should form the basis of teaching better prescribing at all UK medical schools, and elsewhere could be adapted to local needs (75).

It includes the establishment of local student formularies as a teaching tool, a concept that could be extended to the training of junior hospital doctors and other prescribers. The uses of problem-based, computer-aided, and web-based teaching -learning in other countries have been discussed (76). No single intervention can be relied upon to improve prescribing, and a combination of multiple interventions may be required (77). However, education must be the kingpin. An educational intervention program led by the practicing pharmacist will be considered and applied (78). The impact evaluation of such program will be done by detecting level of errors before and after
Clinical pharmacology and therapeutics education has been integrated progressively into the UG curricula of many countries, such as the US, UK, India, Nepal, and the Netherlands (80-84).

The process of rational therapy- A good scientific experiment follows a rather rigid methodology with a definition of the problem, a hypothesis, an experiment, an outcome and a process of verification. This process, and especially the verification step, ensures that the outcome is reliable. The same principles apply when you treat a patient. First we need to define carefully the patient's problem (the diagnosis). After that, specify the therapeutic objective, and to choose a treatment of proven efficacy and safety, from different alternatives. Then start the treatment, for example by writing an accurate prescription and providing the patient with clear information and instructions. After some time monitors the results of the treatment; only then we will know if it has been successful. If the problem has been solved, the treatment can be stopped. If not, then need to re-examine all the steps. Choose P-treatment on the basis of efficacy, safety, suitability and cost (68)

The process of rational treatment

**Step 1: Define the patient's problem**

The Diagnosis/ based on symptoms

**Step 2: Specify the therapeutic objective**

What do you want to achieve with the treatment?

**Step 3: Verify the suitability of your P-treatment**

Check effectiveness and safety

**Step 4: Start the treatment**

**Step 5: Give information, instructions and warnings**

**Step 6: Monitor (and stop) treatment** (68)

6. Continuing in-service medical education as a licensure requirement
Continuing in-service medical education (CME) is a requirement for licensure of health professionals in many industrialized countries. In many developing countries opportunities for CME are limited and there is also no incentives since it is not required for continued licensure. CME is likely to be more effective if it is problem-based, targeted, involves professional societies, universities and the ministry of health, and is face-to-face. Printed materials that are unaccompanied by face-to-face interventions, have been found to be ineffective in changing prescribing behavior. CME need not be limited only to professional medical or paramedical personnel, but may also include people in the informal sector such as medicine retailers. Often CME activities are heavily dependent on the support of pharmaceutical companies, as public funds are insufficient. This type of CME may not be unbiased. Governments should therefore support efforts by university departments and national professional associations to give independent CME.

It has been observed that some of the Medical Institutes in Gujarat have developed and implemented changes in practical training in Pharmacology emphasizing prescription writing skill (84).

7. Supervision, audit and feedback

Supervision is essential to ensure good quality of care. Supervision that is supportive, educational and face to-face, will be more effective and better accepted by prescribers than simple inspection and punishment. Effective forms of supervision include prescription audit and feedback, peer review and group processes. Prescription audit and feedback consists of analyzing prescription appropriateness and then giving feedback. Prescribers may be told how their prescribing compares with accepted guidelines or with that of their peers. Involving peers in audit and feedback (peer review) is particularly effective. In hospitals, such audit and feedback is known as drug use evaluation.

Assessing the problem of irrational use

To address irrational use of medicines, prescribing, dispensing and patient use should be regularly monitored in terms of:

- **Types** of irrational use, so that strategies can be targeted towards changing specific problems;
• **Amount** of irrational use, so that the size of the problem is known and the impact of the strategies can be monitored;

• **Reasons** why medicines are used irrationally, so that appropriate, effective and feasible strategies can be chosen. People often have very rational reasons for using medicines irrationally. There are several well-established methods to measure the type and degree of irrational use. Aggregate medicine (drug) consumption data can be used to identify expensive medicines of lower efficacy or to compare actual consumption versus expected consumption (from morbidity data). Anatomical Therapeutic Classification (ATC)/Defined Daily Dose (DDD) methodology can be used to compare drug consumption among institutions, regions and countries. WHO drug use indicators (69) can be used to identify general prescribing and quality of care problems at primary health care facilities. Focused drug use evaluation (drug utilization review) can be done to identify problems concerning the use of specific medicines or the treatment of specific diseases, particularly in hospitals. The qualitative methods employed in social science, (e.g. focus group discussion, in-depth interviews, structured observation and structured questionnaires), can be used to investigate the motives underlying irrational use. The data collected can then be used to design appropriate interventions and to measure the impact of those interventions on medicine use.

Group process approaches amongst prescribers consist of health professionals themselves identifying a medicine use problem and developing, implementing and evaluating a strategy to correct the problem. This process needs facilitation by a moderator or supervisor.

According to a Cochrane Review, audit and feedback is defined as a summary of health care performance over a specified period of time with or without recommendations for a clinical action. Evidence from 118 randomized controlled trials indicated that audit and feedback resulted in a modest improvement in care. Grimshaw and colleagues undertook a comprehensive review of the effects of using different strategies for implementing guidelines. They found that audit and feedback alone or combined with educational meetings and materials result in a modest improvement in the implementation of guidelines in comparison to no intervention group (85, 86). Other study concluded that constant review of the teaching and evaluation methods through feedback from students and modification of the
methodologies is very important for planning the undergraduate medical curriculum (87).

8. Independent medicine information

Often, the only information about medicines that practitioners receive is provided by the pharmaceutical industry and may be biased. Provision of independent (unbiased) information is therefore essential. Drug information centers (DICs) and drug bulletins are two useful ways to disseminate such information. Both may be run by government or a university teaching hospital or a nongovernmental organization, under the supervision of a trained health professional. Whoever runs the DIC or bulletins must (1) be independent of outside influences and disclose any financial or other conflict of interest, and (2) use evidence-based medicine and transparent deduction for all recommendations made. The WHO Model Formulary provides independent information on all medicines in the WHO Model List of Essential Medicines. Drug information is the provision of written and/or verbal information about drugs and drug therapy in response to a request from other healthcare providing organizations, committees, patients, and public community. Drug information services refer to the activities undertaken by pharmacists in providing information to drug use (88).

Poor drug regulations and lack of independent, unbiased drug information are the main contributing reasons for irrational drug use in India. About 40% of the health care service's budget is consumed by medicines and with a limited resource available, it becomes essential to promote rational drug use (47).

9. Public education about medicines

It is obvious that without adequate knowledge about the risks and benefits of using medicines and when and how to use them, people will often not get the expected clinical outcomes and may suffer adverse effects. This is true for prescribed medicines, as well as over-the-counter medicines. Governments have a responsibility to ensure both the quality of medicines and the quality of the information about medicines available to consumers. This will require:

• Ensuring that over-the-counter medicines are sold with adequate labeling and instructions that are accurate and legible, understood by laypersons. The information should include the medicine name, indications, contra-indications, dosages, drug interactions, and storage.
• Monitoring and regulating advertising, which may adversely influence consumers as well as prescribers, and which may occur through television, radio, newspapers and the internet (71).

• Education about the use of medicines may be introduced into the health education component of school curricula or into adult education programmers such as literacy courses. In India government and regulatory health care amenities developed certain health care awareness programmes like TB awareness programmes, ORS promotions for diarrhea treatment. They are in place and in touch with community through audio visual means (Television advertisements), through banner and display at government hospitals.

10. Avoidance of perverse financial incentives
Financial incentives may strongly promote rational or irrational use. Examples include:
• Prescribers who earn money from the sale of medicines (e.g. dispensing doctors), prescribe more medicines, and more expensive medicines, than prescribers who do not; therefore the health system should be organized so that prescribers do not dispense or sell medicines.
• Flat prescription fees, covering all medicines in whatever quantities within one prescription, lead to over prescription; therefore user charges should be made per medicine, not per prescription.
• Dispensing fees, calculated as a percentage of the cost of the medicines, encourage the sale of more expensive medicines; therefore a flat dispensing fee irrespective of the price of the medicine is preferable. Although it may increases cost of cheaper medicines and it lowers the price of higher cost medicines.

