Minimising risk: a health professional perspective

- **Training and continuing education**
- **Expert support systems**
- **Engaging with colleagues and patients**
- **Effective communications: regulators/HPs/patients/other stakeholders**

Professor Donald RJ Singer

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Reducing or preventing risk

- Minimise prescribing/medication errors
- Early recognition of emerging risk
- Effective intervention
  - Remove hazards
  - Reduce dose
  - Review/improve systems
    - clearer labels, custom delivery technology …

Sources of harm

- Intrinsic risk
- 9 main classes (70% of death and serious ADRs)
- Drug, disease, patient factors
- Medication errors
- Incorrect drug, dose, route, duration, interactions (drug-drug, drug-traditional …)
  - HP errors
  - Patient errors

Key steps

- Risk identification
- Risk analysis
- Prioritising action
  - urgency
  - involving whom
- Improvement (e.g. 5 step methods)
- Audit cycle to confirm sustained improvement

Improving prescribing - I

Prescribing Safety Assessment

- aims to lead to better safety and effectiveness
- promotes better use of medicines by doctors
- compulsory national medical school examination
- process also being taken up by pharmacists
- international quality control and reach (IUPHAR)

Maxwell et al. Lancet 2015

Improving prescribing – 2

Feasible and effective systems?

Computerized decision support

- integrated into electronic health records
- carefully tuned not to disturb workflow
- designed not to create alert fatigue
- risk increased error rates (Esmaeil et al, 2015)

- Case studies
  - Robert Van der Stichele (Belgium)
  - Ylva Böttiger (Sweden)
  - Linda Amundstuen Reppe (Norway)
  - James Coleman (Prescribing Support, UK)

Controlled access

POM

- By whom: doctors (which?), nurses, pharmacists
- Specialist only/shared cared protocols/patient group directives

Additional risk minimisation

- 58/391 active substances
- Pregnancy alerts
- Other special group risks
- …

Better interactions

Reviewing and improving formal and informal communications systems

- Current EMA and FDA themes

Promoting better dialogue between doctors and patients about their medicines “open disclosure”

Recognition that patients

- may have ↓health literacy: 47% in EU (2012)
- may not access reliable sources of information
- may ↓adherence to medicines e.g. NICE:
- https://www.nice.org.uk/guidance/cg76
- experience of patient groups under-recognised

How to improve ADR reporting?

- Serious ADRs common but reporting poor
- HPs at all stages of clinical practice question feasibility and impact
- Managers viewing reports as threshold vs. spur to action

1. UK MHRA open access Yellow Card reports an underused tool
2. Access to WHO UMC and other ADR databases?
3. Embedding reports in training/revalidation portfolios?
4. UK and now EMA black triangle warning schemes – opportunities for Hawthorne effect (in a good way)
5. Evidence loop needed that ADR reporting reduces risk

Burden/ensuring action

- Undue burden on HPs and patients?
- Law of ↓returns with ↑burden of RMM
  - iPLEDGE paradox re isotretinoin
- Sustainability
  - 'must complete' for health records
  - diagnostic list triggers block on further access to system until ADR formally reported eg VTE
  - ↓duplication? local CAE vs. national reports

Issues and opportunities

- Impact of RMM on remaining choices
- Granularity
  - need for general principles across therapeutic categories
  - need for robust registries …
- Timelines overrun by reality e.g. EUReMS
- Great scope for
  - learning from prior projects
  - strategic collaboration