

Pharmacoeconomics and Management in Pharmacy I

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Introduction

- The aim of this unit
 - To impart a basic understanding of the concept of pharmacoeconomics (PE) and pharmacy administration
 - Both PE and pharmacy administration will prove to be useful in whatever roles you develop as pharmacists
 - That is why it is essential to develop the basic skills required to apply this understanding in a practical context
 - One of the greatest failings of modern tertiary education is that we are producing well informed and highly knowledgeable graduands, who are lost in the real-world scenario of multi-disciplinary decision taking and practical application

Introduction

- The aim of this unit
 - To enable you to evaluate and criticise literature on the subject
 - To develop the basic skills required to apply this understanding in a practical context
- At the end of the unit
 - You will have a grasp of the basic principles of pharmacoeconomics(PE) and be in a position to decide what available information is relevant and credible
 - You will realise that PE is applied to everyday situations, including one of those most relevant to us, pharmacy administration
 - You will be in a position to apply your newly acquired knowledge to practical use

Introduction

- I expect

- You to take an open-minded approach and research practical examples and utilise them both in lectures and also in written evaluation

- I will

- Make the subject as interesting as possible and try my best to connect the theoretical with real-world applications
- Lectures will include time dedicated to analysing and discussing ongoing topical news items with relevance to our field

Coursework

- Mandatory
 - A set examination at year end amounting to two credits
- Optional, but vital to your development as students
 - Reading up on subjects mentioned in lectures or even in news feeds taken from everyday events. It is surprising how much more we can learn, and how much more interested we get when a subject is integrated or connected to our own existence and social placement

Why are we here?

- To make a difference!
 - All of us can make an impact on the people we meet and work with, both during and after our studies
 - How much of an impact we make is up to us
 - Simply going through the motions of learning a particular subject is just not good enough, even if that subject is not to our liking
 - At some point in time we will make use of what we would have learnt in the past, if not for our own personal gain, then for that of society in general
 - We have been privileged to be given the opportunity to learn, so lets get on with it!

Basic concepts and definitions

Pharmacoeconomics

- Is a multidisciplinary concept
- Encompasses **pharmacy** and **economics**
- By definition is the study of the financial aspects of pharmaceutical care

Pharmaceutical Care

- The responsible provision of **drug therapy** for the purpose of achieving definite outcomes that improve a **patient's** quality of life¹

¹ Hepler, D.D. & Strand, L.M., Opportunities and Responsibilities in Pharmaceutical Care, Am.J. Pharm.Educ., 53, 7S-15S(1989).

Economics

- The study of the utilisation and distribution of scarce resources which could have a variety of potential applications, both in a present and also in a future context
- By nature, no resource is infinite and thus a system for its allocation must exist, or be devised

Pharmacoeconomics

- Is thus the science of applying economic theory to pharmaceutical healthcare ends
- Scarce pharmaceutical resources are put to the best possible use
- And implemented to achieve the best cost to effect benefits
- A more technical definition is.....

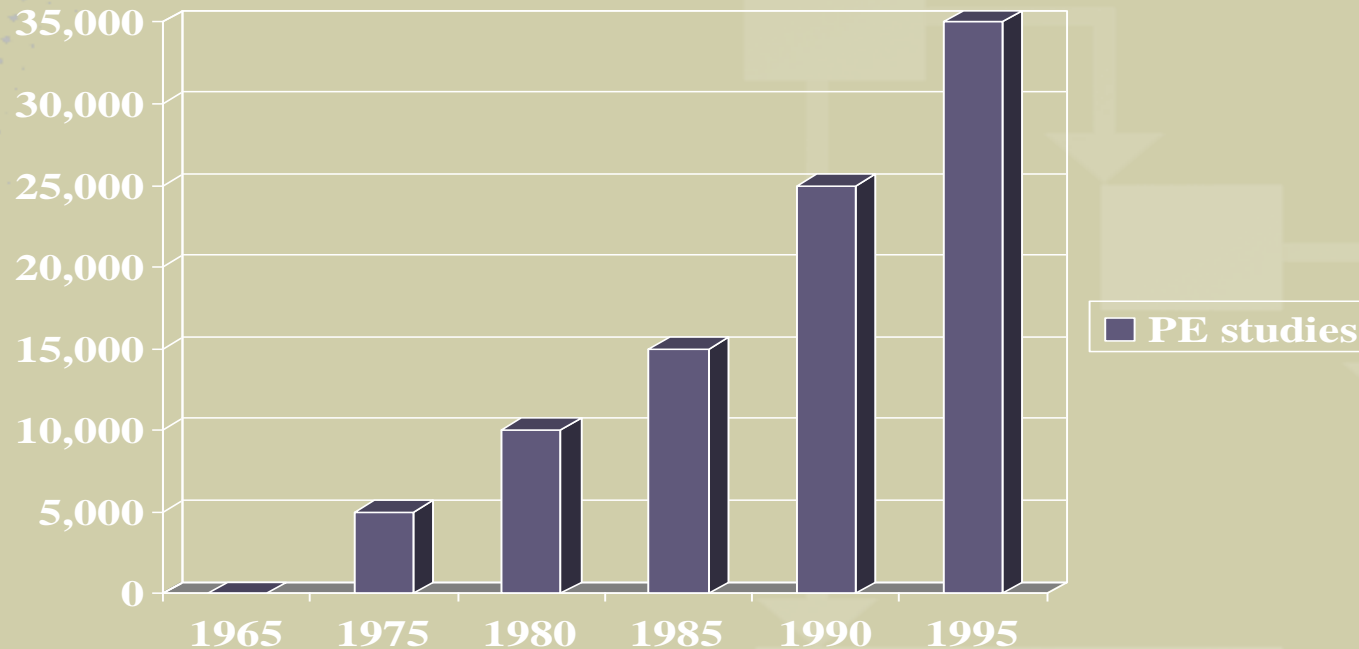
Definition of Pharmacoeconomics (PE)

