Evaluating risk minimisation effectiveness

Where are we now?

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• Why is risk minimisation evaluation important?
• What does TGA look for?
• What has been the experience in Australia?
• Where would we like to be?
Why is evaluation important?

Have the risk minimisation activities worked? If not, why not?
Risk management cycle

DATA COLLECTION
- monitor effectiveness and collect new data

IDENTIFY & ANALYSE
- risk quantification and benefit assessment

SELECT & PLAN
- risk characterisation/minimisation and benefit maximisation techniques

IMPLEMENT
- risk minimisation/characterisation and benefit maximisation

EVALUATE
- benefit risk balance and opportunities to increase and/or characterise

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What does TGA look for?

In the evaluation plan
• Is the evaluation plan well described in RMP/ASA?
• Which parts of the program going to be evaluated and why?
• Are the measures and timeframes clearly defined and appropriate?
• Is the methodology suitable and feasible?
• Has consideration been given to how success will be defined?

In the evaluation reports
• Was the evaluation carried out as intended?
• Is there a conclusion about whether the risk minimisation activity should change, continue as is, or cease?
• Is the conclusion well supported by the information presented?
Resources

- EMA Guidelines on good pharmacovigilance practices Module XVI
- CIOMS IX report: practical approaches to risk minimisation for medicinal products
Risk minimisation evaluation framework

Fig. 5.1: CIOMS IX risk minimisation evaluation framework

Programme

Single or several interventions

Potential moderators
- Comprehensiveness of strategy description
- Strategies to facilitate implementation
- Quality of delivery
- Participant responsiveness

Process indicators to evaluate implementation fidelity of each intervention
- Content
- Coverage
- Frequency
- Duration

Outcome indicators to evaluate the programme success (Safety-related outcome of interest)
- Morbidity/mortality EP
- Composite EP
- Surrogate EP
- Biomarker EP

Programme successful?

Yes
Continue programme (or provide justification to discontinue)

No
(Improve interventions or programme design based on process indicator feedback)

Note to Fig. 5.1: EP = endpoint. The ‘CIOMS IX risk minimisation evaluation framework’ outlines elements to be considered for the evaluation of a risk minimisation programme (modified from Carroll (25)).
RMPs evaluated for Type A applications in 2015

- No additional risk minimisation (n=24)
- Additional risk min with no effectiveness measure (n=7)
- Health professional survey (n=6)
- Routine pharmacovigilance (n=1)
- Patient registry (n=1)
Common challenges

• Evaluation plans not developed before registration
• Description of evaluation lacking necessary detail
• Poor response rates to surveys
• Uncertainty about how to evaluate consumer-directed activities
• Use of process indicators without consideration of outcome indicators
Where would we like to be?

• Clear and comprehensive description of evaluation plan
• Consideration of a number of measures, not just knowledge and awareness
• Use of outcomes data
• Evaluation of consumer-directed activities
• Well-justified goal for success
• Sharing experience through publication/dissemination