ADR Reporting

Methods and design issues

A presentation by

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Aims of PV course

- To establish the critical role of communication in the delivery of effective pharmacovigilance

- The design, marketing and communications issues underlying an effective reporting system

To provide a foundation of knowledge and understanding of the core principles and best practice standards in pharmacovigilance

To familiarise students with the tools and resources necessary for good pharmacovigilance practice
What are the priorities?

• To get health professionals and patients to tell us when they suspect ADRs and other problems
  − To provide a simple, attractive contact mechanism which people will use

• To collect minimum essential, good quality data by the most practical and effective method that is acceptable to reporters
  − Explore alternatives that reduce the burden of reporting
Noncash Charitable Contributions

Part I Information on Donated Property—If you need more space, attach a statement.

1. (a) Name and address of the donee organization
   (b) Description of donated property

Part II Other Information—Complete line 2 if you gave less than an entire interest in property listed in Part I. Complete line 3 if conditions were attached to a contribution listed in Part I.

2. If, during the year, you contributed less than the entire interest in the property, complete lines a-e.
   a. Enter the letter from Part I that identifies the property. If Part I applies to more than one property, attach a separate statement.
   b. Total amount claimed as a deduction for the property listed in Part I:
      (1) For this tax year
      (2) For any prior tax years
   c. Name and address of each organization to which any such contribution was made in a prior year (complete only if different from the donee organization above):
      Name of charitable organization
      Address (number, street, and room or suite no.)
      City or town, state, and ZIP code
   d. For tangible property, enter the place where the property is located or kept
   e. Name of any person, other than the donee organization, having actual possession of the property

3. If conditions were attached to any contribution listed in Part I, answer questions a–c and attach the required statement (see instructions).
   a. Is there a restriction, either temporary or permanent, on the donee’s right to use or dispose of the donated property?
   b. Did you give to anyone (other than the donee organization or another organization participating with the donee organization in cooperative fundraising) the right to the income from the donated property or to the possession of the property, including the right to vote donated securities, to acquire the property by purchase or otherwise, or to designate the person having such income, possession, or right to acquire?
   c. Is there a restriction limiting the donated property for a particular use?

Yes No

For Paperwork Reduction Act Notice, see page 4 of separate instructions.

Cat. No. 622962 Form 8283 (Rev. 10-98)
FDA web reporting form
…factors associated with under-reporting were ignorance (only severe ADRs need to be reported) in 95%; diffidence (fear of appearing ridiculous for reporting merely suspected ADRs) in 72%; lethargy (an amalgam of procrastination, lack of interest or time to find a report card, and other excuses) in 77%; indifference (the one case that an individual doctor might see could not contribute to medical knowledge) and insecurity (it is nearly impossible to determine whether or not a drug is responsible for a particular adverse reaction) in 67%; and complacency (only safe drugs are allowed on the market) in 47% of studies.

Determinants of Under-Reporting of Adverse Drug Reactions: A Systematic Review
Lopez-Gonzalez, Elena; Herdeiro, Maria T.; Figueiras, Adolfo
Drug Safety, Volume 32, Number 1, 2009, pp. 19-31(13)

CONCLUSION: The rate of spontaneous ADR reporting is very low, also for serious and fatal reactions.

Under-reporting of serious adverse drug reactions in Sweden
M Bäckström, T Mjörndal, R Dahlqvist
What makes you irritated when filling in a form? [1]

- Uncertainty why form is necessary
- Form looks complicated and unattractive
- Excessive or bureaucratic detail
- Complexity and length of time required
- Information required demanding troublesome search for details
- Information required which sender could be expected already to have
- Repetition of personal or other details (within form or from form to form)
What makes you irritated when filling in a form? [2]

• Inadequate space for answers
• Questions which are not clear as to their purpose, rationale or requirements
• Information which appears superfluous
• Significant information which you have but are not asked for or cannot fit on the form
• Inability to express your view within constraints of form
• Complex or expensive return mechanism
• No apparent benefit for effort
Is there really no alternative to using a form?

Yes, there is!!
Two distinct issues

• What is the minimum data content and quality necessary for good pharmacovigilance?

• What is the best method for collecting such data? [It may not be reporters filling in forms]

The focus of this presentation is on methods

Everyone assumes that forms are the best method to collect all data, but they are almost certainly not
Horrible forms
Tolerable forms
Anatomy of a form:
Relationship: who’s this from?
Paper size, colour and quality (why A4?)
Font size and colour
Personalisation (this is for me)
Benefits
Print colour (grey is a tint of black: this is 2 colour)
Open boxes for information
Distinct sections and clear sub-headings
Help information at point of data entry
Tick boxes
Visual variety (here, angled items, very minor but effective)
Overall impression: welcoming or alienating?

This form is not presented as an example of ideal design, though it’s not bad
How do forms from the commercial sector compare?

• Generally well designed, easy to fill in and purposes and benefits clear (low benefit = low response)
• Medical forms often badly designed, poorly laid out, complex, demanding with purposes and benefits unclear
• Commercial companies may depend on forms for their survival; take form and context very seriously (applications, contributions, registration of products, customer surveys)
• Keen for people to take notice and fill in
What makes a good form?

