Good Communication Practice in Pharmacovigilance
Scenario 1: Communication with Parents

- You are the Hospital manager who has been informed about a parent whose child has died from an inadvertent massive overdose of quinine in a child with malaria. How would you go about communicating to the parent?
  - To inform the mother about the findings of the investigation.
Scenario 1 (cont)

- How would you communicate with the clinical officer who had administered the medicine to the child. The clinical officer is extremely guilty about this and has submitted a resignation letter to her superior
WHY do we need to improve our communication?

• Improve patient care and understanding

• Improve malaria management
  • i.e. eradicate disease / improve disease control

• Promote transparency and accountability
Understanding the Community

- How do patients feel about coming to the clinic?
- What was their experience with previous visits?
- How are they treated by the clinic staff?
- Have the medicines worked?
- What problems are being faced by the community at the time?
  - (e.g. violence, fear of attack, epidemics)
What is the audience, their perceptions and expectations?

- Parents, patients and consumers
  - concerned, confused and afraid
  - overwhelmed with information
  - tired and overworked
  - harassed and intimidated by health workers
  - listening and acting from a context of religious, cultural and personal beliefs
  - Feeling miserable
Risk predictors

- The public sees risk in terms of:
  - Voluntariness of exposure
  - Familiarity of risk
  - Control over risk
  - Catastrophic potential
  - Fatal consequences
  - Unequal balance between risk and benefit
  - Unequal distribution of risk
  - Vulnerable groups
  - Allegedly attributable to bureaucratic or political culpability

- Experts see risks in terms of:
  - Morbidity and mortality levels
Heuristics of Health Professionals

• tendency to extrapolate from limited data

• fit equivocal data into preconceived patterns
  • “if it is not proven it cannot be true”

• Withhold information for fear of sending out mixed messages
Risk Perception and Predictors of Risk Acceptability

Provider behaviour is extremely influential!
Risk Perception and Predictors of Risk Acceptability

How is the message framed?
- risk/benefit versus risk
- How is the risk framed
Pitfalls when communicating relative risk—a hypothetical example...

“Malaria medicines increases the risk of convulsions in babies by 63%!"

READ ALL ABOUT IT!
Should we communicate relative or attributable increase in risk?

<table>
<thead>
<tr>
<th>Control Event rate (CER) (rate in unexposed group)</th>
<th>Intervention Event rate (IER) (rate in exposed group)</th>
<th>Relative increase in risk: IER/CER (exposed/unexposed)</th>
<th>Attributable risk “Absolute increase in risk” (AR) IER-CER</th>
<th>Number needed to harm (NNH) 1 / AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>8%</td>
<td>13%</td>
<td>13 / 8 = 1.625 (i.e. 62.5% increase in risk)</td>
<td>13%-8% = 5%</td>
<td>1 / 0.05 = 20 patients</td>
</tr>
<tr>
<td>0.00008%</td>
<td>0.00013%</td>
<td>0.00008/0.00013 = 1.625 (i.e. 62.5% increase in risk)</td>
<td>0.00005%</td>
<td>1 / 0.00000005 = 2 000 000 patients</td>
</tr>
</tbody>
</table>
Who are the media?

- Print - magazines, newspapers, community newspapers
- Electronic - radio, TV, internet
- Local and national levels
The media work to........

- Gather and spread balanced information
- Act as the public watchdog
- Highlight controversy
- Expose malpractice and negligence
- Sell newspapers (copy), increase viewers, listeners, make money
What is newsworthy?

- Dramatic (e.g. thalidomide)
- Many people affected
- Unexpected (measles vaccine and autism)
- Polarities
- Conflict (minister versus industry)
- Location (close to own country or hospital)
- Discourse (miracle drug or poison, stereotypes to fall back on)
- Celebrity link
- Scandal
The media like….

- Accuracy and simplicity
- Statistics with explanation
- Context
- Comment from highest authority possible
- Controversial issues - divided messages
- To investigate both sides of story
- Human interest (mother and child)
- Fast response
- People who contact us
A spokesperson must be

- polite, informed and authoritative
- accurate and reliable
- articulate
- available
- trustworthy (honest)
The media do not like....

- evasive people
- unavailable people
- being shunted about (fobbed off)
- being spoken down to (patronised)
- academic jargon and complexity
- dishonesty
Some basic questions a reporter will ask you….

- **WHO** - is affected; responsible
- **WHAT** - has happened and what is being done about it
- **WHERE** - has it happened
- **WHEN** - did it happen
- **WHY** - did it happen
- **WILL** - it happen again
The media are **not** interested in...

- Destroying your reputation
- Ruining your career
- Tricking you into saying something incriminating (although if you do, they won’t mind!)
- Promoting only your point of view
How to deal with journalists

- Make contact with us - don’t wait for a crisis
- Explain your designation, responsibility
- Give us reliable contact numbers
- Be willing to give information
- Say what you do not know and refer the journalist to someone who does
- Get back to us if promised
Special advice

- Be completely honest
- Do whatever you say you will
- Do not speculate
- Check your facts first if you are unsure
- Provide a context
Principles of Good Pharmacovigilance Communication

- Relate the messages to the audience’s perspective
- Avoid comparisons which trivialise the concern
- Ensure completeness of the message
- Be balanced, honest and sympathetic
- Focus on the specific issue that needs to be handled
- Pay attention to what the audience already knows
- Be respectful of people’s right to be concerned
- Be honest about the limits to scientific knowledge
- Acknowledge uncertainty
- Evaluate the impact of your message
Communications practices to avoid

- “Spinning”! (distortion or decoration of facts for beneficial effects)
- All communications are subjective, but do not be manipulative or dishonest
- Avoid “No comment” – rather say why there’s nothing to say and what is being done
- Avoid confusing statistics
- Do not avoid taking responsibility
- Don’t attack the messenger/accuser
- Don’t deny, justify or excuse your mistakes