ADR Reporting

Methods and design issues

A presentation by

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Aims of PV course

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

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

To familiarise students
with the tools and
resources necessary for
good
pharmacovigilance
practice

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



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



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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

Pharmacoepidemiology and Drug Safety (2004) Volume: 13, Issue: 7, Pages: 483-487



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







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*

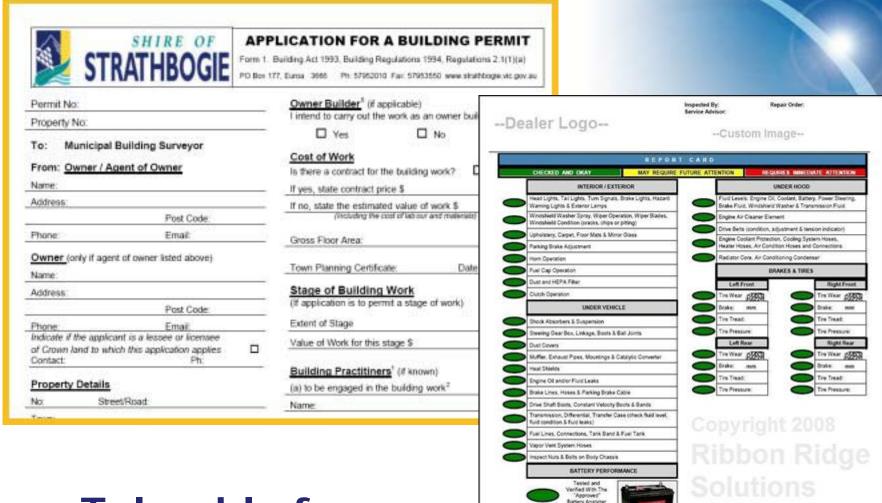
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Horrible forms

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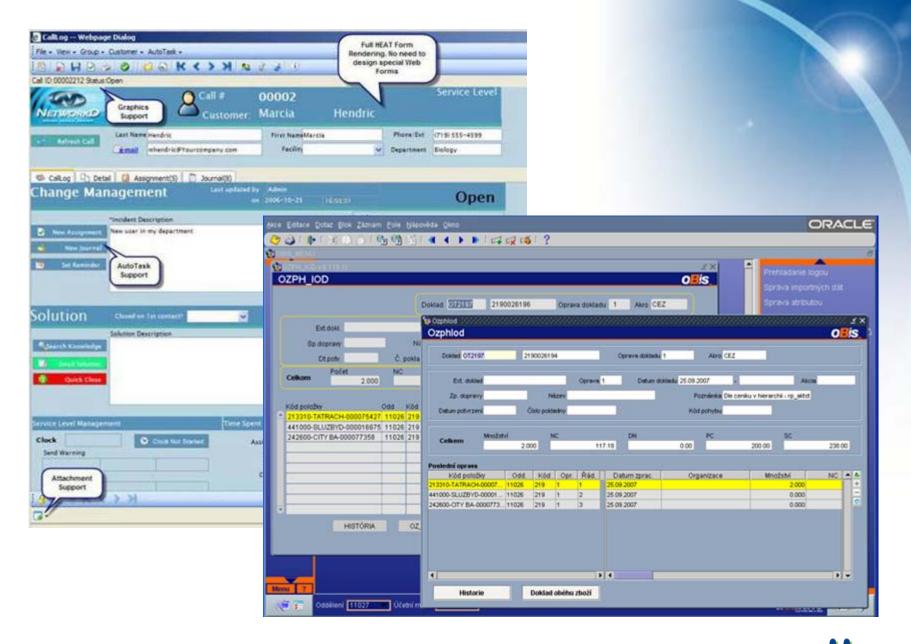




Tolerable forms

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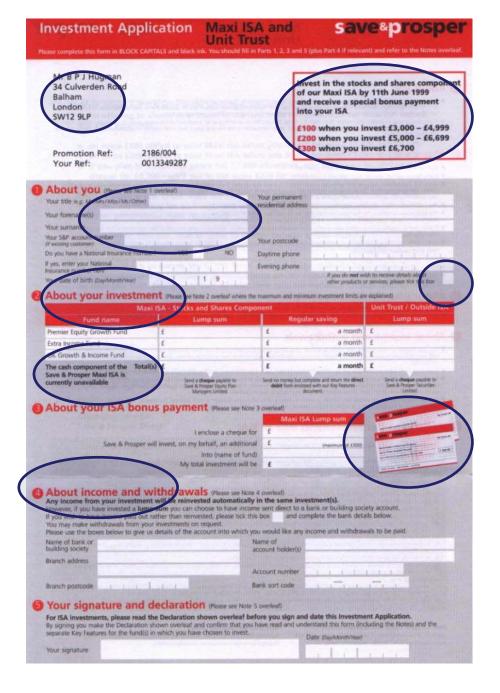


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Anatomy of a form:

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 subheadings

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?

