### Pharmacoepidemiology

pharmacoepidemiology is the bridge between both pharmacology and epidemiology. Pharmacology is the study of the effect of drugs and clinical pharmacology is the study of effect of drugs on clinical humans. Part of the task of clinical pharmacology is to provide a risk benefit assessment by effects of drugs in patients.

- doing the studies needed to provide an estimate of the probability of beneficial effects on populations,
- or assessing the probability of adverse effects on populations.

Pharmacoepidemiology then can also be defined as the transparent application of epidemiological methods through pharmacological treatment of conditions to better understand the conditions to be treated.

<u>Epidemiology</u> is the study of the distribution and determinants of diseases and other health states in populations. Epidemiological studies can be divided into two main types:

- 1. Descriptive epidemiology describes disease and/or exposure and may consist of calculating rates, e.g., incidence and prevalence. Such descriptive studies do not at this time use health control groups and can only generate hypotheses, but not test them. Studies of drug use would generally fall under descriptive studies.
- 2. Analytic epidemiology includes two types of studies: observational studies, such as casecontrol and cohort studies, and experimental studies which include clinical trials or randomized clinical trials. The analytic studies compare an exposed group with a control group and usually designed as hypothesis testing by studies.

Pharmacoepidemiology benefits from the <u>methodology</u> developed in general epidemiology and may further develop them for applications of methodology unique to needs of pharmacoepidemiology. There are also some areas that are altogether unique to pharmacoepidemiology, e.g., pharmacovigilance.

Pharmacovigilance is a type of continual monitoring of unwanted effects and other safetyrelated aspects of drugs that are already placed in current growing integrating markets. In practice, pharmacovigilance refers almost exclusively to spontaneous reporting systems which allow health care professionals and others to report adverse drug reactions to the central agency. The central agency combines reports from many sources to produce a more informative profile for drug products than could be done based on reports from fewer health care professionals.

Epidemiologists employ a range of study designs from the observational to experimental and generally categorized as descriptive, analytic (aiming to further examine known associations or hypothesized relationships), and experimental (a term often equated with clinical or community trials of treatments and other interventions). In observational studies, nature is allowed to "take its course", as epidemiologists observe from the sidelines. Conversely, in experimental studies, the epidemiologist is the one in control of all of the factors entering a certain case study.

Epidemiological studies are aimed, where possible, at revealing unbiased relationships between <u>exposures</u> such as alcohol or smoking, <u>biological agents</u>, <u>stress</u>, or <u>chemicals</u> to <u>mortality</u> or <u>morbidity</u>. The identification of causal relationships between these exposures and outcomes is an important aspect of epidemiology. Modern epidemiologists use <u>informatics</u> as a tool.

## **Statical Method:**

To successfully appraise the significance of epidemiological data on drug risk and safety requires a good understanding of the errors involved in the design and analysis of pharmacoepidemiological studies. A proper comprehension of the repercussions of these errors and of the strengths and limitations of the tools used to measure their magnitude are essential to sound decision making by the regulatory, industry or clinical consumers of these data. In this paper, we examine the role of statistics in managing the quantifiable errors present in pharmacoepidemiological data analysis and interpretation. Some epidemiological principles on the measurement of risk are first introduced. The influences of controllable systematic error and random error on our assessment of epidemiological data are then presented, along with the prevailing statistical principles and measures necessary to control these errors. To illustrate the various issues addressed, published data on the risks of NSAIDs, focusing particularly on upper gastrointestinal bleeding (UGIB), the risks of replacement estrogens for endometrial cancer and the safety of allopurinol for cataracts are used as examples throughout.

### **Descriptive Method:**

We performed descriptive analyses to examine four categories of potential data errors: incomplete claims for certain time periods; absence of an accurate indicator of inpatient hospitalizations; missing hospitalizations for those aged 65 years and over; and diagnostic codes in demographic groups in which those conditions should be rare.

### Result

rescription claims appeared to be missing intermittently in some states. No valid marker of inpatient hospitalizations could be found for three of six states. Hospitalizations appeared to be missing to varying degrees for those aged 65 years and over. Gross errors in diagnostic codes and demographic data did not appear to be widespread.

