EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

From regulatory outputs to health outcomes (3.2)

Session 4 - Reports from breakout sessions: gaps and observations

Workshop: Measuring the Impact of Pharmacovigilance Activities
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Session 3.2 Topics

1. **Methods to go from process outcomes to health outcomes (e.g. use of surrogate measures and interrupted time series)**
   Stephen Evans, London School of Hygiene and Tropical Medicine

2. **Study of liver function monitoring in patients receiving agomelatine in the Estonian Health Insurance (EHI) database**
   Maia Uusküla, State Agency of Medicines Estonia

3. **Modelling methods to estimate the public health impact of regulatory decisions**
   Saad Shakir, Drug Safety Research Unit

1. Discussion points

- Is it possible to relate process outcomes to health outcomes?
- Are the methods for interrupted time series (ITS) adequate to estimate effects of regulatory actions?
- Can major regulatory decisions be accompanied with plans to measure the public health impact?
- What approaches can be used to estimate the effectiveness of RMM such as additional monitoring
- What type of evidence for safety is used to support regulatory decisions
- Quantifying absolute and relative risk from evidence used in PhV decision making
- Seek to identify predictive modelling methods to measure the public health impact in terms of mortality and serious morbidity

2. Key findings

Methods to go from process outcomes to health outcomes (e.g. use of surrogate measures and interrupted time series)

- Effect of media on statin prescribing
- Used an ITS regression modelling approach

Study of liver function monitoring in patients receiving agomelatine in the Estonian Health Insurance (EHI) database

- Adherence to the liver monitoring scheme was shown to be poor
- Further information is required to inform whether regulatory action is needed

Modelling methods to estimate the public health impact of regulatory decisions

- Complicated process which needs a collaborative process for the design

3. Challenges and gaps

- Difficulty in measuring the intended health outcomes
- Challenges to specify time periods
- Difficulty in modelling accounting the impact of the confounding factors
- Limitations of ecological studies
- Other methods may be required to fully understand the effectiveness of RMM
- Importance in measuring the variation (e.g. sub-populations)

4. Recommendations and conclusions

- Modelling approaches such as ITS are a potentially useful method
- Important to ensure key modelling assumptions are met
- Consider examining subpopulations to detect changes in health outcomes
- Potential usefulness of negative control
- Importance of patient characteristics
- May need other methods e.g. survey qualitative to understand reasons
- Study methods – when can be used