- **Description and analysis** of the **costs and consequences** of pharmaceutical products and services and their impact on individuals, health care systems and society.

PE as a science

- It is a new discipline
- Only started being mentioned in literature in the 1980's, with the first PE journal published in 1979
- Becoming even more relevant as financial realities become more important
- In pharmacy one must achieve a balance between needs and resources

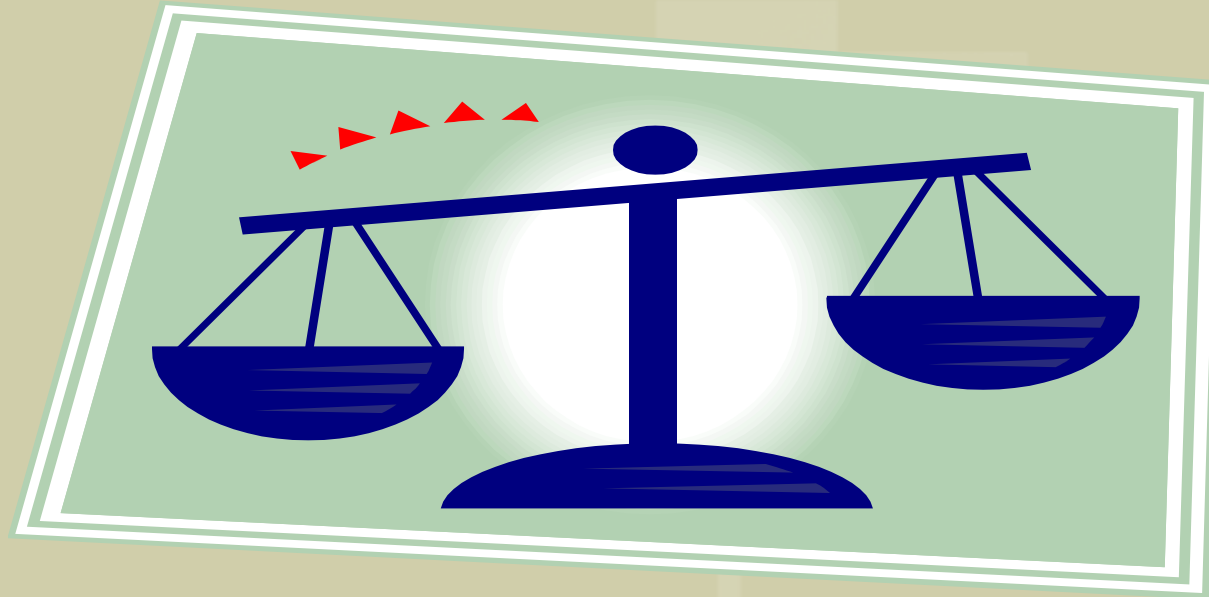
The increase in PE studies over time



PE and pharmacists

- We are at a disadvantage as we do not have a grounding in economics
- This unit will attempt to impart the basic principles of economic reasoning
- Economists who study PE suffer from a lack of depth in medical understanding and context

PE as a dispenser of pharmaceutical 'justice'



Why PE ?

- The definition stated previously is very narrow
- It does not encompass all the possible applications
- However two main divisions can be identified
- The evaluation of new drug therapies and the quantification of the cost/effect ratio for existing interventions

Aims & Uses

Main applications of
pharmacoeconomic studies



Drug Therapy
Evaluations

Justify the cost of
pharmaceutical care

Aims & Uses

- The primary aim is to enable providers to supply a high quality pharmaceutical service at the lowest possible cost
- Outcomes research helps to answer some of the tricky questions posed earlier
- By setting a measure of cost-efficacy to a particular health treatment

Application

Outcomes research-

A manner in which to evaluate the economic implications of research in general

Cost-

A quantification of the value of resources consumed by a program or drug therapy of interest

Consequences-

A measure of the effects, outputs or outcomes of program or drug therapy of interest

PE and the practice of pharmacy

- PE allows decisions to be taken on who, how and when to treat
- Hard choices must be made when practising pharmacy, as there are never enough resources to treat all potential patients
- PE is often ignored by administrators due to time and or budgetary constraints, resulting in even more misuse of valuable resources