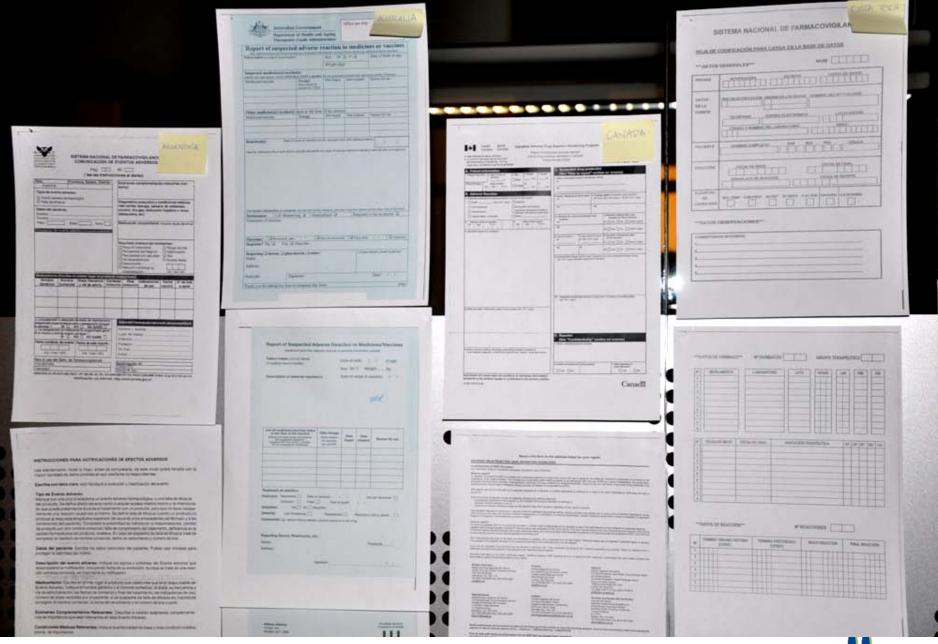
- A good form is one which your target audience wants to fill in
- You must ask them how much effort they are willing to make (e.g. alert or minimum or full data)
- A form without research, testing and discussion is largely a waste of time
- Sit with reporters and watch them completing a form
- What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

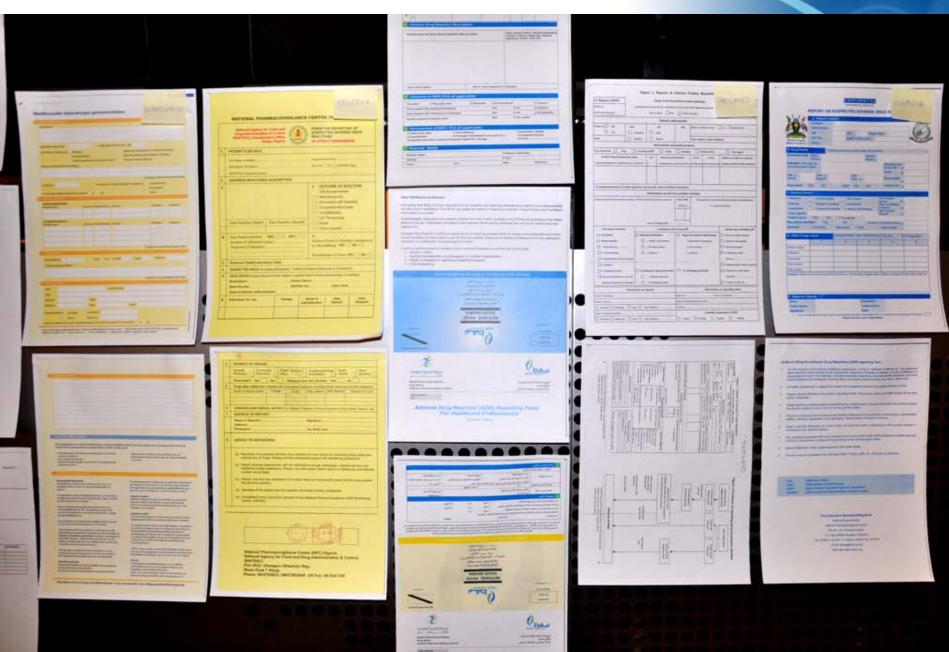


What makes a good form?