- Attractive
- Simple
- Short (but not at the expense of space and accessibility)
What makes a good form?

- A good form is one which your target audience wants to fill in
- You must ask them how much effort they are willing to make (e.g. alert or minimum or full data)
- A form without research, testing and discussion is largely a waste of time
- Sit with reporters and watch them completing a form
- What suits your needs may not suit the needs and wishes of reporters at all: empathy
What makes a good form?

• Simple, open, elegant design and layout
  – Structure; use of colour; white space; typeface; tick-boxes, space for response
• Short where possible (one page/10 min)
• Clear headings and detailed requirements
• Minimum necessary information (+personalised data)
• Clear purposes and benefits
• Simple return mechanisms
A4 is not the only option: it may be convenient for officials but is it fit for audience? [Lazy choice?]

All the pictures, colour and creativity are to persuade the recipient to fill in the form.
Notice:

- Distinct sections, indicated by colour variations and sub-headings
- Open white space for completing information
- Overall inviting and comfortable appearance
- Notice three weights of green – solid, and medium and light tints
Nigerian ADR form and booklet

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**NATIONAL PHARMACOVIGILANCE CENTRE (NPC) NIGERIA**

**FORM FOR REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS IN STRICT CONFIDENCE**

1. **PATIENT'S DETAILS**
   - Full Name or Initials:
   - Age/Date of Birth:
   - Hospital/Treatment Centre:
   - Sex: M [ ] F [ ]
   - Weight (Kg):

2. **ADVERSE REACTIONS DESCRIPTION**
   - Date Reaction Started:
   - Date Reaction Stopped:
   - C OUTCOME OF REACTION
     - Tick as appropriate
     - Recovered fully
     - Recovered with Disability
     - Congenital Abnormality
     - Hospitalization
     - Life Threatening
     - Death
     - Other (specify)

3. **Relevant Tests/Laboratory Data:**

4. **SUSPECTED DRUG (including Biologicals, Traditional/Herbal Medicines & Cosmetics)**
   - A DRUG DETAILS (sub name and other details if available/Attach Product label/sample if available)
     - Brand Name:
     - Generic Name:
     - Batch Number:
     - NAFDAC No:
     - Expiry Date:
     - Name & Address of Manufacturer:
   - B Indications for use
     - Dosage
     - Route of Administration
     - Date Started
     - Date Stopped

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**Safety Of Medicines In Nigeria**

A guide for detecting and reporting adverse drug reactions.

Why health professionals need to act.

Bruce Hugman, Uppsala Monitoring Centre
Branding

Downloadable paper form (09)
**Old Australian ADR form**

- **Report of Suspected Adverse Reaction to Drugs and Vaccines**
- **A5 size**

<table>
<thead>
<tr>
<th>Adverse Reaction Description:</th>
<th>Date of Onset of Reaction:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Sex: M / F</td>
<td>Sex: M / F</td>
</tr>
<tr>
<td>Weight:</td>
<td>Weight:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All Drug Therapy/Vaccines Prior to Reaction</th>
<th>Date of Recovery:</th>
<th>Not Yet Recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Describe any other names and adverse associated drug)</td>
<td>Date Begun</td>
<td>Date Stopped</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment of Reaction:</th>
<th>Date of Recovery:</th>
<th>Not Yet Recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>Recovered</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>Unknown</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>Fatal</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>Sequelea:</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>No</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
<tr>
<td>Yes</td>
<td>Date of Recovery:</td>
<td>Not Yet Recovered</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity:</th>
<th>Required a visit to Doctor:</th>
<th>Required a visit to Doctor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Threatening</td>
<td>Required a visit to Doctor:</td>
<td>Required a visit to Doctor:</td>
</tr>
<tr>
<td>Hospitalised</td>
<td>Required a visit to Doctor:</td>
<td>Required a visit to Doctor:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
<th>Required a visit to Doctor:</th>
<th>Required a visit to Doctor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>In:</td>
<td>Required a visit to Doctor:</td>
<td>Required a visit to Doctor:</td>
</tr>
</tbody>
</table>

**Reporting Doctor, Pharmacist, etc:**
- Name: [ ]
- Address: [ ]

**Delivery Address:**
- PO Box 100
- WODEN ACT 2006

**Use of Personal Information:**
- For the purpose of monitoring adverse reactions to drugs and vaccines, the information provided will be used for the purposes specified in these guidelines.
- The information will be held in confidence and will not be disclosed to any third party without the consent of the person whose information is held, except as required by law.
- The information will be stored in a secure manner and will be accessible only to authorized personnel.
- The information will be destroyed when it is no longer required or when the purpose for which it was collected has been fulfilled.

**Sender's Name and Address:**
- [ ]

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Netherlands in the first league, but...
How do forms from the commercial sector compare?