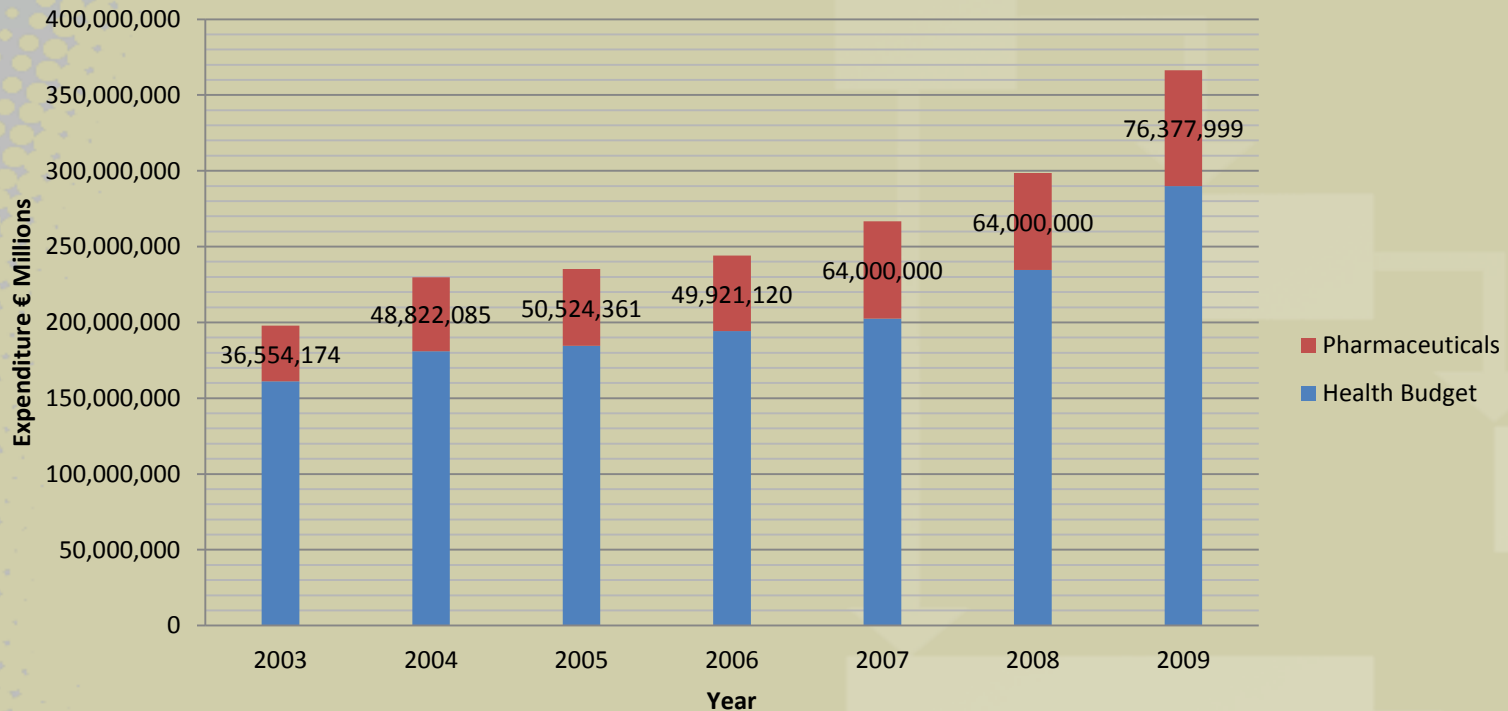
PE and the local scene

- In various EU and other countries HTAs(Health Technology Assessments) are now mandatory prior to MA(Marketing Authorisation Applications) and introduction to national formularies
- Locally this has been mentioned but never implemented