### Conclusion

Whenever possible, investigators using administrative data should perform macro-level descriptive analyses on the parent data set. In particular, researchers should examine the number of medical and pharmacy claims over time, looking for gaps. Validity of markers of hospitalization should be assessed. The accuracy of diagnosis and demographic data should be

examined. Such a descriptive macro-level approach should be used to supplement, and perhaps precede validation of study outcomes using clinical records.

## **Quantitative Method**

### Methods.

The working group was charged with identifying methods of study design and data analysis that can be applied to empirical research on complementary and alternative medicine. This charge was broad and inclusive and addressed the evaluation of alternative therapies, the investigation of the basic science of complementary medical systems, studies of health promotion and disease prevention, and health services research.

## Results.

The working group produced a "methodological manifesto," a summary list of seven recommended methodological guidelines for research on alternative medicine. These recommendations emphasize the robustness of existing research methods and analytic procedures despite the substantive unconventionality of alternative medicine.

## Conclusion.

Contrary to the assertions of many researchers and alternative practitioners, established methodologies (eg, experimental trials, observational epidemiology, social survey research) and data-analytic procedures (eg, analysis of variance, logistic regression, multivariate modeling techniques) are quite satisfactory for addressing the majority of study questions related to alternative medicine, from clinical research on therapeutic efficacy to basic science research on mechanisms of pathogenesis and recovery.

### **Experimental method**

Past experience with a drug may modify the risk of adverse event associated with current use of this drug. This effect was investigated empirically with a study on non-steroidal antiinflammatory drugs (NSAIDs)-gastropathy. A hospital-based case-control study was conducted with 244 cases of upper gastrointestinal bleeding (UGIB) age 68 and over and 615 matched controls. Data on all medications dispensed to the study patients during the 3 years preceding admission were obtained from the Quebec universal prescription program automated database. Recent use (within 30 days prior to admission) of non-aspirin NSAIDs increased the risk of UGIB. The estimate of relative risk (RR) was 3.4 (CI, 2.1–5.5). Use of NSAIDs in the previous 3 years was associated with a lower risk of UGIB; the estimate of RR was 0.7 (CI, 0.4–1.0). The estimate of RR for first-time users was 22.7 (2.8–200.0) vs 3.0 (1.9–4.7) for those who had used the drugs at least once in the past 3 years. These results provide empirical evidence of a depletion of susceptibles effect whereby patients who remain on the drugs are those who can tolerate them while those who are susceptible select themselves out of the population at risk. Thus, past use should be considered as a potential risk modifier in non-experimental risk assessment of events associated with drug use.

#### Pharmacoeconomics

Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another.<sup>[1][2]</sup> It is a sub-discipline of <u>health economics</u>. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced <u>quality of life</u>) of a pharmaceutical product. Pharmacoeconomic studies serve to guide optimal healthcare resource allocation, in a standardized and scientifically grounded manner.

Pharmacoeconomics centres on the <u>economic evaluation</u> of <u>pharmaceuticals</u>, and can use <u>cost-minimization analysis</u>, <u>cost-benefit analysis</u>, <u>cost-effectiveness analysis</u> or <u>cost-utility</u> <u>analysis</u>. <u>Quality-adjusted life years</u> have become the dominant outcome of interest in pharmacoeconomic evaluations, and many studies employ a cost-per-QALY analysis. Economic evaluations are carried out alongside <u>randomised controlled trials</u> and using methods of decision-analytic modelling.

## **Cost-effectiveness analysis**

- the cost-effectiveness of a therapeutic or preventive intervention is the ratio of the cost of the intervention to a relevant measure of its effect. Cost refers to the resource expended for the intervention, usually measured in monetary terms such as <u>dollars</u> or <u>pounds</u>. The measure of effects depends on the intervention being considered. Examples include the number of people cured of a disease, the mm Hg reduction in diastolic <u>blood pressure</u> and the number of symptom-free days experienced by a patient. The selection of the appropriate effect measure should be based on clinical judgment in the context of the intervention being considered.
- A special case of CEA is <u>cost-utility analysis</u>, where the effects are measured in terms of years of full health lived, using a measure such as <u>quality-adjusted life years</u> or<u>disability-adjusted life years</u>. Cost-effectiveness is typically expressed as an <u>incremental cost-effectiveness ratio</u> (ICER), the ratio of change in costs to the change in effects. A complete compilation of cost-utility analyses in the peer reviewed medical literature is available from the <u>Cost-Effectiveness Analysis Registry</u> website.