- Determined their forms (and image) should be more attractive and compelling than competitors’
- Design and test forms to suit audiences (empathy and research)
- Take communications design very seriously, spending time and money, always using designers and information graphics specialists
Web forms

• Simple, attractive appearance
• Clear structure and instructions
• Distinct sections and sub-headings
• Drop down options when suitable (including ‘other’ category)
• Rapid and smooth functionality
• Go back for review if more than one screen
• Save (complete or partially complete) and print options
Design and test

- Get experts to draft the form
- Design the form for visual quality as well as content
- Seek advice from reporters about what they’re willing to do
- Test the form with your target audience
- Sit with reporters and watch them complete the form: what are the problems?
- Do what they suggest!
What makes you want to fill in a form?

• Attractive
• Simple
• Short
What makes you want to fill in a form? [1]

• It’s a good form, and looks inviting
• It’s seen as a priority
• Context and meaning are understood
• You feel well disposed towards the sender
• Appears to be good reason for completing the form
• Evident beneficial personal, medical or scientific effects from completing form
Use experts

• Forms are a challenging, specialist item, requiring specialist design skills
• Officials and scientists are not designers and do not produce good design
• In common use, Microsoft Word is not a design tool and its output is flat and unimaginative
Software for forms

- Many options
- One software package: www.flysoftware.com
What makes you want to fill in a form? [2]

- You know the effort will be appreciated
- You know there will be personal and professional feedback

- It’s worth the effort!
Psychological issues

- Attitude of the sender of form towards the person completing the form (empathetic or bureaucratic?)
- The attitude of the person completing form towards the sender of form (alienated or collaborative?)
- Motivation of person completing form and perceived benefits (indifference or enthusiasm?)
- Balance between effort/time involved and satisfaction or reward of completing it
- The whole context of reporting: culture (is the relationship one of friendly professional collaboration?)
Is there really no alternative to using a form?
Learn from others...

- For decades, Poison Centres have collected vital safety information on millions of cases without having reporters fill in forms at all.

Who Can I Call for HELP?

POISON Help
1-800-222-1222

Texas Poison Center Network

Your source of HELP for:
- Poisonings
- Or
- Toxic Substance Emergencies, including during Natural Disasters or Terrorist Events.

If you suspect that you have been exposed to a poison or toxic substance, call for HELP. The call is free...peace of mind is priceless!

The North Texas Poison Center began a 24-hour hotline staffed by registered nurse specialists in 1984.
Many alternatives

*Remove the burden of detail from the reporter*

- SMS or email alert to NC that there’s an ADR to report
- Pre-paid, addressed postcard (or fax sheet) pre-printed with all reporter’s details, with tick-box ‘I have an ADR to report’
- Direct telephone line to NC
- Mechanism for providing ABSOLUTE minimum info (e.g. ADR, suspected drug, patient sex and age)
Bruce Hugman, Uppsala Monitoring Centre

New Zealand
Further alternatives
Paper or web form

- Absolute minimum essential information
- Second level useful information (optional)
- Full additional information (optional)
What makes you irritated when filling in a form? [1]

- Uncertainty why form is necessary
  - Simplicity and clarity of purpose
- Form looks complicated and unattractive
  - Open, inviting design, with breathing space
- Excessive or bureaucratic detail
  - Absolute minimum detail for acceptable first stage
- Complexity and length of time required
  - Simplicity of enquiry and sensible time limit
What makes you irritated when filling in a form? [2]

- Information required demanding troublesome search for details
  - Reduce to absolute minimum; make optional
- Information required which sender could be expected already to have
  - Pre-print all reporter’s professional data
- Repetition of personal or other details (within form or from form to form)
  - Pre-print all reporter’s professional data
What makes you irritated when filling in a form? [3]

- Inadequate space for answers
  - Provide adequate space
- Questions which are not clear as to their purpose, rationale or requirements
  - Make it clear why data is needed
- Information which appears superfluous
  - Make it clear why data needed OR remove requirement
What makes you irritated when filling in a form? [4]

- Significant information which you have but are not asked for or cannot fit on the form
  - Space for extra comments or observations
- Inability to express your view within constraints of form
  - Space for extra comments or observations
- Complex or expensive return mechanism
  - Provide simplest and cheapest possible mechanism
- No apparent benefit for effort
  - Promise acknowledgement and feedback
Key points

• ADR forms are an element of the regulatory and general medical culture (good or bad)
  - Engage actively with your audience

• Communicating and motivating are high-energy activities; require skill and creativity
  - Get expert help (design and information graphics) and consult your audience

• Reporting methods must be developed and tested collaboratively (joint enterprise)
  - Get to know your audience and test materials
Key points

• Reporting methods must be easy to complete, attractive, self-explanatory
  - Research maximum effort reporters are willing to make; keep it simple

• Reporting methods must be part of ongoing positive, *interactive* processes and relationships
  - Bureaucrats and officials struggle to get results; you must be *partners*
A cynical ending...

• Few of the essential lessons in this session have been translated into action anywhere in the world

• Bureaucratic inertia, lack of imagination, laziness and following well-trodden paths always get in the way of imagination and creativity

• Boring, traditional forms and processes mean alienated reporters and low levels of reporting – and unnecessary harm to patients
Do something original and effective!

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