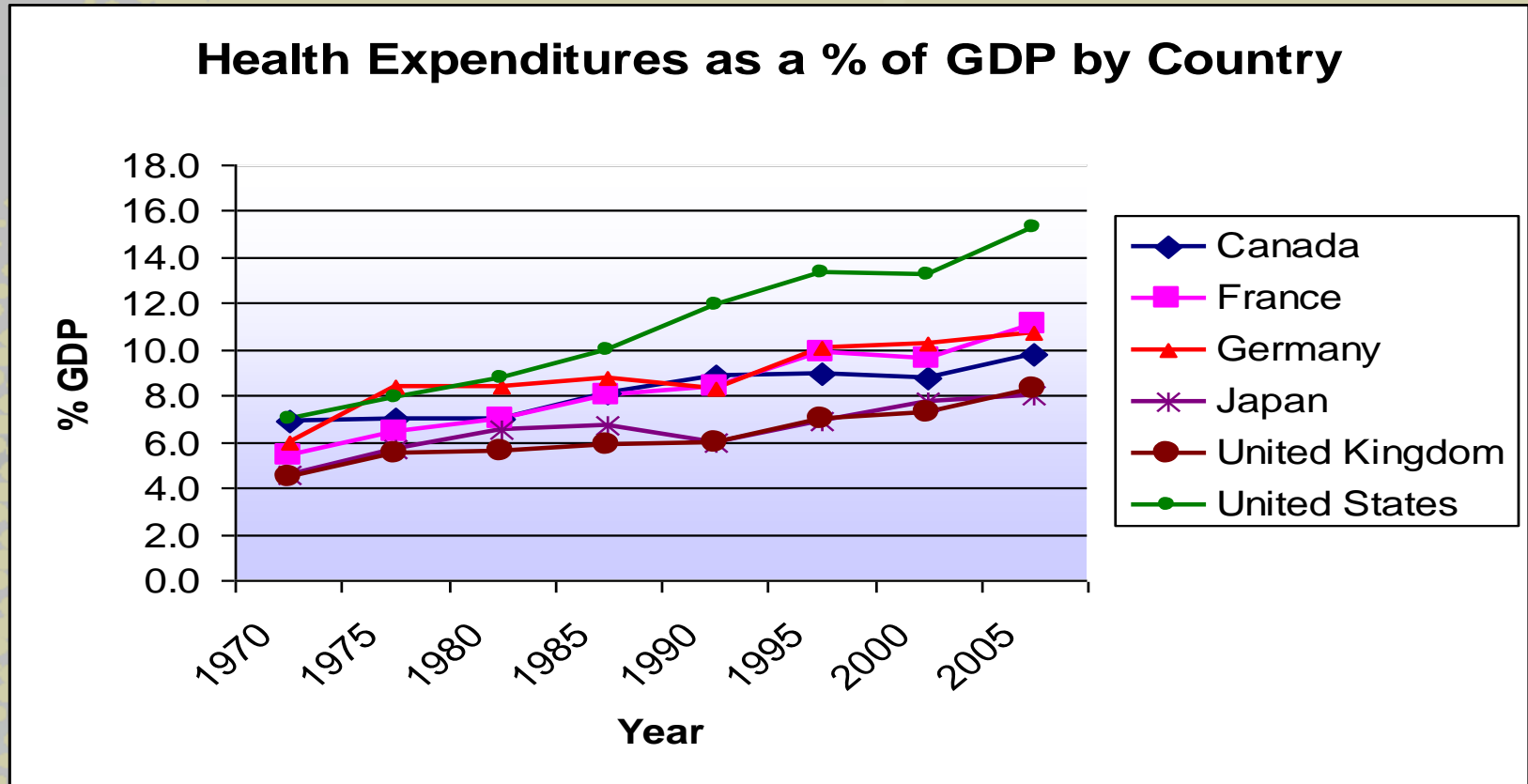
PE and the local scene

- No data is available to enable the analysis of state pharmaceutical expenditure in Malta
- The graph on the following page illustrates the dramatic increase in expenditure in the last 10years
- Without the appropriate facts and consequent analysis there is no way of knowing what return on investment we are getting with respect to state-funded pharmaceutical care

PE and the local scene



Pharmaceutical costs elsewhere



PE and the local scene

- The first step would be the development of a set of indicators representative of the effects of pharmaceutical care
- These could then be studied over time to establish any correlation with the considerable increase of the cost of care, taking into consideration the other variables (e.g. demographics and inflation), involved

Social Context

- PE thus enables pharmaceutical care to be put into real-life context
- Innovation and increased expenditure within the (local) pharmaceutical field is futile without the possibility of evaluating the economic implications
- This would further increase its widespread, affordable and accessible application
- Can be on a macro- or micro-economic scale

News round-up

Avastin – pay for performance

- Roche has offered refunds in instances where the drug does not work
- An attempt to regain market share
- Ethically suspect
- Not the first pay for effect contract in Germany

Pay for effect

- Can set the wrong incentive to hospitals
- They might provide sub-optimal treatment to be refunded cash
- On the other hand, why pay for a pharmaceutical that might have no beneficial effect

Pay for effect

- Innovative drugs will get to patients faster
- Has been implemented in Spain
- A variation of a much larger paradigm being championed in the United States
- Value Based Healthcare is being described as a holistic approach to intervention evaluation

The cost of new drugs

U.S. Phase IV Budgets Top \$12,000 Per Patient

Global average across the pharmaceutical and biotechnology industries now almost \$6,000 per patient

The Research team's new study found that drug companies spend an average \$5,856 per patient to fund a [Phase IV clinical trial](#) in the United States. The project spanned several types of Phase IV studies, including investigator initiated trials, registries and observational trials and large simple safety trials.

Companies' costs per patient ranged from \$1,000 at the low end to more than \$12,000 at the high end. Typically, the more expensive per-patient costs are for Phase IV trials that study oncology or urology. The new study, "Phase IV Clinical Trials: Best Practices in Post-Marketing Study Management," found that the per-patient costs for Phase IV oncology studies average more than \$7,000.

"Increased scrutiny from regulatory agencies, as well as greater demands from payers, has driven recent growth in Phase IV research," said David Richardson, research team leader at Cutting Edge Information.