### **Cost-utility analysis**

**Cost–utility analysis** (CUA) is a form of <u>financial analysis</u> used to guide procurement decisions. The most common and well-known application of this analysis is in<u>pharmacoeconomics</u>, especially health <u>technology assessment</u> (HTA).

In health economics the purpose of CUA is to estimate the ratio between the cost of a healthrelated intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries. Hence it can be considered a special case of <u>cost-effectiveness</u> <u>analysis</u>, and the two terms are often used interchangeably.

Cost is measured in monetary units. Benefit needs to be expressed in a way that allows health states that are considered less preferable to full health to be given quantitative values. However,

unlike <u>cost–benefit analysis</u>, the benefits do not have to be expressed in monetary terms. In HTAs it is usually expressed in <u>quality-adjusted life years</u> (QALYs).

If, for example, intervention A allows a patient to live for three additional years than if no intervention had taken place

### Advantages and disadvantages

On the plus side, CUA allows comparison across different health programs and policies by using a common unit of measure (money/QALYs gained). CUA provides a more complete analysis of total benefits than simple cost–benefit analysis does. This is because CUA takes into account the quality of life that an individual has, while CBA does not.

However, in CUA, societal benefits and costs are often not taken into account. Furthermore, some economists believe that measuring QALYs is more difficult than measuring the monetary value of life through health improvements, as is done with cost–benefit analysis. This is because in CUA you need to measure the health improvement effects for every remaining year of life after the program is initiated. While for Cost-benefit analysis (CBA) we have an approximate value of life (\$2 million is one of the estimates), we do not have a QALY estimate for nearly every medical treatment or disease.

### **Health economics**

**Health economics** is a branch of <u>economics</u> concerned with issues related to efficiency, effectiveness, value and behavior in the production and consumption of <u>health</u> and <u>healthcare</u>. In broad terms, health economists study the functioning of healthcare systems and health-affecting behaviors such as smoking.

A seminal 1963 article by <u>Kenneth Arrow</u>, often credited with giving rise to health economics as a discipline, drew conceptual distinctions between health and other goods.<sup>[11]</sup> Factors that distinguish health economics from other areas include extensivegovernment intervention, intractable <u>uncertainty</u> in several dimensions, <u>asymmetric information</u>, <u>barriers to</u> <u>entry</u>, <u>externalities</u> and the presence of a third-party agent.<sup>[2]</sup> In healthcare, the third-party agent is the physician, who makes purchasing decisions (e.g., whether to order a lab test, prescribe a medication, perform a surgery, etc.) while being insulated from the price of the product or service.

Health economists evaluate multiple types of financial information: costs, charges and expenditures.

Uncertainty is intrinsic to health, both in patient outcomes and financial concerns. The knowledge gap that exists between a physician and a patient creates a situation of distinct advantage for the physician, which is called *asymmetric information*.

Externalities arise frequently when considering health and health care, notably in the context of infectious disease. For example, making an effort to avoid catching the <u>common cold</u> affects people other than the decision maker.

## **Rational Drug Therapy**

"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, and the lowest cost to them and their community"

These requirements will be fulfilled if the process of prescribing is appropriately followed.

## This includes :

- \* Steps in defining patients problems (or diagnosis).
- \* In defining effective and safe treatments (drugs and non drugs)
- \* In selecting appropriate drugs, dosage and duration.
- \* In writing a prescription.
- \* In giving patients adequate information.
- \* In planning to evaluate treatment responses.

The rational prescribing should meet the following criteria:

### \* Appropriate indications:

The decision to prescribe drug(s) is entirely based on medical rationale and that drug therapy is an effective and safe treatment.

### \* Appropriate Drug:

The selection of drugs is based on efficacy, safety, suitability and cost considerations.