Patients prefer medicines that are free or reimbursed. If only essential medicines are provided free by government or reimbursed through insurance so patients will pressure prescribers to prescribe only essential medicines. If medicines are only reimbursed when the prescription conforms to clinical guidelines, there may be an even stronger pressure on prescribers to prescribe rationally (67).

11. Appropriate and enforced regulation
Regulation of the activities of all actors involved in the use of medicines is critical to ensuring rational use. If regulations are to have any effect, they must be enforced, and
the regulatory authority must be sufficiently funded and backed up by the judiciary (67).

12. Sufficient government expenditure to ensure availability of medicines and staff
Lack of essential medicines would lead to the use of nonessential medicines, and lack of appropriately trained personnel leads to irrational prescribing. Furthermore, without sufficient competent personnel and finances, it is impossible to carry out any of the core components of a national programme to promote rational use of medicines. Poor clinical outcome, needless suffering and economic waste are sufficient reasons for large government investment.
Governments are responsible for investing the necessary funds to ensure that all public health facilities have sufficient, appropriately trained health professionals and enough essential medicines at affordable prices for all the population. Achieving these will require limiting government procurement and supply to essential medicines only, and investing in adequate training, supervision and health staff salaries (67).

Regulatory measures to support rational use
• Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market and that unsafe non-efficacious medicine are banned;
• Limiting prescription of medicines by level of prescriber; this includes limiting certain medicines to being available only with a prescription and not available over-the-counter;
• Setting educational standards for health professionals and developing and enforcing codes of conduct; this requires the cooperation of the professional societies and universities;
• Licensing of health professionals – doctors, nurses, paramedics – to ensure that all practitioners have the necessary competence with regard to diagnosis, prescribing and dispensing;
• Licensing of medicine outlets – retail shops, wholesalers – to ensure that all supply outlets maintain the necessary stocking and dispensing standards;
• Monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative,
balanced, up-to-date, capable of substantiation and in good taste. WHO’s ethical
guideline (1988) may be used as a basis for developing control measures (67, 71).
3.5 Why Do We Need Prescribing Quality Evaluation?

In spite of all measures developed at various stages like local, state, national & international level, the situation still needs improvement and as reviewed previously inappropriate or irrational prescribing is widespread all over the world. To improve the situation further stringent continuous efforts will be required. The first step in this direction would be to assess the quality of prescribing at local, state, national & International level. Several tools have been developed and introduced from time to time for this purpose. They ranged from simple tools (WHO core prescribing indicators) to complex tools (Beer’s criteria, explicit criteria, Medication Appropriateness Index).

3.5.1 Introduction to tools to assess quality of prescribing

During the last few decades there has been an increased focus on quality development in medical care, and the area of pharmacotherapy and prescribing is no exception from this general tendency. Using a slight modification of an existing well-established definition, Lawrence, M. has define prescribing quality indicator as “a measurable element of prescribing for which there is evidence or consensus that it can be used to assess quality, and hence change in the quality, of treatment provided” (89). Quality of drug treatment in this context can be considered equivalent to rational pharmacotherapy, covering the aspects of effectiveness (maximizing benefit), safety (minimizing harm), economy (minimizing costs or maximizing cost-effectiveness) and patient acceptance of treatment (45). Quality indicators can be valuable tools both in the hospital and primary care setting. This review will focus on prescribing quality indicators in general practice.

A large number of candidate indicators of prescribing quality based on register data have been constructed and validated by consensus methods. Few studies have systematically analyzed other validity aspects of these indicators. (90) Indicators are used for a number of different purposes, covering quality management in a broad sense. At the professional level, physicians use indicators for quality development and educational activities, assisting learning processes (91). The indicators or tools are used by researchers to evaluate interventions, for example in experimental randomized studies testing new methods for changing prescribing behavior (92).
Finally, indicators are increasingly used by administrators of the health system for monitoring quality, screening for quality problems, benchmarking and providing feedback to physicians (90).

Different types of drug use studies evaluating the quality of prescribing are reported from all over the world (8). However, one of the great limitations in measuring the quality of prescription is lack of a method that is sufficiently valid and reliable to allow systematic use in clinical setting (8). Various measures have been developed to evaluate prescribing quality, e.g. explicit indicators (26, 27) like The Medication Appropriateness Index (MAI) developed by Hanlon et al. (28) at Duke University Medical Centre (Durham, NC, USA) to evaluate the appropriateness of medication use in individual patients has been found to be reliable and valid in a number of clinical settings, WHO prescribing indicators, it has been formulated as a set of "Core drug use indicators" namely prescribing indicators, patient care indicators and facility indicators (29) and multidimensional indicators, it includes multidisciplinary medication review (28, 30).

The Swedish National Board of Health and Welfare has established explicit indicators for evaluation of drug therapy among elderly patients (31). For geriatric prescribing, several criteria or tools are used. Beers' criteria include explicit (criterion-based) or implicit (judgement-based) prescribing indicators (29) for evaluating prescribing practice for elderly patients. More recently, the STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions) criteria were validated in a European setting (30) and the START (Screening Tool to Alert doctors to the Right Treatment) criteria, which highlight under prescription or omission of clinically indicated, evidence based medications (31), for evaluating quality of prescribing to elderly were introduced but they are not specifically designed to address the multiple problems associated with prescription quality(8).

However, there is no universal definition of medication appropriateness, because quality may be assessed in different ways, depending on data available (prescription database vs. individual assessments), setting, and comprehensiveness. Most of measures are based on expert judgment of practitioners or consensus (93, 97, 34-36), without information on the psychometric properties of the instruments. Thus there is
a lack of a single tool that will capture all facets of prescription quality and which is applicable for measurement of prescription quality in chronic diseases, especially those with multiple co morbidities (8).

Elderly patients are at high risk of drug-related problems, for several reasons: age-related changes in the pharmacokinetics and pharmacodynamics of medicines; higher incidence of polymedication; lack of knowledge of the prescriber specific to the use of medicines in the elderly; frequent cognitive and physical impairment; multiple prescribers. There is strong evidence from the literature that use of medicines in that population is often far from ideal. More than 50% of adverse drug events are potentially preventable. Opportunities for improvement can occur at several steps of medication use process (prescription, administration, follow-up, education, and compliance) (94, 95).

3.5.2 Brief Introduction to Various Indicators and tools

Prescribing indicators are commonly used in the public sector to gain an impression of a quality of services. If they are developed and used appropriately they can help to identify potential problems and encourage quality improvement and/ or improved safety. In the UK, there is a long history of indicators being used to show how prescribing performance of NHS general practices might compare with other practices, local and national averages or with themselves over time. The National Prescribing Centre and the Prescribing Indicators National Group recommend that prescribing indicators should:

- be based on scientific evidence and supplemented in a systematic way by expert opinion
- cover a range of process and outcome measures
- represent areas where change is largely within the control of the clinician
- represent areas of practice that are regarded as important by clinicians and consistent with national health policy initiatives
- represent areas of practice where the most important case mix and risk adjustment factors are known and data about them can be collected
- be based on clinical data that:
  - should be recorded by clinicians as part of the process of clinical care
- should be electronically recorded in clinical records using current clinical terminologies and codes
- can be extracted in a timely manner
- are sensitive to changes in quality of care
- can be easily checked for validity and reliability (96).

Indicators based on the use of GP prescribing data continue to be employed regularly in the UK, and continue to form part of local prescribing incentive schemes. Nevertheless, while potentially extremely useful for analyzing prescribing patterns, these data are rarely linked to diagnoses and patient characteristics and so they have limitations when assessing quality and safety. Other indicators have required very detailed analysis and assessment of clinical records e.g. the medication appropriateness index (97). These are potentially very useful for research purposes, but are not feasible for the large-scale assessment GP prescribing.