- 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









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

A4 is not the only option: it may be convenient for officials but is it fit for audience? [Lazy choice?]







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





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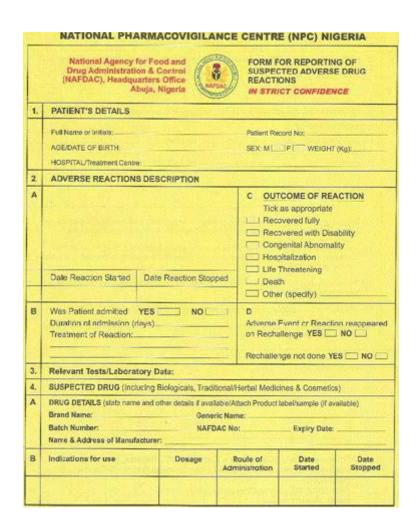
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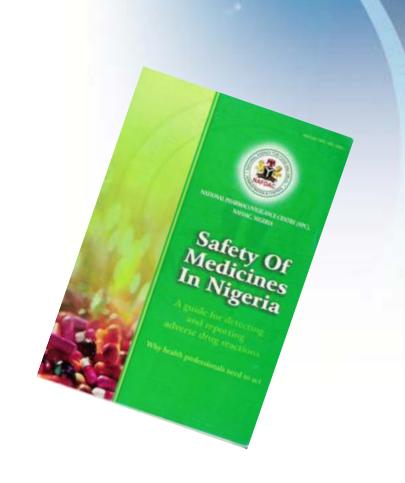


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Nigerian ADR form and booklet



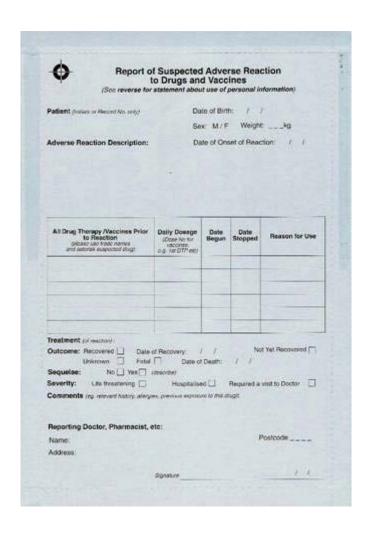


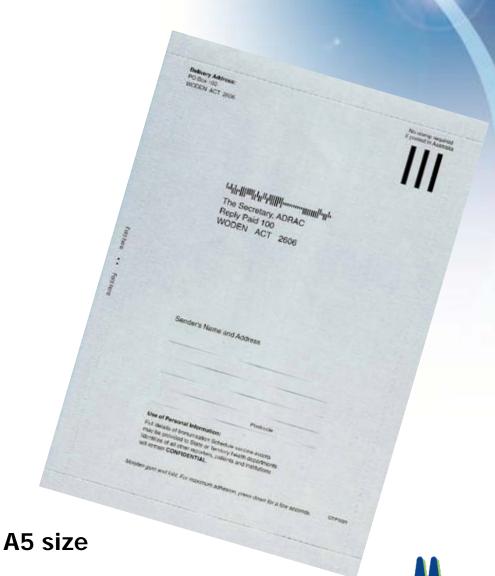


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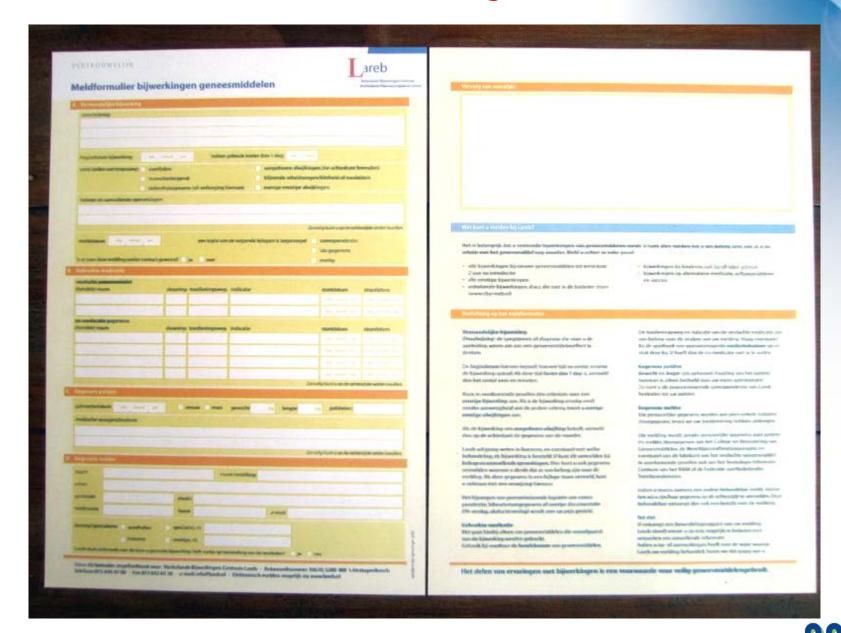