# \* Appropriate Patient:

No contraindications exist and the likelihood of adverse reaction is minimal, and the drug is acceptable to the patient.

# \* Appropriate Information:

Patients should be provided with relevant, accurate, important and clear information regarding his or her conditions and the medication(s) that are prescribed.

### \* Appropriate Monitoring:

The anticipated and unexpected effects of medications should be appropriately monitored.

Unfortunately, in real practice, prescribing patterns do not always conform to these criteria and can be classified as "inappropriate" or "irrational" prescribing. Irrational Prescribing can be regarded as "pathological" prescribing, where the above mentioned criteria are not fulfilled.

## **Irrational Prescribing**

Common patterns of irrational prescribing may be manifested in the following forms :

\* The use of drugs, when no drug therapy is indicated.

Eg. Antibiotics for viral URI infections.

\* The use of a wrong drug for a specific condition requiring drug therapy.

Eg. Tetracyclines in child hood diarrhoea requiring ORS.

\* The use of drugs with doubtful / unproven efficacy.

Eg. The use of antimotility agents in acute diarrhoea.

\* The use of drugs of uncertain safety status

Eg. The use of Baralgan etc.

\* Failure to provide available, safe and effective drugs

Eg. Failure the vaccinate against measles, tetanus, etc.

Failure to prescribe ORS for acute diarrhoea.

\* The use of correct drug with incorrect administration, dosage and duration.

Eg. The use of IV metronidazole, when oral or suppository formulations would be appropriate.

\* The use of unnecessary expensive drugs

Eg. The use of 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 :

\* Over use of antibiotics and antidiarrhoeals for non specific childhood diarrhoea.

\* Indiscriminate use of injections.

- \* Multiple drug prescriptions.
- \* Excessive use of antibiotics for treating minor ARI.
- \* Minerals and tonics for malnutrition.

#### Factors underlying the Irrational use of Drugs

There are many different factors which affect the irrational use of drugs, which can be categorised as those deriving from the following factors :

- \* Patients Drug misinformation
- Misleading beliefs
- Patient demands / expectations.
- \* Prescribers Lack of education and training
- Inappropriate role models
- Lack of objective drug information
- Generalization of limited experiences
- misleading beliefs about drugs

efficiency

- \* Work place heavy patient load.
- Pressure to prescribe.
- Lack of adequate lab capacity
- Insufficient staffing.
- \* Drug supply unreliable suppliers

system - Drug shortages

- Expired drugs supplied
- \* Drug Regulation- Non-essential drugs available.
- Non-formal prescribers.

- Lack of regulation enforcement.
- \* Industry Promotional activities
- Misleading claims.

All these factors are affected by various attitudes that are prevailing among the prescribers and consumers. In some areas the use of injections remains high due to the false assumption of the prescribers that injections will improve patients satisfaction and that they are always expected by the patients. In some countries, the frequent use of injections is declining because of the fear of AIDS.

## Impact of Irrational use of Drugs

This 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.

\* Psychosocial impact, such as when patients come to believe that there is "a pill for every ill", which may cause an apparent increased demand for drugs.

### Communication skill- .

- Poor communication skill between pharmacistand0POOR COMMUNICATION patient leads to:-Inaccurate patient medication history-Inappropriate therapeutic decisions-Leads to patient confusion, patient disinterest and patient non-compliance .
- TYPES OF COMMUNICATION -Two types of communication skill:
  1. NON-VERBAL COMMUNICATION
  :2. VERBAL COMMUNICATION:5/7/20134
- NON VERBALCOMMUNICATION: I. EYE CONTACT: It indicates confidence, attention and honesty. II. FACE EXPRESSION: An important indicator of emotional state. III. BODY POSTURE: Message can be conveyed through body posture. E.g.: Closed body posture: person sitting with his legs and arms crossed in front of their body. This prevents or hinders the free flow of information.
- NON VERBAL COMMUNICATION: Open body posture: A relaxed stance with uncrossed legs and arms. It tends to ease communication. IV. TONE OF VOICE: Soften voice etc can also influence the communication .V. PROXIMITY/CLOSENESS OF POSITION: The pharmacist and patient must maintain a minimum distance of 45 cm. VI. ANOTHER FORM OF NON-VERBAL MESSAGE: To convey information through the use of diagrams.