A major advance in recent years in terms of developing and using more sophisticated indicators of quality and safety of prescribing has involved the interrogation of electronic medical records. This has come about because of considerable improvements in the quality and completeness of electronic records in general practices, and also due to developments in the ability to run electronic searches and analyze the results across large numbers of practices. Table 2 summarizes some of the indicators.
<table>
<thead>
<tr>
<th>Indicator /Tool</th>
<th>Content</th>
<th>Type / Method</th>
<th>Strength</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO core Prescribing Indicators (29)</td>
<td>5 Indicators</td>
<td>Explicit (criterion-based)</td>
<td>data expressed as percentage, mean and total numbers</td>
<td>Cover limited parameters of appropriate therapy reliability is lower when assessed by researchers different from the authors</td>
</tr>
<tr>
<td>Medication Appropriateness Index (28)</td>
<td>10 Criteria</td>
<td>Implicit (judgment-based)</td>
<td>Addresses all medications</td>
<td>Requires expertise in geriatric medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Addresses multiple aspects of prescribing</td>
<td>Variable inter-rater reliability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Does not require regular updating</td>
<td>Time consuming (10 min per medication)</td>
</tr>
<tr>
<td>McLeod (1997)</td>
<td>38 Indicators</td>
<td>Delphi Validation Explicit (criterion-based)</td>
<td>A Canadian initiative, were developed following the Beers criteria 1991, based on risk-benefit ratios, drug-drug interactions and drug-disease interactions, and describing 38 prescribing practices</td>
<td>limited applicability to geriatric clinical practice</td>
</tr>
<tr>
<td>IPET 2000 Improving Prescribing in the Elderly Tool -</td>
<td>14 different drug/disease interactions</td>
<td>Based on McLeod Criteria</td>
<td>does not address the occurrence of potential prescribing omissions</td>
<td></td>
</tr>
</tbody>
</table>
Canadian guideline which was derived from the criteria developed by McLeod et al., not been widely or extensively used

**Beers criteria**

(27) (updated in 2003) for potentially inappropriate medication use in older adults
Recently updated in 2012

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Delphi Validation</th>
<th>Relatively quick to use</th>
<th>Need regular updating</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Explicit (criterion-based)</td>
<td>Some criteria do not require clinical data and can be applied to large prescribing databases</td>
<td>Address a limited range of medications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can be used as indicators of quality of care</td>
<td>Do not address all aspects of prescribing, e.g. duration of therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can be integrated into decision support software</td>
<td>Do not take into account patient’s clinical situation, e.g. life expectancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>May not be easily transferable between Countries</td>
</tr>
</tbody>
</table>

**STOPP/START**

(33) Developed to assess the appropriateness of prescribing for older people

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Delphi validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOPP – 65 criteria</td>
<td>Explicit Delphi validation</td>
</tr>
<tr>
<td>START- 22 Criteria</td>
<td>Widely used in different settings to study the prevalence of inappropriate prescribing in the older population</td>
</tr>
</tbody>
</table>

**ACOVE (Assessing Care of Vulnerable Elders)**

(99) UK and the Netherlands

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Aimed to develop a set of evidence-based, quality of care indicators relevant to vulnerable older people</th>
</tr>
</thead>
<tbody>
<tr>
<td>102</td>
<td></td>
</tr>
</tbody>
</table>
• Indicators that focus primarily on elderly potential prescribing safety:

ACOVE (Assessing Care of Vulnerable Elders) – this RAND project aimed to develop a set of evidence-based, quality of care indicators relevant to vulnerable older people using systematic literature reviews, expert opinion and guidance from expert groups and stakeholders. The indicators have been considered for use in the UK and the Netherlands. A multidisciplinary panel of 10 health professionals in the UK accepted 102 (86 per cent) of the 119 quality indicators as being valid for use in England (99).

PINCER trial indicators – a cluster randomized trial took place in the UK between 2005 and 2009 to assess a pharmacist-led intervention versus simple feedback in correcting clinically important problems in medicines management in general practices in England (100). This was a parallel-group, pragmatic, cluster trial in which 72 general practices in England were randomized to either: (1) computer-generated feedback (‘simple feedback’) in which practices were asked to make changes to patients’ medication within a 12-week period, or (2) the pharmacist-led intervention comprising computer-generated feedback, educational outreach and dedicated support. The pharmacist-led complex intervention was successfully delivered in all 36 general practices. Preliminary results indicate that compared with simple feedback, the pharmacist-led intervention resulted in reductions in the proportion of patients at risk of prescribing and monitoring errors (100).

STOPP and START tools (Gallagher et al 2008) – these sets of indicators have been developed to assess the appropriateness of prescribing for older people (the STOPP tool relates to potentially inappropriate drugs and the START tool relates to potentially indicated appropriate drugs). The tools have been developed and validated by a team from Cork, Republic of Ireland (33).

The Medication Appropriateness Index: (MAI) measures the appropriateness of prescribing for elderly patients, using 10 criteria for each medication prescribed. For
each criterion, the evaluator rates whether the medication is appropriate, marginally appropriate, or inappropriate. Support is provided through explicit definitions and instructions. The MAI has been used in observational and interventional studies. Its feasibility, content validity, predictive validity, and reliability have been demonstrated in ambulatory settings. Its limitations are that reliability was lower when assessed by researchers different from the authors and that the original instrument does not address some areas (drug allergy, adverse drug reactions, compliance) (28).

### Table 3: Medication Appropriateness Index

<table>
<thead>
<tr>
<th>Table 1. Medication Appropriateness Index*</th>
</tr>
</thead>
<tbody>
<tr>
<td>To assess the appropriateness of the drug, please answer the following questions and circle the applicable score:</td>
</tr>
</tbody>
</table>

| 1. Is there an indication for the drug? | 1 | 2 | 3 | 9 | DK* |
| Comments: | 1 | 2 | 3 | 9 | DK* |
| 2. Is the medication effective for the condition? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 3. Is the dosage correct? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 4. Are the directions correct? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 5. Are the directions practical? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 6. Are there clinically significant drug-drug interactions? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 7. Are there clinically significant drug-disease/condition interactions? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 8. Is there unnecessary duplication with other drug(s)? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 9. Is the duration of therapy acceptable? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |
| 10. Is this drug the least expensive alternative compared to others of equal utility? | 1 | 2 | 3 | 9 | DK |
| Comments: | 1 | 2 | 3 | 9 | DK |

*Complete instructions in the use of the scale are available upon request.  
**Don’t know.

### Explicit criteria

Several studies have been conducted to determine and formulate lists of explicit criteria.
• **McLeod criteria**

McLeod et al. developed a Canadian consensus-based, explicit list of criteria to identify PIP in older patients in 1997. The criteria were validated by a panel of 32 experts in geriatric pharmacotherapy from diverse locations in Canada and consisted of clinical pharmacologists, geriatricians, GPs and pharmacists. The final list of criteria contains 38 scenarios of PIP (18 medications contraindicated in older adults, 16 drug-disease interactions and 4 drug-drug interactions that should be avoided in the older person) (McLeod et al. 1997). The criteria are divided into four main headings: medicines for the Cardiovascular System (CVS) (n=8), psychotropics (n=12), non-steroidal anti-inflammatory drugs (NSAIDs) (n=11) and miscellaneous (n=7). Each criterion was qualified with a statement of a risk to patients and an alternative therapy was suggested. This screening tool did not address under-prescribing of indicated medicines (PPOs) and did not state medication dosages that should be avoided in older patients (98).

• **Improving Prescribing in the Elderly Tool (IPET)**

Naugler et al. formulated the Improving Prescribing in the Elderly Tool (IPET) (99). It is a Canadian guideline which was derived from the criteria developed by McLeod et al., based on the most prevalent instances of PIP found in a geriatric unit using the McLeod criteria. IPET lists 14 different drug/disease interactions which should be avoided in the older person but does not address the occurrence of potential prescribing omissions (PPOs). This tool has not been widely or extensively used in determining PIP, possibly owing to its brevity and that one of the listed instances of PIP has been superseded with newer evidence i.e. it states that β blockers should not be used in patients with CCF (98).

• **Beers’ Criteria**

Beers’ criteria, a United State (US) based guideline, was originally formulated in 1991 (Beers et al. 1991). This screening tool contains a list of 30 medicines that should not be used in older patients. It was compiled for nursing home residents who are considered frailer, older and sicker than the general elderly population. The authors therefore cautioned that modifications may be necessary if the criteria were to be applied to older patients in a non-nursing home setting. The 1991 criteria were
updated and expanded in 1997 to make the criteria more applicable to the general older population (26).