The cost of new drugs

THE COST OF CREATING A NEW DRUG

YEAR	R&D (BILLIONS)	APPROVED PER YEAR	COST PER APPROVED DRUG (MILLIONS)
1987	\$5.5	21	\$262.0
1988	\$6.5	20	\$326.9
1989	\$7.3	23	\$318.7
1990	\$8.4	23	\$366.1
1991	\$9.7	30	\$323.5
1992	\$11.5	26	\$441.1
1993	\$12.7	25	\$509.6
1994	\$13.4	22	\$611.3
1995	\$15.2	28	\$543.1
1996	\$16.9	53	\$319.0
1997	\$19.0	39	\$487.4
1998	\$21.1	30	\$702.0
1999	\$22.7	35	\$649.1
2000	\$26.0	27	\$964.1

Source: Pharmaceutical Research and Manufacturers of America

Out of stock items

- Drug shortages have been around for years in the United States, but they were previously intermittent and largely temporary
- They have shot up in a very short time, with a record of over 200 scarce medicines this year alone, up from 56 in 2006, according to FDA data.

Out of stock items

- In a July survey of 820 hospitals by the American Hospital Association, more than four-fifths of hospitals said they had to delay treatment and more than half could not provide patients with the recommended drug for their disease.
- The non-profit Institute for Safe Medication Practices (ISMP) has reports of at least 15 patients dying from drug shortages since last September.

Reform on the way?

TIMESOF
MALTA.COM

Wednesday, October 12, 2011, 21:19

Reform of free medicines system announced



Health Minister Joe Cassar has announced an overhaul in the free medicine system – nearly doubling the number of medical conditions in the formulary and consequently increasing the number of free medicines.

Speaking during the debate in second reading amending the Social Services Act, Dr Cassar told parliament that the reform aimed at reflecting today's realities and medical advances. The list of medical conditions under which patients are entitled to free medicines will go from 18 to 34 and include 11 conditions related to cancer.

The reform, which includes a stock take and an analysis of the system, aims at reducing inefficiencies in the procurement and fair distribution of free medicine. This also includes an investment in the IT system to curb abuses. A tender for an IT system, making access for entitlement simpler and more efficient, is to be issued in the coming months.

Dr Cassar said that with immediate effect the number of free syringes for diabetes sufferers will be tripled and the entitlement to testing apparatus will not be limited according to age. A number of administrative procedures have been established for foreigners and irregular immigrants.

The restructuring process includes the transfer of such diseases as polio, diabetes; tuberculosis and leprosy from the second (*Kartuna Roza*) to the fifth schedule (*Kartuna Safra*). These sufferers will now be entitled to free medicine irrespective of age.

Healthcare reform

- Almost twice the amount of conditions under Schedule Five
- A consequent increase in the amount of free state pharmaceuticals
- No workings or figures available or published
- Is it feasible?

Healthcare reform

- Dementia sufferers excluded
- Will only be supplied if suffering from a psychiatric condition
- 2% of the population will be affected by 2050
- We need to spend over € 120 million per year to match spending in the UK

American Pharmacy Owners!

The True Economics of Pharmacy Ownership

Hooray! It's time for my annual disambiguation of independent pharmacy owners' true economics, courtesy of the new [2011 NCPA Digest sponsored by Cardinal Health](#).

You may believe that independent pharmacies are unprofitable and pharmacy ownership is a bad deal. However, data from the NCPA's latest Digest show otherwise. Here are four fun economic observations about pharmacy ownership:

- Pharmacy profit margins remain stable.
- An independent pharmacy's profits from prescriptions are increasing, not decreasing.
- The average pharmacist owning a single pharmacy earned over \$250,000 in 2010, but 7% less than 2009.
- The average pharmacist owning multiple pharmacies earned over \$1 million, up 17% vs. 2009.



Pharmacy profits

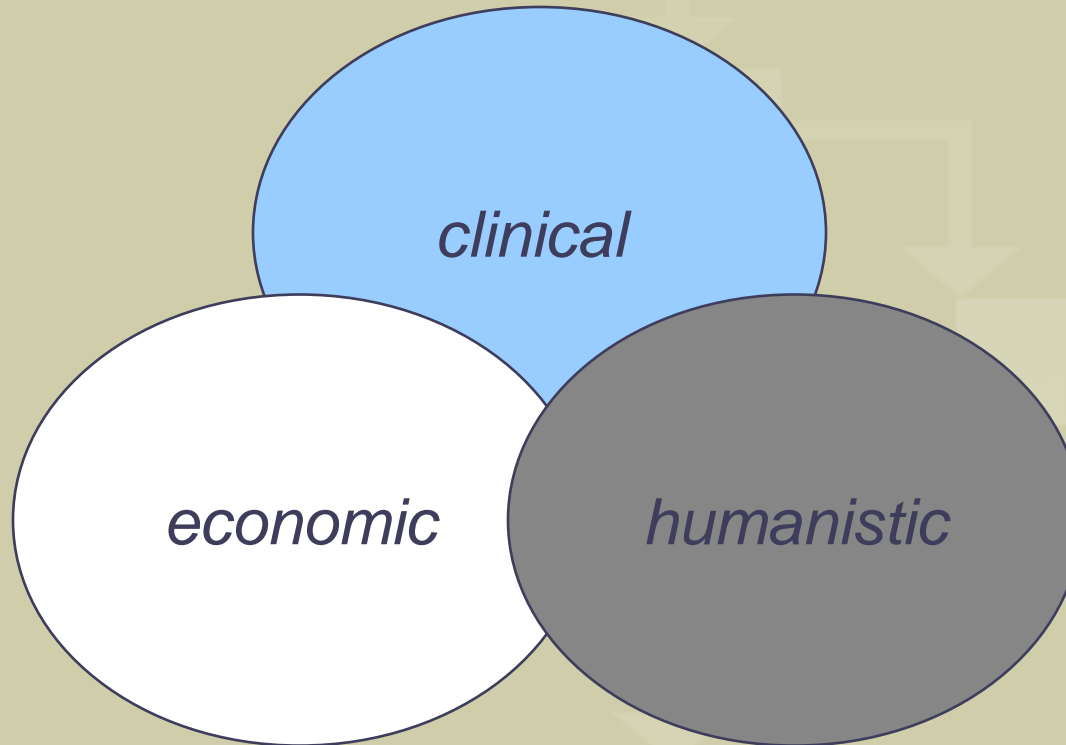
- The previous news clipping illustrates the differences between the Maltese market and the United States
- Medicinals are much more costly in the US and allow for greater profits, combined with greater margins on generic products