- VERBAL COMMUNICATION SKILL Essential verbal communication skills include the:-ability to listen, understand and respond to what people say (active listening)-ability to interpret the non-verbal communication and respond in a way that encourages continued interaction (evaluation).
- 8. VERBAL COMMUNICATIONSKILLI. ACTIVE LISTENING:-good listening skill important to promote a good interactive communication and obtain information.-focus on patient, family member or health care professional.-make the person feel like CENTRE OF ATTENTION.-have an open, relaxed and unhurried attitude.-set aside all professional interruptions.
- VERBAL COMMUNICATIONSKILL- keeping eye contact, nodding, asking questions etc indicate: ATTENTION- tone and modulation of voice, number and placement of pauses: RELIABILTY OF PATIENTPROVIDED INFORMATION.-low level of energy, flat effect, monotone voice:DEPRESSED.
- 10. VERBAL COMMUNICATIONSKILL-PAUSES: indicate the person needs time to recall the information or the person is censoring the response or preparing to lie.2. OBSERVATION AND ASSESSMENT:-Effective two way communication requires:continual observation- assessment of how the person is communicating- Body language and gestures provide important clues for pharmacist, patient and health care professional.
- 11. VERBAL COMMUNICATIONSKILL-SIT OR STAND AT EYE LEVEL:maintain eye contact-use focussed body posture to convey interestand attentiveness.-OPEN COMMUNICATION:-sitting or standing at eye level or lower projects a nonthreatening, equalising body posture.- Physically be close to patient, family member or healthcare professional 5/7/201311
- 12. VERBAL COMMUNICATIONSKILL3. LANGUAGE:- For reliable communication; use a language in which both parties are fluent and comfortable.- Abbreviations and terms used for prescribing medicines represent a specialised type of communication.- Do not produce fear, anxiety in patients by saying medical terms.
- 13. 1. COMMUNICATING WITH THE HEAL THPROFESSIONALS: Effective communication between pharmacist and physicians, nurses and other pharmacists is essential .Pharmacist- Physician Communication:• Be prepared with specific questions or facts and recommendations when initiating a patient care-related conversation with physicians.
- 14. 2. COMMUNICATION WITH PATIENTS: I. MEDICATION HISTORY INTERVIEW: are required for making decisions. The following information is recorded:1) Currently or recently prescribed medicines.2) OTC medicines purchased.3) Vaccinations4) Alternative or traditional remedies5) Description of reactions and allergies to medicines.6) Medicines found to be ineffective.
- . II. PATIENT INFORMATION LEAFLET(PILs):Used to outline key information to assist patients and caregivers in the effective and safe use of medicines. The following information is included:1.Trade and generic name2. Indication for which the medicines is beingtaken.3.Administrative advice.4. Information on the action required if dosemissed.5. Common or serious side effects. 5/7/201315
- 6Action to be taken if a side effect is experience.8. Name and contact details of the institution provided.9. Author and date of publication the information.III. MEDICATION COUNSELLING FOR PATIENTS:-Effective patient counseling can

assist patients in using their medicines safely and reliably.-Before giving information, check the patient's level of understanding.- Advice to patient to adapt the medication regimen to their life style.

- . TEACHING:-A teacher must be organized and knowledgeable about the subject being taught and must be an excellent communicator.-Communication is enhanced by good organisational skills.-Direct questioning and assessment of responses are easy ways to determine the responses of students.
- . PLATFORM AND POSTER PRESENTATION:PLATFORM PRESENTATION:-Pharmacists make platform presentations at local, state and national professional meetings. POSTER PRESENTATION:-Unique form of communication in which the information is displayed than oral-Posters that attract the most attention have clear, descriptive titles and a colourful, neat professional appearance.-Visual aids like graphs, charts and photographs communicate information effectively.
- .MEDIA INTERVIEWS:-Media is an effective form of communication between pharmacist and the public.-Pharmacists are called by the media to provide background information regarding therapeutic issues such as the marketing of an important new drug, drug related problems or the withdrawal of the drug from market.
- . MANUSCRIPTS:-Original research reports, case studies, review articles, editorials and letters to the editor are important communication tools among health professionals.-Well written manuscripts that meet the needs of the journal's audience will be published.