The guidelines consist of two different lists or situations in which medicines should be avoided; one considering diagnosis (CD) and one independent of diagnosis (ID). Doses or frequencies of administrations that should not be exceeded were also listed. The 1997 criteria were revised and updated in 2003 (27). A 12-member expert panel consisting of psycho-pharmacologists, pharmacoepidemiologists, clinical geriatric pharmacologists and clinical geriatricians from diverse geographical locations in the US completed the study which used a modified Delphi technique to reach consensus for each criterion. Eleven criteria that were listed in the 1997 tool were excluded from the 2003 list, one from the ID lists (phenylbutazone) and ten from the CD lists. Twenty five medicines were added to the ID list and 19 were added to the CD list. Four criteria were modified. The new criteria list 48 medicines ID and 20 medicines CD that should be avoided. It also rates the severity of the PIM into instances of “high severity” or “low severity” and provides a qualifying statement as to why the scenario is considered potentially inappropriate. Beers’ criteria do not address errors of prescribing omission and list several medicines as inappropriate that are not available or prescribed in Northern Ireland and the Republic of Ireland.

Beers criteria (Fick et al 2003) are a set of criteria from the US for assessing potentially inappropriate medication use in people aged 65 years and older. The original list of criteria was published in the 1990s and updated in 2003. Beers criteria have been recently revised by American Geriatrics Society 2012 (101).

**Screening Tool of Older People’s potentially inappropriate Prescriptions (STOPP) and Screening Tool to Alert doctors to Right i.e. appropriate, indicated but often omitted Treatments (START)**

Screening Tool of Older People’s Prescriptions (STOPP) and Screening Tool to Alert doctors to Right i.e. appropriate, indicated but often omitted Treatments (START) were formulated collaboratively by the Department of Geriatric Medicine, Cork University Hospital (CUH) and the School of Pharmacy, University College Cork (UCC) (33). The new screening tool addresses common instances of PIP (STOPP) and potential prescribing omissions (PPOs) (START). The STOPP tool lists 65 instances of PIP and is divided into ten sections according to the physiological
systems to which the instances of PIP relate. The START tool lists 22 common instances of PPOs divided into six physiological systems to which the PPOs pertain. The initial list of criteria was formulated based on a combination of evidence and common instances of PIP and PPOs observed throughout clinical working practice.

The STOPP and START tools were validated by the Delphi validation method. Eighteen experts in geriatric pharmacotherapy from diverse geographical locations throughout Ireland and the UK rated their level of agreement with each criterion on a five-point Likert scale. Agreement was achieved by the first Delphi validation round for all of the 22 criteria in the START tool and therefore all of these were included in the final published version of the START tool. Two postal rounds of the STOPP tool were required as the panel did not reach full consensus on the first round, the initial STOPP tool contained 68 criteria and the final STOPP tool contained 65 criteria. A number of studies have reported on the prevalence of IP in the older population from different health care settings (33).

- **Indicators that focus general prescribing quality:**

  **National Patient Safety Agency (NPSA) documents** – the NPSA has produced a number of documents that are relevant to the safety of prescribing in primary care (102). For example, the fourth report from the Patient Safety Observatory (103) highlighted medication incidents in the community and at the interface between community and hospital care and also suggested ways in which risks of harm could be reduced. In addition, the NPSA has highlighted a number of specific safety issues relevant to primary care including anticoagulant prescribing, dosing errors with opioid medicines and the prescribing of methotrexate (NPSA 2009). A number of these issues could be incorporated into indicators (102).

  **WHO prescribing indicators:** the World Health Organization (WHO) in 1993 has formulated a set of "Core drug use indicators" namely prescribing indicators, patient care indicators and facility indicators. Among them, for this study only "prescribing indicators" were taken which measure the performance of prescribers. The core prescribing indicators are average number of drugs per prescription, percentage of drugs prescribed by generic name, percentage of encounters with an antibiotic
prescribed, percentage of encounters with an injection prescribed and percentage of drugs prescribed from essential drug list or formulary.

Some additional indices are percentage of encounters with a NSAID prescribed, percentage of encounters with an antiulcerant prescribed, percentage of encounters with a calcium preparation prescribed and the data was expressed as percentage, mean and total numbers (29).

Selected WHO/INRUD drug use indicators for primary health care facilities (WHO, 1993) (29)

**Prescribing Indicators:**
Average number of medicines prescribed per patient encounter
% medicines prescribed by generic name
% encounters with an antibiotic prescribed
% encounters with an injection prescribed
% medicines prescribed from essential medicines list or formulary

**Patient Care Indicators:**
Average consultation time
Average dispensing time
% medicines actually dispensed
% medicines adequately labeled
% patients with knowledge of correct doses

**Facility Indicators:**
Availability of essential medicines list or formulary to practitioners
Availability of clinical guidelines
% key medicines available

**Complementary Drug Use Indicators:**
Average medicine cost per encounter
% prescriptions in accordance with clinical guidelines
### Table 4: Review of relevant studies