PE, clinical pharmacy and pharmaceutical care

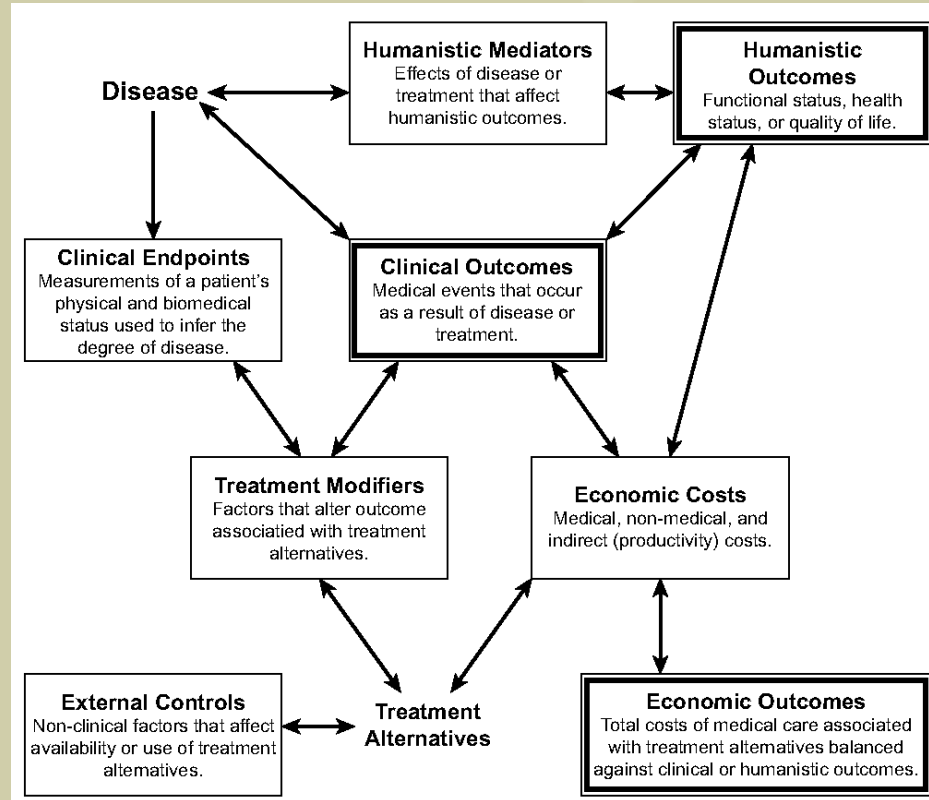
Conflicting interests in healthcare administration

- There is an overlap of functions
- Various interests vie for primacy
- Taking an objective view while prioritising the patient's well-being

Interlinked Subsets of PE Decision-Making



ECHO model – conceptual framework



The Echo Model

- There is an overlap of functions
- Developed by Kozma, Reeder & Schulz (1993)

