

Pharmacovigilance: Partnering for Patient Safety

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International Alliance of
Patients' Organizations

A global voice for patients

Content of Presentation

- A short introduction to the International Alliance of Patients' Organizations (IAPO)
- Patient-Centred Healthcare
- The Patients Role in Patient Safety
- IAPO Toolkit on Patient Safety – Taking Medicines Correctly
- IMI PROTECT – Innovative Methods for Reporting
- Conclusion

About IAPO

- Unique global alliance of 215 national, regional and international organizations representing patients
- Crossing borders and diseases
- Vision: Patients throughout the world are at the centre of healthcare
- Membership spans over 60 countries and all world regions
- Representing an estimated 365 million patients



Capacity Building



Advocacy



Partnerships

IAPO's Mission

Our mission is to help build patient-centred healthcare in every country by:

1. **Realizing active partnerships with patients' organizations**, maximizing their impact through capacity building
2. **Advocating internationally** with a strong patients' voice on relevant aspects of healthcare policy, with the aim of influencing international, regional and national health agendas and policies
3. **Building cross-sector alliances** and working collaboratively with like-minded medical and health professionals, policy makers, academics, researchers and industry representatives

An approach to healthcare is needed that focuses on the person rather than the disease and involves people in their healthcare aligning healthcare systems with patients' needs:

→ **Patient-Centred Healthcare**

“The people have the right and duty to participate individually and collectively in the planning and implementation of their healthcare”

**Alma Ata Declaration –
Principle IV (1978, WHO)**



What is patient-centred healthcare?

The IAPO Declaration on Patient-Centred Healthcare outlines five principles:

- Respect and support for the individual patient, their wants, preferences, values, needs and rights
- Choice and empowerment
- Patient engagement in health policy

(See www.patientsorganizations.org/involvement)

- Access and support
- Information that is accurate, relevant and comprehensive

(See www.patientsorganizations.org/information)

The essence of patient-centred healthcare is that the healthcare system is designed and delivered so that it can answer the needs of patients

What can patients and patient groups do?



Advocate – Advocate to raise political will to take action and implement appropriate patient safety strategies and partner with healthcare systems to develop solutions for patient safety



Educate – Educate and train patient groups to make an informed contribution to patient safety initiatives and patients be informed and empowered to make a personal contribution to safety



Raise awareness – Raise awareness of patient safety issues with the public and the media

The Quality and Safety of Medicines



ACT NOW!

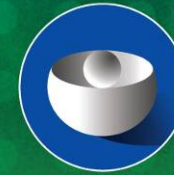
- Work with patients and health professionals to improve communication of medicines information and the importance of monitoring of adverse drug reactions
- Advocate for good quality information for patients
- Advocate for stronger political will and action to combat substandard and counterfeit medicines, including appropriate penalties for counterfeiters
- Raise awareness of the dangers of substandard and counterfeit medicines.

The Quality and Safety of Medicines



Key information, facts and figures

- Medicines contain potent ingredients and therefore carry an inherent risk that they may cause unexpected and sometimes harmful reactions or side effects in some people. Because of this, many countries have laws and regulations to ensure that medicines are safe and meet certain quality criteria relating to their development, manufacture, storage and distribution.
- Adverse Drug Reaction related hospital admissions represent around 10% of total admissions in many developed countries.
- Counterfeit and substandard medicines are those whose ingredients and/or composition do not meet required standards as set by authorities and regulatory agencies.
- During a meningitis epidemic in Niger in 1995, 50,000 people were inoculated with fake vaccines (a gift from another country that thought they were safe) causing 2,500 deaths.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PROTECT



Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

PROTECT: Pharmacoepidemiological Research on Outcomes of Therapeutics by an European Consortium

Presented by:

An agency of the European Union



PROTECT Goal

To strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods

to enhance early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies)

to enable the integration and presentation of data on benefits and risks

These methods will be tested in real-life situations.

Work Package 4

Objectives:



- To assess the feasibility, efficiency and usefulness of modern methods of data collection including using web-based data collection and computerised, interactive voice responsive systems (IVRS) by telephone
- To pilot approaches between data sources
- To measure the acceptability of these methods and assess the transferability of data collection methods in different countries and for other conditions

Prospective study in pregnant women in four countries is under development:

• Denmark 

• United-Kingdom 

• The Netherlands 

• Poland (tbc) 

Work Package 5

Objectives:



To DO:

- To assess and test methodologies for the benefit-risk assessment of medicines
 - To develop tools for the visualisation of benefits and risks of medicinal products
-
- ➔ Individual and population-based decision making
 - ➔ Perspectives of patients, healthcare prescribers, regulatory agencies and drug manufacturers
 - ➔ From post-approval through lifecycle of products

Conclusion

Patients need access to quality and safe medicines.

Pharmacovigilance is essential to medicines safety and patients are key to its success.

Improve information on pharmacovigilance for patients:

- What is it?
- Why is it important?
- How should patients act?

Above all – **Global commitment to improve regulation and monitoring**

Contact us



Please visit our website to find out more:
www.patientsorganizations.org

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