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Studies related to</th>
<th>Reported/findings</th>
<th>Inference</th>
<th>Authors (Reference No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prescribing errors</td>
<td>A total of 1,115 clinically significant prescribing errors involving medication dosage forms were detected</td>
<td>Hospitalized patients are at risk for adverse outcomes due to prescribing errors related to inappropriate use of medication dosage forms. This information should be considered in the development of strategies to prevent adverse patient outcomes resulting from such errors</td>
<td>Timothy S Lesar - 2002, (104)</td>
</tr>
<tr>
<td>2</td>
<td>Prescribing error</td>
<td>A total of 196 (89.9 %) MAEs were identified from the 218 observations made. From these, 178 (90.8 %) occurred with intravenous (IV) bolus medications while 16 (8.2 %) of them pertained to oral medications.</td>
<td>There is a need to modify the way information is handled and shared by professionals as wrong time error was the most implicated error.</td>
<td>Yemisirach Feleke et al. - 2010, (105)</td>
</tr>
<tr>
<td>3</td>
<td>Prescribing error</td>
<td>Of all prescriptions collected, 21% (n = 373) contained at least one error. Prescriptions with omissions accounted for 39% of those with errors and 5% of all prescriptions.</td>
<td>The physician's effort in determining the correct diagnosis and then choosing the best medication for the</td>
<td>Allen F et al. - 1989, (106)</td>
</tr>
<tr>
<td>No.</td>
<td>Prescribing Error</td>
<td>Prescription Details</td>
<td>Literature Review</td>
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<tr>
<td>4</td>
<td>Prescribing error</td>
<td>Errors in dosage or directions or incomplete directions were found in 117 (6%) of the study prescriptions.</td>
<td>Patient and illness can be undermined by a written prescription with erroneous intention of the prescriber</td>
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<tr>
<td>5</td>
<td>Prescribing error</td>
<td>The medication errors were analyzed by means of Micromedex Drug-Reax database. Of the 304 cases, 103 (34%) cases had at least one error. The total number of errors found was 157.</td>
<td>Strong Intervention could be made by clinical pharmacist, and to begin with, could confine to identification of the medication errors</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Prescribing error</td>
<td>Out of total 397 prescriptions screened, 96.7% had one or more of the legal or procedural requirements missing. Additionally, 8.4% of the prescribed drugs had errors of commission. A total of 39 drug–drug interactions were identified.</td>
<td>This indicates a need for pharmacy and medical educators to further emphasize the importance of writing clear and complete prescriptions. It also calls for the implementation of educational and monitoring programmes and hence minimize the occurrence of prescribing errors.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Prescribing error</td>
<td>From a total of 6340 prescriptions, 43 prescriptions</td>
<td>There should be the importance of Chua Siew</td>
<td></td>
</tr>
<tr>
<td>Error</td>
<td>Description</td>
<td>Source:</td>
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<tr>
<td>Error</td>
<td>(0.68%) required interventions by the pharmacy staff. These included 54% errors of omission and 46% that contained the wrong drug, dose regimen, strength and dosage form (errors of commission).</td>
<td>Siang et al. - 2003, (110)</td>
<td></td>
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<tr>
<td>Prescribing error</td>
<td>Out of 756 inpatients included, overall 23.9% of prescriptions were illegible and 29.9% of prescriptions were incomplete. Legibility and completeness are higher in unusual drugs prescriptions. The overall illegibility and incompleteness (above 20%) were unacceptably high.</td>
<td>Laura Calligaris et al. - 2009, (111)</td>
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<tr>
<td>Prescribing error</td>
<td>The prescription error related to prescriber’s name, qualification, NMC registration number and signature were 85.4%, 99.6%, 99.6% and 15.7% respectively. Similarly, the symbol Rx was missing in 66.8%. Dosage form, quantity, dose, frequency and route of administration were not mentioned in 12%, 60%, 19%, 10% and 63% of the prescriptions respectively. Likewise, strength of the prescribed medicines was not stated in 40% of the cases.</td>
<td>Ansari M et al.- 2009, (112)</td>
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<td>10</td>
<td>Patient error</td>
<td>Authors synthesized the ideas that emerged from the nominal groups into taxonomy of patient errors. The taxonomy is a 3-level system encompassing 70 potential types of patient error. The first level classifies 8 categories of error into 2 main groups: action errors and mental errors. The action errors, which result in part or whole from patient behavior, are attendance errors, assertion errors, and adherence errors. The mental errors, which are errors in patient thought processes, comprise memory errors, mindfulness errors, misjudgments, and—more distally—knowledge deficits and attitudes not conducive to health.</td>
<td>The taxonomy is an early attempt to understand and recognize how patients may err and what clinicians should aim to influence so they can help patients act safely.</td>
<td>Stephen Buetow et al.-2009, (113)</td>
</tr>
<tr>
<td>11</td>
<td>Prescribing error</td>
<td>Of 4238 prescriptions evaluated, one or more error was observed in 1857 (43.8%) prescriptions, with a total of 3011 errors observed. Of these, 1264 (41.9%) were minor, 1629 (54.1%) were significant, 109 (3.6%) were serious and 9 (0.30%) were potentially life threatening.</td>
<td>The electronic prescribing systems could potentially have prevented up to a quarter of (but not all) errors.</td>
<td>Seden K et al.-2012, (114)</td>
</tr>
<tr>
<td>12</td>
<td>Prescribing error</td>
<td>Approximately 113 (7.1%) prescribing errors were detected during the study period out of 1580 medication</td>
<td>Lack of knowledge of prescribing skill was the main cause of such</td>
<td>A.A. Al-Dhawailie -</td>
</tr>
<tr>
<td>No.</td>
<td>Title</td>
<td>Description</td>
<td>Reference</td>
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<tr>
<td>13</td>
<td>Rationality of prescriptions according to WHO indicators</td>
<td>A total of 4231 prescriptions were encountered with the total of 10591 drugs prescribed. The average number of drug per prescription was 2.5. Only 13% (n= 10591) of drugs were prescribed by generic name. Percentage of drug prescribed from WHO model list of Essential drugs, Essential drug list of Nepal and Nepalese National Formulary was 21.7%, 32.8% and 42.3% respectively. Antibiotics and injections encountered were 28.3% and 3.1% respectively.</td>
<td>Saurav Ghimire et al.-2009, (116)</td>
<td></td>
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<tr>
<td>14</td>
<td>E-Prescribing &amp; its impact on prescribing errors</td>
<td>Study was conducted before and after involving medication chart audit of 3,291 admissions (1,923 at baseline and 1,368 post e-prescribing system) at two Australian teaching hospitals. In Hospital A, the Cerner Millennium e-prescribing system was implemented on one ward, and three wards, which did not receive the e-prescribing system, acted as controls. In Hospital B, the iSoft MedChart system was implemented on two wards.</td>
<td>Westbrook JI et al.-2012, (117)</td>
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<td>Implementation of these commercial e-prescribing systems resulted in statistically significant reductions in prescribing error rates.</td>
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</table>
and authors compared before and after error rates.

<table>
<thead>
<tr>
<th>15</th>
<th>Rational use of drugs-interventional study</th>
<th>At baseline, more prescriptions from private hospitals had hospitals’ addresses (p=0.005) and patients’ ages (p=0.015); more from public hospitals were signed (p=0.001) and 20% of prescriptions were clearly legible. Post-intervention, more prescriptions from public hospitals were signed (p=0.017); more from private hospitals had the doses (p=0.04) and routes (p=0.05) of administration, and the intervention group in private hospitals wrote patients’ ages more frequently than controls (p=0.05).</th>
<th>Prescriptions lacked details and most were not clearly legible. Intervention resulted in modest changes, which in public hospitals were more significant among doctors who had group seminars.</th>
<th>Obehi A and Isah AO.-2007, (118)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Rational use of drugs according to WHO indicators</td>
<td>Total 200 prescriptions comprising of 92 prescriptions of Private Sector and 108 prescriptions of Service Sector were audited. In pediatric prescriptions (30% of the paediatric prescriptions)85 % of prescriptions were without the age of the patient. Superscription was not mentioned in 71% of the prescriptions. Inscription, subscription and signature were inadequate in 50%, 18% and 35% of the prescriptions, respectively. In more than 52 % prescriptions, drugs were inappropriately</td>
<td>Large number of prescriptions does not conform to ideal pattern and lack in their rationality.</td>
<td>K.U. Ansari et al.-1998, (11)</td>
</tr>
<tr>
<td>17</td>
<td>Prescription quality &amp; prescribing indicators</td>
<td>Author had developed, validated and checked reliability of indicators of the appropriateness of long term prescribing in general practice medical records in the United Kingdom. Consensus was reached on 30, from which 13 indicators suitable for application were produced.</td>
<td>Nine indicators of prescribing appropriateness were produced suitable for application to the medical record of any patient on long term medication in United Kingdom general practice. Although the use of the medical record has limitations.</td>
<td>Judith A Cantrill et al. - 1998, (119).</td>
</tr>
<tr>
<td>18</td>
<td>Prescription quality &amp; prescribing indicators</td>
<td>The meeting was organized by the European Drug Utilization Research Group (EuroDURG), the Belgian National Health Insurance Institute (RIZIV-INAMI), and the World Health Organization Regional Office for Europe (WHO-Euro). The field of prescribing quality was defined and delineated from the medical error field. A</td>
<td>The state of the art of the development and application of prescribing quality indicators in all represented countries was made, together with a first draft of a database of prescribing quality indicators, already subjected to</td>
<td>JL Hoven et al. -2005, (120).</td>
</tr>
</tbody>
</table>
A conceptual grid for classifying quality indicators was discussed, combining two axes (a drug/disease/patient axis and a structure/process/outcome axis). Validation procedures.

| 19 | Prescription quality & prescribing indicators | Total 247 prescriptions were randomly selected for analysis, wherein 720 drugs were prescribed. Only 15% of drugs were prescribed by generic name, 21.67% of the total drugs consisted of fixed-dose combinations, only 40% of drugs were from the Essential drug list of Nepal and 29.44% (n=212) were from the WHO Essential drug list. It was found that more than half (54.17%) of the drugs were from Nepalese National Formulary and 35.69% were from WHO model formulary. | There is a need for educational intervention for prescribers and both managerial and educational intervention for the hospital pharmacists to improve prescribing and dispensing. | Alam K et al.-2006, (121) |

| 20 | Prescription quality & prescribing indicators | A review of a large number of prescribing quality indicators has been proposed and many are used routinely in quality management. Often the content and face validity of indicators have been assessed by consensus methods. Prescription data are frequently used for indicators, but they do not provide any direct information about disease and patient factors important for judging the quality of prescribing. The concurrent validity of indicators should | Furthermore, the statistical and epidemiological properties of prescribing quality indicators need more attention. | Morten Andersen et al.-2003, (92) |
be assessed by comparing to a “gold standard” quality assessment at the patient level using all available clinical information. In the future, detailed clinical information from practice databases and computerized hospital records will be an important data source for indicators and for validation studies.