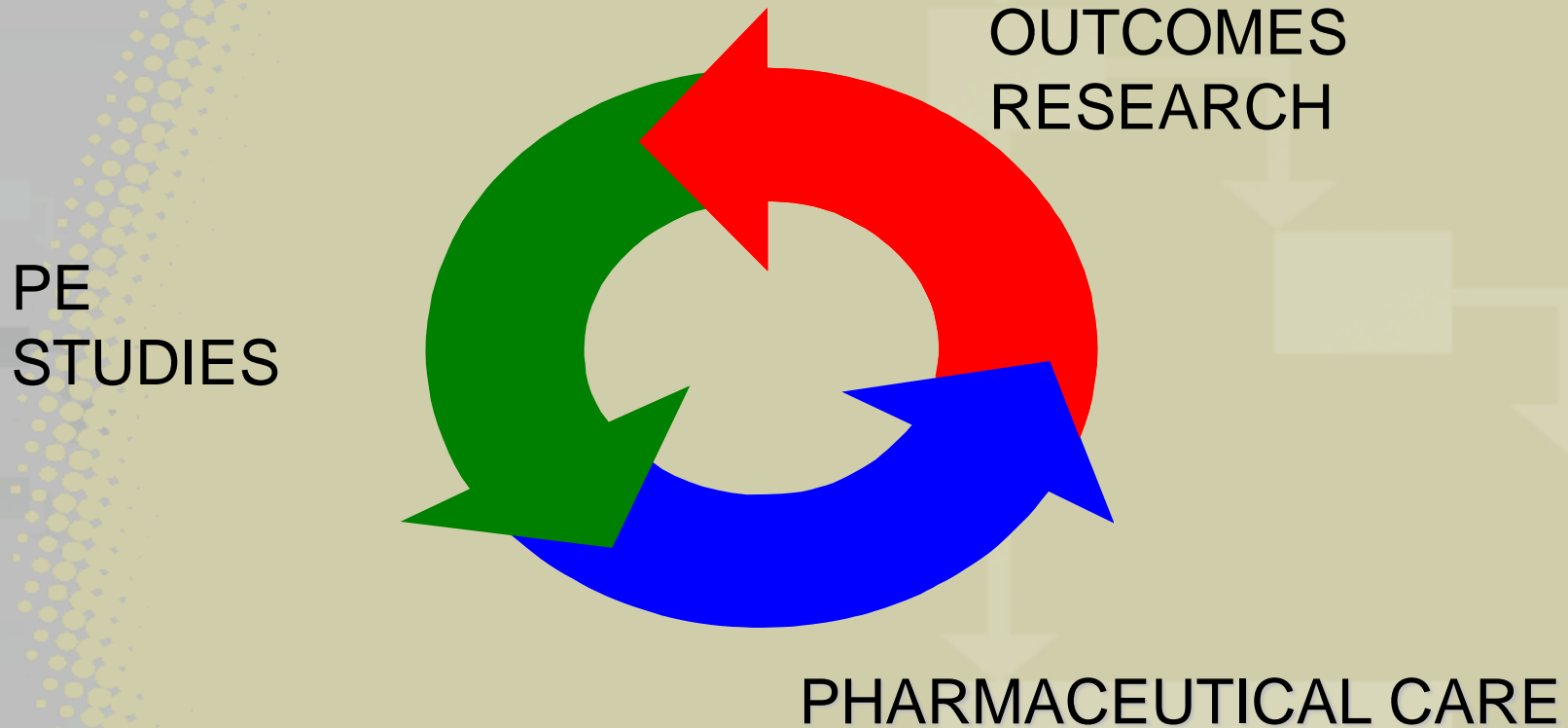
Outcomes to be considered

Outcome	
Clinical	Eradication of disease and physical survival
Humanistic	Quality of life, including physical, emotional and social well-being
Economic	Cost of treatment options, alternatives, and the global effect on society