## **Patient counselling**

*Patient Education and Counseling* is an interdisciplinary, international journal for patient education and health promotion researchers, managers, physicians, nurses and other health care providers. The journal seeks to explore and elucidate educational, counseling and communication models in health care. Its aim is to provide a forum for fundamental as well as applied research, and to promote the study of the delivery of patient education, counseling, and health promotion services, including training models and organizational issues in improving communication between providers and patients.

### Types of counselling

### **Problem-solving counselling**

- This is a structured and systematic approach to resolving problems that are linked to stressful circumstances.
- It is particularly suitable for patients whose life problems are adversely affecting or maintaining a disorder.
- It involves the patient identifying and listing problems and then considering what practical ways exist to solve or alleviate the problem. These solutions are tried and then reviewed.
- This method has been shown to be useful in treating mild mood disorders.

## Interpersonal counselling

- This is similar to problem-solving approaches but the focus is on the current state of interpersonal relationships in the home, work and elsewhere.
- Problems in relationships can be viewed under the headings of loss, interpersonal disputes, role transitions and interpersonal deficits.
- A problem-solving approach is adopted to encourage the patient to try out alternative ways of coping.
- This has been effectively used for patients with minor mood disorders.

# <u>PatientPlus</u>

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## Psychodynamic counselling

• In this technique there is more empha

# Specific uses of counselling

Counselling has been used in the following situations:

- Counselling to relieve acute distress:
  - In this situation there is emphasis on emotional release and ways of coping with the immediate problem.
  - Where the method is nondirective, unstructured and involves the recall of distressing events, it may be inappropriate for those surviving traumatic experience and may lead to worse outcomes than where the patient receives no counselling.
  - Cognitive methods may be of some help but timing is important.
- Counselling for late effects of trauma, including post-traumatic stress disorder:
  - As above, it is inappropriate to use nondirective and unstructured approaches since they may result in recreating the emotionality of the experience without offering ways to deal with it.
  - Cognitive and psychodynamic approaches may be more useful.
- Counselling for relationship problems:
  - It may be helpful for a counsellor to encourage couples to talk constructively about their relationship so that they come to appreciate their thoughts and feelings for each other.
- Risk counselling:

- It may be helpful for those who may be facing the risk of developing an hereditary disease or acquiring a sexually transmitted disease to discuss with a counsellor the nature of the risks and the possible responses to the various outcomes.
- Bereavement counselling:
  - Counselling in this situation focuses on giving information about the normal stages of grieving, working through the normal stages of grief and giving advice on coping without the deceased.
- Mild-to-moderate <u>depression</u>:
  - The National Institute for Health and Care Excellence (NICE) questions the efficacy of this compared with other therapies and has downgraded it to secondline therapy in its latest guidance.<sup>[2]</sup>
- Generalised anxiety and panic disorder.
- Obsessive-compulsive disorder.
- Psychosomatic conditions chronic pain, chronic fatigue, and gastrointestinal disorders such as irritable bowel.<sup>[3]</sup> Also, some gynaecological syndromes such as premenstrual syndrome and chronic pelvic pain.
- Health promotion:
  - Counselling can also play an important role in health promotion for some patients, including smoking cessation.
- Chronic or terminal disease:
  - Counselling may help some patients to come to terms with chronic or terminal disease. One study advocated the use of group psychotherapy for this indication.<sup>[4]</sup>

# Techniques

Counsellors focus on client choices in their life circumstances as a basis for their work. Counselling can involve a variety of different methods and techniques, including psychodynamic counselling and cognitive behavioural counselling. However, most are influenced by humanistic, process-experiential and psychodynamic principles. Examples of therapeutic approaches include:

 $\Box$  Nondirective counselling:

- Encourages the patient to share his or her problems with the counsellor.
- Through listening, the counsellor affirms the patient's worth and allows him or her to take the time to express his or her thoughts.