| 21 | Prescription quality & prescribing indicators | One hundred ninety-six outpatients aged 65 and older who were taking five or more medications. Inappropriate prescribing was assessed using a combination of the Beers drugs-to-avoid criteria (2003 update) and subscales of the Medication Appropriateness Index that assess whether a drug is ineffective, not indicated, or unnecessary duplication of therapy. Underuse was assessed using the Assessment of Underutilization of Medications instrument. Use of one or more inappropriate medications was documented in 128 patients (65%), including 73 (37%) taking a medication in violation of the Beers drugs-to-avoid criteria and 112 (57%) taking a medication that was ineffective, not indicated, or duplicative. | Inappropriate medication use is most frequent in patients taking many medications, but underuse is also common and merits attention regardless of the total number of medications taken. | Michael A et al.-2006 (122) |

<p>| 22 | Prescription quality &amp; | The prescribing knowledge of first-year postgraduate | Efforts are needed to develop a | Prema |</p>
<table>
<thead>
<tr>
<th>Prescribing Indicators</th>
<th>Prescribing Audit and Feedback Interventions</th>
<th>This Retrospective Survey Conducted on a Total of 7999530 Prescriptions from All General and Specialist Physicians. Assessment of Prescribing Indicators Revealed</th>
<th>Upadhyaya et al.- 2012 (87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing indicators</td>
<td>Prescribing Audit and Feedback Interventions such as routine feedback, revised feedback, and printed educational material and a no intervention control arm was compared to assess effectiveness and cost effectiveness.</td>
<td>This is the most effective interventions in improving prescribing pattern. If the interventions are cost effective, they will likely be applied nationwide.</td>
<td>Soleymani et al-2012 (59)</td>
</tr>
<tr>
<td>23</td>
<td>Prescription quality &amp; prescribing indicators</td>
<td>This retrospective survey was conducted on a total of 7999530 prescriptions from all general and specialist physicians. Assessment of prescribing indicators revealed</td>
<td>Gholam-Hossein Sadeghiane</td>
</tr>
<tr>
<td>24</td>
<td>Prescription quality &amp; prescribing indicators</td>
<td>Because of the wide variability in the pattern of drug prescribing depending on the medical specialties, specific</td>
<td></td>
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</tbody>
</table>
### Literature Review

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>25</strong></td>
<td>Prescription quality indicators</td>
<td>Poor-quality prescribing performance by general practitioners including high number of medicines prescribed per client, wide range of prescribed medicines in each prescription, over-prescribing of antibiotics, corticosteroids and injectable drugs. There were also wide differences in the pattern of drug prescribing depending on the medical specialties.</td>
</tr>
<tr>
<td><strong>26</strong></td>
<td>Prescription quality indicators</td>
<td>Main outcome measures Face validity (median rating of 7-9 on a nine point scale without disagreement) and reliability (rating 8 or 9) of indicators for assessing quality and cost minimization. The median rating was 7 for cost minimization and 6 for quality, and in all except four cases individual respondents rated indicators significantly higher for cost than for quality. The 12 indicators rated as valid by leading prescribing advisers had a narrow focus and would allow only a limited examination of prescribing at a general practice, primary care group, or health authority level.</td>
</tr>
<tr>
<td><strong>27</strong></td>
<td>Prescription quality indicators</td>
<td>Review study identified Australian studies involving the area of expanded pharmacist prescribing. The available Australian literature indicated support from pharmacists and pharmacy clients for an expanded pharmacist prescribing role, with preference for doctors retaining a primary role in diagnosis. Australian pharmacists and</td>
</tr>
<tr>
<td><strong>28</strong></td>
<td>Prescription quality indicators</td>
<td>Present evidence of studies carried out in Australia provides valuable insight of pharmacist prescribing in order to move the agenda of pharmacist prescribing forwards and to relevant policymakers on the issue.</td>
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<td>Page</td>
<td>Topic</td>
<td>Description</td>
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<tr>
<td>27</td>
<td>Prescription quality &amp; prescribing indicators</td>
<td>A set of potential prescribing-safety indicators for the purposes of revalidation of individual GPs in the UK was identified. A final set of 34 indicators was obtained.</td>
</tr>
<tr>
<td>28</td>
<td>Prescription quality with WHO indicators</td>
<td>Out of total of 485 morbid episodes, 302 were treated at some healthcare facility. Injection use was seen in 9.49% of the prescriptions. In all, 29.20% prescriptions contained at least one antibiotic. Overall 63.51% prescriptions were found to be irrational.</td>
</tr>
<tr>
<td>29</td>
<td>Prescription quality with WHO indicators</td>
<td>WHO guidelines was used to evaluate the practice of rational prescription in patients. The most commonly prescribed drugs were vitamins and tonics (57.5%). There was a high incidence of irrational prescribing practice that increased with the total number of</td>
</tr>
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</table>
followed by anti-microbial agents (12.7%), non-steroidal anti-inflammatory drugs (10.5%), anti-hypertensive (5.2%), anti cough remedies and acid peptic disease drugs. Generic drug prescription was very low as most of drugs prescribed were proprietary.

<p>| 30 | Prescription quality with WHO indicators | A total of 1944 prescriptions were analyzed after excluding those that were illegible. 7146 drugs were prescribed and the numbers of drugs prescribed per patient per visit were between 1 and 8 with a mean value of 3.7. Injections were prescribed for 349 (18.0%) patients and artemether 144 (41.3%) was the most frequently prescribed injection. Only 141 (7.3%) of the drugs were prescribed with pure generic names. | To improve rational use of medicine continuous medical education with a focus on evidence based medicine is required. | K A Oshikoya et al.- 2006 (127) |
| 31 | Prescription quality with WHO indicators | WHO prescribing indicators were used. The average number of drugs per encounter was 3.78 and no single drug was prescribed by generic name. Use of an antibiotic and an injection was in 6.67% and 3.33% of encounters respectively. Only 4.32% drugs were prescribed from national essential drug list (EDL). Percentage of encounters with a NSAID, an antiulcerant and a calcium drugs per prescription | The pattern of drug prescribing in the OPD of orthopaedics was inappropriate. | Afsan M et al.-2012 (128) |</p>
<table>
<thead>
<tr>
<th></th>
<th>Prescription quality with WHO indicators</th>
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</thead>
<tbody>
<tr>
<td>32</td>
<td>Preparation prescribed were 97%, 97.33% and 67.33% respectively.</td>
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<tr>
<td></td>
<td>Average number of drugs/prescription is 8.8. Drugs were prescribed by generic names in 4.16% of cases, drugs on EDL are only 36.92% and fixed dose combinations are 35.87% of total drugs. Dosage forms used were mostly oral 84.40%. Injectable were only 12.07% and topical forms were least 0.58%. Basic information of patient was written in 100% prescriptions. Complete diagnoses were written in 73.26% prescriptions. Total 86.80% prescriptions were legible.</td>
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<td></td>
<td>To promote rational drug usage standard policies on use of drugs must be set, and practice of prescribers would be audited frequently.</td>
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<td></td>
<td>Balbir kaur et al.- 2013 (61)</td>
</tr>
<tr>
<td>33</td>
<td>The average number of drugs prescribed per encounter or mean was 1.9 (SD 0.91) with a range between 1 and 4 as evaluated using WHO core prescribing indicators. The percentage of encounters in which an antibiotic or injection was prescribed was 58.1% (n = 749) and 38.1% (n = 491), respectively. The Percentage of drugs prescribed by generic name and from an essential drug list was 98.7% (n=2419) and 96.6% (n=2367), respectively.</td>
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<td></td>
<td>Promoting use of EDL will promote rational use of medicine. EDL were not found to be a problem in this study.</td>
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<td>Anteneh Assefa Desalegn- 2013 (129)</td>
</tr>
<tr>
<td>34</td>
<td>Prescription quality with WHO indicators</td>
</tr>
</tbody>
</table>
3.7 Introduction to PQI tool (8)

The Prescription Quality Index (PQI) is a newly developed tool intended for health care providers such as clinicians and pharmacists to evaluate the quality of drug prescriptions in chronic diseases. Donabedian conceptualization of structure, process, and outcome quality model was used as an approach for the index construction. The PQI was developed based on published literatures (9, 28, 29, 131), peer reviews and expert consensus. The criteria in the PQI were specifically chosen to measure the common problems related to prescription quality in general and clinical practice. The PQI is expected to serve as a way of measuring and monitoring prescription quality in practice and to extend knowledge on other information related to prescription quality.