Old Australian ADR form





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





report handling

search and statistics

tools

exit

new report

send report

list reports

home

contacts give feedback user guide

| 0. | report info |
|----|-------------------------------|
| 1. | patient |
| 2. | tests and procedures |
| 3. | relevant medical history |
| 4. | relevant past drug therapy |
| 5. | reactions |
| 6. | drugs |
| 7. | assessment |
| 8. | overview |
| 9. | save |
| A. | print report |

Report information - standard case

| | date first received at sender | | date first received at national centre | | | | |
|----------------------------------|--|----------|---|-------------|----------------|------|--|
| | | | 02 | 05 | 2012 | | |
| | (dd mm ccyy) | | (dd m | m ccyy) | | | |
| report title | | | | (| 0 | | |
| type of report | spontaneous | | • | | | | |
| serious | O yes O no <u>clear</u> | | | | | | |
| | reason for seriousnes | 5 | | | | | |
| | death | | life-thre | atening | | 0 | |
| | hospitalization/prol | onged 🔳 | disabling |) | | | |
| | congenital-anomaly | | other m | edically in | nportant condi | tion | |
| country of occ | currence | country | of prim | ary sour | ce | | |
| Sweden | - | Sweden | | | - | | |
| does this case for an expedit | e fulfill local criteria ted report | O yes | no <u>cle</u> | <u>ar</u> | | | |
| additional doc | uments held by sender | o yes | no <u>clea</u> | a <u>r</u> | | | |
| was the case r | medically confirmed @ | yes 🔘 no | | | | | |

Information on sender

| type of sender | pharmaceutical company regulatory authority other | health professional regional pharmacovigilance center | <u>clear</u> |
|----------------|---|---|--------------|
| Other case id | entifiers in previous trans | missions | |



contacts

report handling

search and statistics

tools

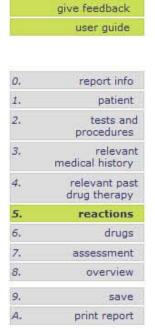
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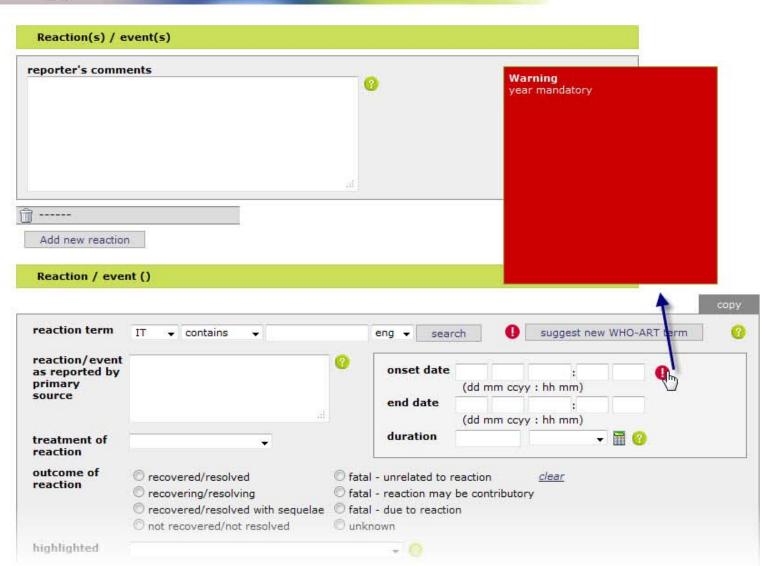
new report

send report

list reports

home





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

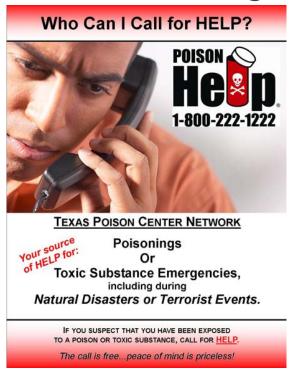
- Attitude of the sender of form towards the person completing the form (empathetic or bureaucratic?)
- The attitude of the person completing form towards the sender of form (alienated or collaborative?)
- Motivation of person completing form and perceived benefits (indifference or enthusiasm?)
- Balance 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





The North Texas Poision 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)





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 highenergy 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





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