THE ROLE OF PHARMACOVIGILANCE IN PHARMACOECONOMICS

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PHARMACOVIGILANCE

• A Scientific discipline that focuses on monitoring the benefit-risk profile of medicinal products.
• Deals with the safety of marketed drugs under the practical conditions of clinical use in large communities.
• Concerned with the development of science and regulation in the area of drug safety.

DEFINITION:
The World Health Organization (WHO) defines PV as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
Overview of Pharmacovigilance

Collect… Collate… Analyze… Communicate…

- Spontaneous Reports
- Literature Reports
- Clinical Trial Data
- Regulatory Reports
- Licensing Partners

Data Review

Signal Generation

- Amend Prescribing Information
- Review marketing status
- Licensing Partners
- World-wide Regulatory Reports (expedited and periodic)
- Enquiry Response
- Submission
PHARMACOECONOMICS

• Science dealing with the description and analysis of the costs of drug therapy to health care systems and society.

Definition:
• Pharmaco economics is the scientific discipline concerned with the cost and value of drugs, often with the goal of optimizing the allocation of healthcare resources. (Ref: Nature)
Pharmacoeconomic Methods

Pharmacoeconomics

Economics
- Cost benefit
- Cost effectiveness
- Cost minimization
- Cost utility

Humanistic
- Quality of life
- Patient preferences
- Patient satisfaction
PHARMACOECONOMICS
Why PE needs PV?

• Optimal usage of available resources in a healthcare system to achieve the maximal health gain for the population, at the minimal possible cost.

• PE does not mean always using inexpensive drugs. Sometimes, an expensive drug with lesser number or less serious ADRs is more PE-friendly.

• Benefits of drug therapy need to outweigh not only the cost but also the associated risks.

• Investing in PV is an insurance policy for positive PE.
PV Approach to PE

- Detecting an ADR at the right time:
  - Reduces suffering by facilitating treatment.
  - Reduces the expense of treatment of the ADR.

Intensity, frequency and severity of ADRs can increase burden on pharmacoeconomics and hence this detection can help in pharmacoeconomic evaluation and choosing the drug.

- Efficient and organized assessment of drug molecules is essential for clinical research, treatment planning and referrals, which is made available by a robust PV system.
Applied PV in PE

- Assessing the causality in Clinical Development stages - Decreased burden of PE by not begetting unsafe drugs.

- ADRs assessment - Signal detection & risk–benefit decisions can result in preventing ADRs and the linked cost.

- Right causality assessment instead of casual assessment – Prevents or speeds up drug withdrawal or usage change.
ROLE OF PHARMACOVIGILANCE

To improve **patient care** and safety in relation to medicines and all medical & para-medical interventions.

To improve **public health** and safety in relation to the use of medicines.

To contribute to the assessment of **benefit**, **harm**, **effectiveness** and **risk** of medicines.

To promote understanding, clinical training & effective **communication** to health professionals and the public.
CONNECTING PV TO PE

Reduce hospitalization and/or other costs secondary to adverse drug reactions

Select most suitable drug for any patient among the available choices

Safety not compromised for efficacy

Maximal efficacy at a minimal cost.

Choosing right drug for right patient and right patient for right drug.

Rational use of medicine by comparing the cost and consequences.
Economics of PV

• Systematic assessments of the economic value of PV can support rational decision making.

• Studies have demonstrated the substantial mortality burden and economic loss associated with adverse drug events.

• There are considerable costs involved in running a PV programme and it has to justify the investment by positively shifting the benefit-risk ratio & thereby the cost-benefit ratio.

• Industry also invests in PV to meet their regulatory obligations and by the fees paid make an indirect contribution to the PE of the country.
Some Data

• In the US, the treatment of medicine related problems (MRPs) was estimated to cost $US177 billion in 2000. In the UK, the projected annual cost of admission related to ADRs to the National Health System was £847 million in 2004.

• Studies have demonstrated the economic impact of different individual treatments in terms of their cost per AE prevented.

• PV can protect the public’s health by identifying the risks of and the risk factors for drug AEs in a timely manner and using information for risk mitigation. Information collected through PV allows for the assessment of the risks and benefits of a medicinal product throughout its life cycle.
Why PV for PE?

• A country’s lack of a functional PV system leads to greater costs in terms of the resources used to manage and prevent MRPs as well as worse health outcomes in terms of medicines-related morbidity and mortality and medicines-related quality-of-life (QoL) reductions and disability.

• Quantifying these impacts in terms of the opportunity cost of the resources used and the adverse health impacts is important in assessing the potential value of starting or strengthening national PV centres.
Key Takeaways

• No degree of care and caution can guarantee absolute safety.

• PE & PV professionals need to understand each other’s goals and collaborate further for society’s benefit.

• PE & PV are young developing sciences whose methodologies continue to get refined by implementation.

• PE has a wide role in health policy decision making by different healthcare professionals, policy makers, healthcare providers, health-care administrators, and health managers.

• Good PV is a key determinant for Good PE.
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