Prescriptions may contain a single drug or multiple drug therapy. For prescriptions which consist of more than one drug, each drug is rated individually. Similarly, if patients suffer from more than one disease state or condition or problem, each disease state is rated separately. Then, minimum scores for each criterion are selected for summation. Compliance criterion is measured using physician notes written in patient’s medical record. To use the PQI, drug prescription and basic patient information are required at a minimum. However, to obtain a more valid and reliable assessments, patients’ social, clinical and laboratory information are necessary. When it is not possible to obtain certain data such as cholesterol level or compliance status, indicators are rated as having no information and score of 9 is given.

The rate-based PQI consists of 22-criteria in question forms and the total score ranges from 0 to the maximum of 43. The range of scales in the PQI varies from 0 to 4 for very important criteria, 0 to 2 for criteria considered as important and 0 to 1 for the less important criteria. If criterion 1 for drug indication was scored as 0 (not indicated), then criterion 2 (dosage), criterion 11 (duration) and criterion 12 (cost) are all scored as 0 (poor prescription quality). The PQI total score is obtained by summing up all the minimum scores for the 22 criteria with the maximum possible score of 43. Prescription with the PQI total score of ≤ 31 is interpreted as poor quality, 32 - 33 as medium quality and 34 – 43 as high quality (8). The criteria for PQI are shown in table 4.
### Table 5: List of PQI Criteria

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<th>Criteria</th>
<th>0</th>
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<th>4</th>
<th>9</th>
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<tbody>
<tr>
<td>1</td>
<td>Is there an indication for the drug?</td>
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<td>Is the dosage correct?</td>
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<td></td>
<td>Is the medication effective for the condition?</td>
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<td></td>
<td>Is the usage of the drug for the indication supported by evidence?</td>
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<td>Is the medication being</td>
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**Legend:**
- 0: Not Indicated
- 1: Marginally Correct
- 2: Correct
- 4: Indicated
- 9: No Information
<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Yes</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Is the medication available in the formulary or essential drug list?</td>
<td>0</td>
<td>1</td>
<td>9</td>
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<tr>
<td>15. Does the patient comply with the drug treatment?</td>
<td>0</td>
<td>2</td>
<td>9</td>
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<tr>
<td>16. Is the medication’s name on the prescription clearly written?</td>
<td>0</td>
<td>1</td>
<td>2</td>
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<tr>
<td>17. Is the prescriber’s writing on the prescription legible?</td>
<td>0</td>
<td>1</td>
<td>2</td>
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<tr>
<td>18. Is the prescriber’s information on the prescription adequate?</td>
<td>0</td>
<td>2</td>
<td></td>
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<tr>
<td>19. Is the patient’s information on the prescription adequate?</td>
<td>0</td>
<td>1</td>
<td>2</td>
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<tr>
<td>20. Is the diagnosis on the prescription clearly written?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>21. Does the prescription fulfil the patient’s requirement for drug therapy?</td>
<td>0</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>22. Has the patient’s condition(s) improved with treatment?</td>
<td>0</td>
<td>1</td>
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The PQI is claimed to be a promising new instrument for measuring quality of prescription. The PQI captured the multidimensional criteria of prescription quality. The PQI incorporates the concept of rational drug therapy, evidence-based approach and other criteria required for prescription quality. The PQI was shown by the developers to be a valid, reliable and responsive tool to measure the quality of prescription in chronic diseases.
STEPS for using THE PQI

Step 1: Select the prescription to be rated

To evaluate the quality of the prescription, past or current prescription should be available for assessment

Step 2: Obtain patient information

Review patient’s demographic information, including age, weight, height, gender, race, etc.

Step 3: Obtain patient’s medical history

Review past and current medical problems, physical assessments and relevant laboratory results

Step 4: Obtain patient’s medication profile

Review past and current medication regimens

Step 5: Read the questions in the PQI carefully

If you don’t understand the question, refer to the specific instructions below

Step 6: Circle the most applicable answer from your assessment

- For judgemental questions rated as 0 (poor quality), please give your reasons for your rating.
- If you don’t know the answer to the question, consult at least two standard references available in your facility. Standard references could be either pharmaceutical/pharmacological texts or softwares or credible clinical journals or established online websites. Examples are Martindale, British National Formulary, Drug Facts and Comparison, USPDI, AHFS Drug Information, Micromedex, Evidence Based Medical Reviews (EBMR), Medline, Pub Med, etc.
- If the specific instructions for the particular questions mention specific references, follow the instructions.
• At times, you may require additional information from the patient's chart to answer a question. If the information is not available, circle ‘No Information’ (scale 9) and may state the necessary requirements in the comments section.

Step 7 If prescriptions consist of more than one drug, rate each drug separately. Similarly, if patients suffer from more than one disease state or condition or problem, rate each disease state separately. Then choose the MINIMUM score for summation of overall score.

Step 8 If criteria 1 is scored as 0 (not indicated), then criteria 2 (dosage), criteria 11 (duration) and criteria 12 (cost) are all scored as 0 (poor quality).

Step 9 Sum up the total scores of your assessment

Step 10 Evaluate the quality of prescription

Specific Instructions for Raters & Definition of each Criterion

Criterion 1

| Is there an indication for the drug? |

Definition: **Indication** is defined as the sign, symptom, disease, or condition for which the medication is prescribed. The question assesses whether there is sufficient reason for the use of the drug. Sufficient reason includes not only curative and palliative therapy but also preventive therapy for a disease, condition or drug effect, assistance in diagnostic process and correction of abnormal laboratory values (132).

Instructions: Answer the question taking into consideration the conditions found in the current medical problems. If score = 0 (not indicated), then indicator 2 (dosage), indicator 11 (duration) and 12 (cost) are also scored as 0. For repeat prescription, check whether the drug is still appropriate for the patient if considerable time has elapsed between repeats.

Criterion 2

| Is the dosage correct? |
Definition: Dosage is defined as the total amount of medication taken per 24-hour period for regularly scheduled medications.

Instructions: Correct dose is the amount specified within the dosage range for initial and maintenance therapy in the standard pharmacological or medical references. Other sources may specify newer or more appropriate therapeutic dosage ranges (e.g. Micromedex) or specific geriatric dosage ranges (e.g., BNF, USPDI, APhA Geriatric Drug Dosage Handbook). These ranges should supersede the standard texts as long as references are given.

The dosing regimen is determined primarily by the pharmacokinetics of the drug in the patient. Dosage should take into account known age-related changes in drug pharmacokinetics and pharmacodynamics. Objective data such as vital signs, calculated creatinine clearance and laboratory values (e.g., blood chemistries, cholesterol, PT/INR) should also be considered. For patients who have drug laboratory values/levels.

Criterion 3

Is the medication effective for the condition?

Definition: Effective is defined as producing a beneficial result. The question assesses whether the drug prescribed is effective for the indication.

Instructions: Indication and effectiveness are tightly but not perfectly linked items. Physicians may prescribe a drug for a given condition because of theoretical and standard practice reasons (indication) but clinicians may find in clinical practice that the drug is ineffective.

Criterion 4

Is the usage of the drug for the indication supported by evidence?

Definition: Evidence-based clinical practice is an approach to decision making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the best option which suits that patient.

Criterion 5
Are the directions for administration correct?

**Definition:** Directions are defined as the instructions in the use of a medication for the patient. The question assesses the route of administration, relationship to food and liquid, the schedule and time of the day.

**Criterion 6**

Are the directions for administration practical?

**Definition:** Practical is defined as capable of being used or being put into practice without sacrificing efficacy. This question assesses whether the directions for use are practical for the patient to take, or for the pharmacy to dispense or for the nurse to administer and take into consideration the potential for patient compliance without sacrificing efficacy.

In this study, practical direction is rated from the patient’s perspective only.

**Criterion 7**

Are there clinically significant drug-drug interactions?