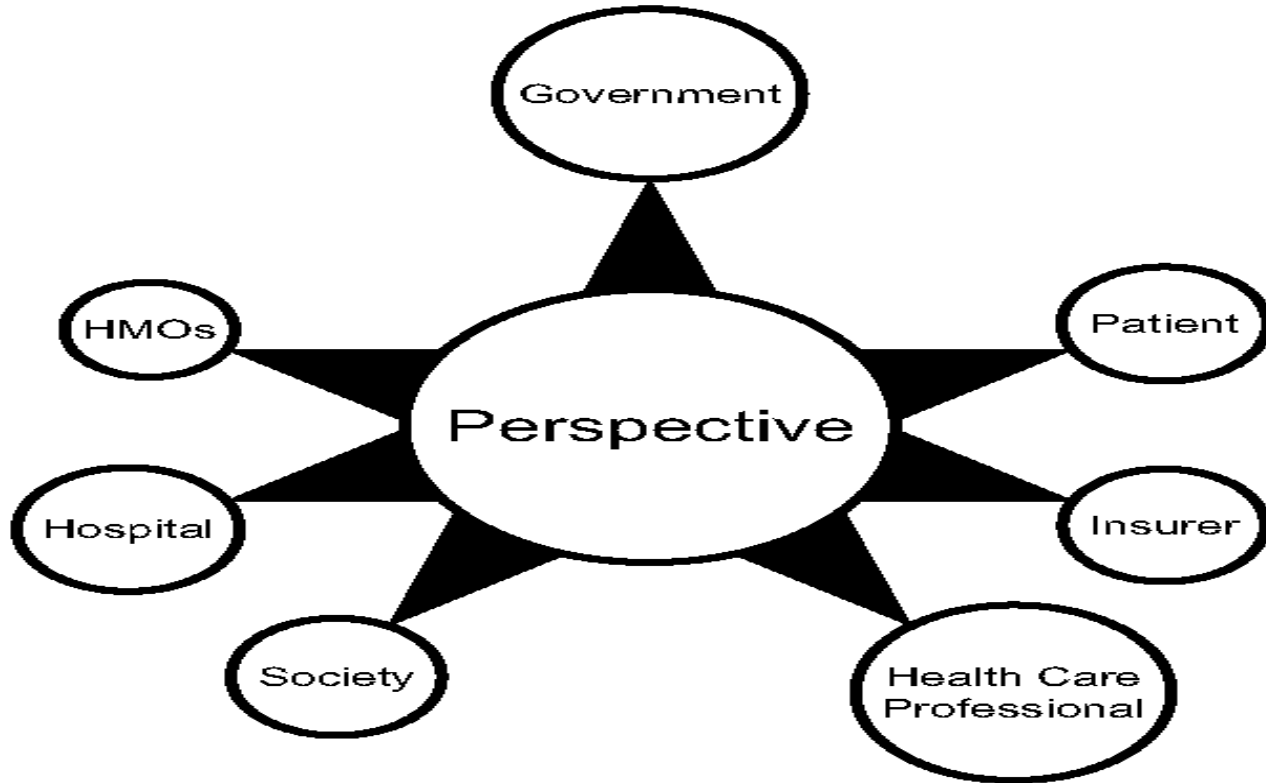
Clinical implications of PE

- Time and money can only be spent once-choice is inevitable
- Pharmacoeconomics and outcomes research strengthens the evaluation process
- Enables the delivery of better value in patient care
- Increases access to pharmaceutical care

Cyclical relationship between Outcomes, Pharmacoeconomics and Pharmaceutical Care



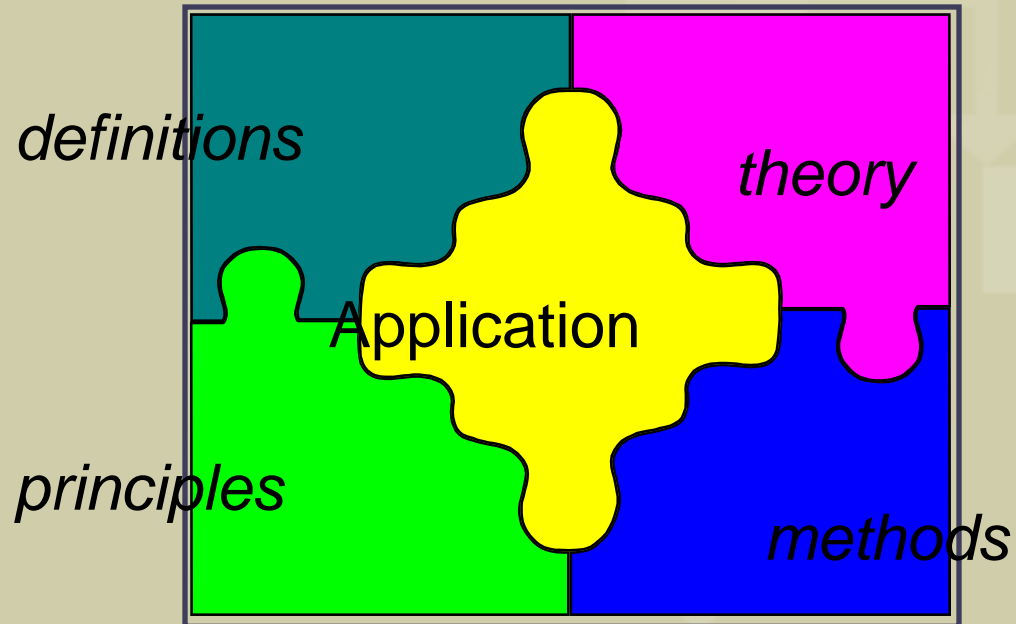
Perspective of a PE study



Perspective of a PE study

- Patient- the actual recipient of treatment
- Prescriber- the professional choosing the treatment
- Provider-the institution supplying it
- Payer- the one forking out the money
- Societal- the global effect of the cost on others

Applied Pharmacoeconomics



Applied Pharmacoeconomics

- Apart from the obvious of clinical decision making
- formulary management, practice guidelines, drug policy, individual patient treatment, and resource allocation are other applications

Management in Pharmacy



Pharmacy administration

- This is often disregarded within the context of pharmacy undergraduate courses.
- It is, however, a vital skill within our multiple-disciplinary mindset, especially in the Maltese Islands.
- One must consider that amongst those of you that will be entering the field of community practice, most will be required to carry out the duties of professional pharmacist and shop manager.

Pharmacy administration

- These duties require as a bare minimum a working knowledge of administrative functions and procedures. This is also relevant outside the area of community practice
- Running a state owned pharmacy, or managing the budget and expenditure of a pharmaceutical distributor, still imposes the knowledge of money and people management.

Pharmacy administration

- Human resources are also an important aspect of pharmacy management
- We will tackle certain basic issues pivotal to maintaining a healthy and comfortable work environment

Basic accounting

- As mentioned earlier administrative duties have wide-ranging remits
- Among these are budgeting and book-keeping (on a daily basis)
- We will take a look at the accounting basics required to keep on top of the responsibilities asked of a professional post

Ethics

- We will approach this subject at a later date, but it suffices for now to say, that imposing a high level of integrity and moral high ground from day one, will set you up for professional and personal success in the long haul.
- Short -termism does not work in this respect.

Course Material

- Please refer to:
- *PH 3340 – Facebook page*
- *Pharmablog-malta.blogspot.com*
- *www.stsimonpharmacy.com/education*