Ioana Agache
European Academy of Allergy and Clinical Immunology (EAACI)

Stakeholder perspective and use cases –Healthcare professionals

Disclaimer

- Presenting as the healthcare professional representative in the joint HMA/EMA Big Data Steering Group
- Presentation prepared with contributions from:
  - European Academy of Allergy and Clinical Immunology (EAACI)
  - European Union of General Practitioners (UEMO) with specific feedback shared in slides 7-9
  - European Geriatric Medicine Society (EuGMS) with specific feedback shared in slide 10

Data standardization for HCPs

1. collaborative research
2. large-scale analytics
3. sharing of sophisticated tools and methodologies

Data is most valuable when you have something to compare it to However, comparisons aren't helpful if the data is bad or irrelevant.

Challenges identified	Proposed solution
Incomplete and inaccurate medical data collection	Quality, accessible, timely and reliable disaggregated data
Heterogeneous coding landscape	Harmonised coding system for real world data
Secondary use of HR combined with data from other sources, e.g., census tracts, surveys, morbidity and mortality data.	Strengthening data collection and capacity building in Member States
Multiple disconnected data capture systems	Customised data collection
Changing data standards and practice guidelines over time	Develop interconnected national and EU guidelines

Challenges identified

Clinical research data are often collected in a variety of formats

70% of researchers failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments

Baker M. Nature. 2016

The greater the flexibility in designs, definitions, outcomes, and analytical modes in a scientific field, the less likely the research findings are to be true

Proposed solution

Clinical trials and research findings imparted and shared in a clear and understandable way

Clinical research data

1. **traceable**
2. **accessible**
3. **interoperable**
4. **reproducible**
5. **of good quality**

The FAIR criteria

Alignment between funding bodies and regulatory agencies for research standards

Harmonise coding

There are many different coding systems being used by GP's across Europe. Although there is one developed by WONCA (ICPC-2 / ICPC-3), it is not used in most European countries.

There aren't many training opportunities on coding during GP training,

In primary care coding systems reflect the non-specific nature of symptoms and signs that patients present
In specialised care - disease oriented coding systems.

Within a country there are many different IT systems being used in primary care

Need for a system which require less training / experience to master and code signs, symptoms and diagnosis.

Better prepared to be linked with hospital and other types of administrative databases.

UEMO (1) – harmonise coding

In the UK GPs have been extensively coding their patients' diseases, since the 1980s

The Read codes, implemented in 1992 were, until recently the only codes used in primary care

In an effort to harmonise GP coding with Hospital coding the government decided to bring in SNOMED

Though it may be easy for hospitals to adapt to, it has proved less amenable to the undifferentiated diagnoses of general practice.

UEMO (2) – harmonise coding

General practice EHRs are done with a consistent and clinically administered system, the same is not true for hospital system

In a local hospital, there are 33 different computer systems spread over different departments which do not communicate with each other.

Because hospitals rely for their income on coding of procedures, coding is often done by administrative staff and while it may attract the best tariff, it may not always be clinically accurate

Within the EU, with varying systems in different countries, it seems even harder.

UEMO (3) – harmonise coding

EU mandating the use of a reliable coding system

The coding should be taught in medical schools (initial training) and regularly reminded (continuous education)

Supported by the medical file management software

- **structured file**
- **problem-oriented,**
- **allowing automatic coding help**

EUGMS- harmonise clinical trials in older adults

Any clinical trial in older adults should always include a measure of physical frailty for harmonisation purpose

as 1) confounder/ variable of interest for stratification/ sensitivity analysis (best option baseline and follow-up, mimimum baseline) and as an outcome measure (secondary outcome)

EAACI – standardised RWE collection

A lack of data on the reliability of RWE in allergen immunotherapy (AIT) and consequently, a lack of information on how AIT effectively works in real life.

A hierarchy of RWE in AIT was proposed, which places pragmatic trials and registry data at the positions of highest level of evidence

The RELEVANT tool to evaluate the data

AIT registries that collect data in a cohesive way, using standardised protocols

Paoletti G, et al Allergy. 2021 Feb 14. doi: 10.1111/all.14773. Epub ahead of print

How can HCPs help build a common data model

Provide a collaborative, interdisciplinary network of various specialities

Expertise on medical products/devices and diseases and translation into meaningful data and health outcomes of interest

Implement the data source standardisation

Regular feedback and quality control