**Definition:** A drug-drug interaction is defined as the effect that the administration of one medication has on another drug. Clinical significance connotes a **harmful** interaction. This question assesses whether the drug in question interacts with another drug in the patient’s regimen by affecting its pharmacokinetics (i.e., absorption, distribution, metabolism and excretion) or pharmacodynamics (i.e., the effect that it has on the body).

**Instructions:** A drug interactions text, such as Hansten's Drug Interactions and Updates, and Micromedex will serve as the reference for significant interactions. The decision should be based on the **severity of potential** interaction, the availability and quality of clinical documentation.

**Criterion 8**

Are there clinically significant drug-disease/condition interactions?

**Definition:** Significant drug-disease interaction is defined as the harmful effect that the drug has on a pre-existing disease or condition. This question assesses whether
the drug in question may be worsening the patient's disease or condition. A previous history of an idiosyncratic allergic reaction to a drug (e.g., penicillin, sulfonamides) is considered a pre-existing condition.

**Criterion 9**

| Does the patient experience any adverse drug reaction(s)? |

**Definition:**
Adverse drug reaction (ADR) means an unwanted or harmful side effect experienced following the administration of a drug or combination of drugs and is suspected to be related to the drug. The reaction may be a known side effect of the drug or it may be a new previously unrecognized adverse drug reaction.

WHO definition: any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. This excludes therapeutic failures, intentional or accidental poisoning or drug abuse, and adverse effects due to errors in administration or compliance.

**Criterion 10**

| Is there unnecessary duplication with other drug(s)? |

**Definition:** Duplication is defined as simultaneous prescribing or usage of drug(s) from the same chemical or pharmacological class.

Unnecessary duplication is defined as **non-beneficial or risky** copying of drug(s) when two drugs from the same chemical or pharmacological class are prescribed simultaneously. In general, 2 drugs from the same subclass of major therapeutic classifications will be considered unnecessary duplication.

**Instructions:**
The evaluator will look up the generic names of all regularly scheduled medications in the index to determine the class of each individual drug. The latest version of USPDI or BNF may be used as reference. The evaluator will look up the generic names of all regularly scheduled medications to determine the class of each individual drug.
Criterion 11

Is the duration of therapy acceptable?

**Definition:** Duration is defined as the length of therapy. This question assesses whether the length of time that the patient has received the drug is acceptable.

**Instructions:**
Duration of therapy should be written clearly so that patients will not stop taking drugs prematurely and will understand why prescription probably need not be renewed. For chronic condition, a prolonged duration of therapy will be acceptable. However, duration for the prescription should take into consideration the need for continued contact with the clinic or physician, the cost, drug accumulation, storage & stability problems, potential for drug toxicity, drug overdose or drug abuse. Some institutions may have their own policy regarding the acceptable length of therapy in prescription. In this study, 3 months is considered as maximum duration for a drug to be prescribed.

Criterion 12

Is this drug the cheapest compared to other alternatives for the same indication?

**Definition:** This question assesses how the cost of the drug compares to other drugs for the same indication with similar efficacy and safety.

**Instructions:** Alternatives should be considered as medications within the same therapeutic class. For the rating, evaluator can use the local institutional setting prices (e.g., cost per month or per day supply or cost per dose) as their standard. Whenever possible, administrative costs should be included. If the drug is not indicated in item 1, then the score should be 0.

Criterion 13

Is the medication being prescribed by generic name?

**Definition:**
Generic name refers to the actual scientific name of the drug. Generic name or nonproprietary name is preferred than brand name or proprietary name.
* Exception:
Trade name or brand name may be used and scored as 1 in these circumstances:
1) Certain drugs such as lithium, phenytoin and theophylline from different manufacturers have significant differences in bioavailability.
2) Combination products such as Lomotil, Bactrim, Hyzaar.

Criterion 14
Is the medication available in the formulary or essential drug list?

Definition:
Many institutions have their own drug formulary or drug list. Others may follow national drug list or WHO essential drug list.
Instructions: Check each drug in the prescription carefully and refer to the formulary/drug list available in your facility. If the drug is not listed, then the score should be 0.

Criterion 15
Does the patient comply with the drug treatment?

Definition:
Compliance describes the extent to which a person’s behaviour coincided with medical advice (132,133). Garfield & Caro (1999) defined compliant patients as those who accepted their physician’s advice to start drug therapy and who take their medication at least 80% of the time (134). Non-compliance means constant neglect rather than just temporary forgetfulness or neglect of treatment (135). In selecting and prescribing medications for patients, prescribers should consider drugs which enhance compliance.

Instructions:
The evaluation of compliance continues to be a key methodological problem, particularly in terms of the most valid measurement scale that measure compliance comprehensively (135). The direct methods are those by which the drug can be identified in the patient. The indirect methods include those where there is an
assessment, either by the patient himself or some other individual, as to whether the patient is likely to have taken the medication. Direct methods generally give higher figures of non-compliance than indirect methods. Assessment of compliance can be evaluated by self report, physician’s judgement, pill count, and checking repeat prescriptions. Examples of direct methods are measuring blood levels or urinary excretion of medication.

**Criterion 16**

| Is the medication’s name on the prescription clearly written? |

**Definition:**
Medication name refers to the generic name or trade name of the drug. Drug names should be written out fully and acronyms should not be used.

**Criterion 17**

| Is the prescriber’s writing on the prescription legible? |

**Definition:**
Legible means easy or capable of being read or deciphered or understood or distinct to the eye. The quality of handwriting can have a profound impact upon medication treatment since illegible handwriting may lead to serious medication error. The widely used four keys to assess legibility are shape, slant, spacing, and size of the letters. Illegible means difficult to read or understand the handwriting.

**Criterion 18**

| Is the prescriber’s information on the prescription adequate? |

**Definition:**
Prescriber’s information refers to prescriber’s name, address and signature.

**Criterion 19**

| Is the patient’s information on the prescription adequate? |
Definition:
Patient’s information refers to the patient’s full name, registration number, age, bodyweight, gender, date and address/name of the clinic where patient is treated.

Criterion 20

Is the diagnosis on the prescription clearly written?

Definition:
Diagnosis – the process of determining the nature of a disorder by considering patient’s signs and symptoms, medical background, and when necessary, results of laboratory tests and X-ray examinations. The diagnosis is best written according to the latest International Classification of Diseases

Criterion 21

Does the prescription fulfil the patient’s requirement for drug therapy?

Definition:
This question refers to circumstances when a patient is suffering from an illness or develops a new or worsening condition and is in need of pharmacotherapy. The major causes for requiring new or additional drug therapy are as follows:

- To treat an untreated condition
- To add a synergistic or potentiating drug therapy
- To fill the need for prophylactic or preventive drug therapy

This problem may occur when patients are transferred from another hospital, from one physician care to another, or from one pharmacy to another and their therapies are not continued.

Instruction:
A comprehensive assessment of each patient’s drug-related need is required. Simply reviewing an existing prescription or patient medication profile may result in missing this problem.

Criterion 22

Has the patient’s condition improved with treatment?
Definition:
Improve refers to positive progress in achieving the desired outcomes, stabilizing patient’s condition or resolving problems. Not improve refers to lack of progress, worsening in patient condition, treatment failure, or death while receiving drug therapy.

Instructions:
Improvement in patient’s condition can be measured by clinical outcome such as absence, presence, degree of magnitude or severity of a particular condition such as pain, discomfort, or distress, change in functional status of the patient, overall patient satisfaction or quality of life.

For acute disorders, follow-up evaluations can serve to evaluate the actual (final) outcomes. For chronic conditions, evaluations can only establish the present status of the patient and the progress or lack of progress in achieving desired therapeutic goals.

Physical or laboratory results may be used to assess the improvement of the outcome treatments such as level of blood pressure, blood sugar, patency of a coronary artery on an angiogram, the size of a mass on a radiology examination, or the titer of an antibody. Subjective assessment include bodily comfort, physical activity, social activity, personal and professional role function, sexual function, cognitive function, sleep, vitality and overall perception of health.

Optimal timing for evaluation should be based on the most likely period for the desired benefits to manifest, balanced with the most likely time for harm or side effects to appear. Researcher may choose only one outcome or several outcomes for evaluation. For multiple outcomes, rate each outcome separately. Then take the minimum value for overall score.