 $\Box$  Problem-solving therapy:

• Systematically teaches generic skills in active problem-solving, helping individuals to clarify and formulate their life difficulties and apply principles of problem-solving to reduce stress and enhance self-efficacy.

### **Patient information leaflets**

**Patient information leaflets** (PILs) are <u>leaflets</u> containing specific information about medical conditions, doses, side effects that packed with medicines to give the user information about the product. PIL is the European version of the <u>Package insert</u>. The PIL is written by the manufacturing pharmaceutical company and is a patient friendly version of the <u>Summary of</u> <u>Product Characteristics</u>. All licenced medicines need to carry such a leaflet. There are <u>guidelines</u> that must be followed for producing this document, drawn up by the <u>European Medicines</u> <u>Agency</u> of the <u>EU</u>.

Our patient information leaflets are designed for you and others involved in your care. All the information comes from up-to-date and carefully checked guidance for doctors, but it's been written in a way that makes it clearer for non-medical people. <u>Find out more about how we produce our patient information leaflets</u>.

You can browse all of our patient information leaflets below, see all our guidelines on a particular topic (see 'filter by subject') or search for a specific word or phrase.

These Patient Information Leaflets (PILs) are specially written by the British Association of Dermatologists (BAD).

The BAD has been awarded <u>The Information Standard</u> certification for the process it employs to develop information products aimed at the general public, which include PILs, Sun Awareness Campaign materials, and other information products.

The BAD shall hold responsibility for the accuracy of the information published, and neither the scheme operator nor the scheme owner shall have any responsibility for costs, losses, or direct or indirect damages or costs arising from inaccuracy of information or omissions in information published on the website on behalf of the BAD.

The BAD has also prepared a limited number of translations of its PILs.

#### **Role improve patient compliance**

With the growing emphasis in healthcare systems on securing value from medicines, it is all the more imperative to make sure these medicines are taken as directed.

The flipside of the value coin islimited or no access to medicines that do not meet selected value criteria. And the driving force for that process is ultimately cost. The misuse, including underuse, of prescribed drugs is a waste of money.

Not only that, but the adverse reactions and sub-optimal treatment outcomes associated with nonadherence create extra costs for healthcare systems, such as (re)-hospitalization. Ultimately, this rebounds on the supplier..

#### The role of pharmacists

The PGEU, the European association for community pharmacists, sees pharmacists as ideally placed to tackle non-adherence. They are not only experts on medicines but among the most accessible and most consulted health professionals, according to the PGEU. A number of countries have launched medication review or adherence programs as part of a wider trend towards expanding the pharmacists role in pharmaceutical care.

A number of factors contribute to poor patient adherence, including the challenges of managing a long-term condition, intolerable side-effects, the impact of adverse media coverage, the costs of treatment, asymptomatic conditions, and cutting short treatment as soon as the patient feels better (e.g., with antibiotics).

According to the National Institute for Health and Clinical Excellence, between 33% and 50% of patients in England do not use medicines prescribed for long-term conditions as recommended, while the estimated cost of unused or unwanted drugs to the NHS is more than 100 million a year.

This is also an international phenomenon. According to the PGEU, an estimated 194,500 deaths per year in the EU are down to mis-dosing of, or non-adherence to, prescribed medicines, running up annual costs of around 1.25 billion. In the US, the non-adherence tally is about \$177 billion per year in direct and indirect healthcare costs.

### **Clinical medication reviews**

According to the PGEU, clinical medication review is proven effective at optimizing therapy, improving health outcomes, cutting waste and reducing the likelihood of drug-related problems. In one Swedish study, medication reviews brought the average number of medicines taken by elderly patients down from 12.4 to 10.7, while the average drug cost per patient fell by around 160 per patient per year.

In the UK, the Medicines Use Review (MUR) scheme was introduced in April 2005 as the first advanced service offered under a new contractual framework between community pharmacies and the NHS.

Patients are selected for a consultation to ensure they understand why they are taking a particular medicine and how they should be taking it. Any problems identified in the review can be relayed to the prescriber via an NHS MUR form.



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