COMMENTARY

Drug Saf 2011; 34 (8): 705-707
0114-5916/11/0008-0705/$49.95/0

The Fatal Love of Forms

Bruce Hugman

Uppsala Monitoring Centre, Uppsala, Sweden

Ask any group of people how many of them love completing forms, and the number is likely to be ‘nil’. Observe the practice of almost any bureaucratic operation and assess the extent of their dependence on forms, and the answer is likely to be ‘substantial to obsessive’. These conclusions apply respectively, no less, to health professionals and pharmacovigilance centres.

Why is it then, that against all the evidence of human preferences and low levels of engagement, adverse drug reaction (ADR) reporting systems rely almost entirely on forms and, it must be added, on horrible, long, complicated, time-consuming forms?

If you take a look at reporting forms across the globe (and I have recently studied 50 or so), you are struck by how uninviting, oppressive and dreary most of them look (almost all decisively quarantined from modern design or typographical talent), and how intensely motivated any busy health professional would have to be to even consider completing one of them. There are 1-, 2- and 3-page forms, many of them with extensive guidance notes; they demand heroic commitment.

If ADR reporting is a vital component in the protection of patient safety, how is it that the primary mechanism for its operation is so unimaginative, so off-putting, so unreasonably demanding?

Sadly, it results from that familiar, centralized, bureaucratic corruption: people at desks want data so they send out forms. They send them without any grasp of how they might be perceived, the reactions they might provoke or the context in which they arrive; without any empathy for the audience (and without asking anyone in advance). How will a busy physician with 50 patients waiting feel about the possibility of spending 10 or 15 minutes (or more) completing this complex form? If officials really thought about such issues, they would grasp that their forms and hopes were largely futile. Startlingly poor reporting rates confirm this conclusion,[1,2] with the exception of those few heroic, dedicated individuals who wrestle with the obstacles against the odds, and do report.

If you ask people what they dislike about forms, amongst much else, they say:

- too time-consuming;
- unclear purpose;
- too much, sometimes repetitive, detail, requiring research or reference to other documents;
- information that seems superfluous;
- the person completing the form has data or observations that the form does not allow for;
- insufficient space for the data requested (including signature);
- no incentive or evident benefit;
- no acknowledgement or specific, useful, personal feedback.

All these are relevant to the reality of ADR forms (for example, patient notes need to be consulted; common ignorance or misunderstanding of what to report or why; reporter’s name, role and contact details have to be entered on every form; many reporters receive no acknowledgement, let alone benefit for their effort, or useful, personal feedback).

What needs to be done? *The threshold for reporting and the burden of reporting for the health professional need to be reduced to an absolute minimum*. In the context of a good system – strongly marketed national commitment to ADR reporting, lively personal engagement, motivation and communications – health professionals need to be asked what is the maximum effort they are willing to make to report a suspected ADR. The responses may include no effort, a couple of minutes, five minutes, some, even ten, minutes. This needs to be coupled with enquiries about a range of reporting options that match the level of willingness, from minimum to more demanding.

A minimal option would be sending a simple SMS by mobile phone or Skype, a fully pre-printed, pre-paid addressed postcard, an empty email to a dedicated address, or calling a hotline number, as a means of alerting the national or regional pharmacovigilance centre that there was an ADR to report. The next level could be a pre-paid addressed postcard, or pre-formatted fax sheet with no more than patient age, sex, reference number and suspected drug. Could there be a place for social networking media in the scheme? It is certainly possible. Decisions and methods must be determined by what reporters say they prefer and what they would be willing to do, not by what is cheap and convenient for officials at the centre.

Once alerted to the existence of a suspected ADR, it would then be the job of the pharmacovigilance centre to follow up and collect the data, transferring the burden of data collection from the field to the centre. Ideally, this would be done by telephone, on the plausible grounds that professionals would be more likely to be willing to talk through the case than write it down, and that the data collected would be of better quality. This would also provide the invaluable opportunity of relationships developing between reporters and central officials, personal contact with a known individual being a key element in any successful collaborative effort and in the development of trust. (The absence or abolition of local pharmacovigilance centres is a symptom of the system's blindness to this compelling truth about human relations.)

Successful reporting schemes do exist in hospitals where there is a communal commitment to them,[3] where the lifeless hand of remote bureaucracy is absent. A shifting of burden from the frontline can also be very positively managed by having a local pharmacist or clerk responsible for following up ADR notifications and completing the data, as happens very effectively in some hospitals already,[4] especially where pharmacists see patient safety as an active priority.[5]

'Make it easy' should be the driving principle. Tick boxes are items of ideal, minimalist simplicity. The New Zealand duplicate prescription form project and its tick boxes ('Event since last script: yes/no; first script or not'), demonstrated this with spectacular results on adverse event notification rates (an 11-fold increase).[6]

For a paper or web-based form, we can envisage options for the reporter (with, at best, automated population of patient demographic information, drop-down options and/or tick boxes), after completion of part 1 of which the choice is given to send off the basic information or to continue to a second (or maybe third) section or screen if the reporter feels inclined to do so. (We could speculate that, given such choices, more reporters might be willing to provide more comprehensive information, simply because they were not compelled to do so and were given the choice.)

Can we imagine personalized forms, preprinted with a health professional's name, role and contact details, so that they did not have to be repetitively completed for every form? Demanding, yes, but possibly influential in engaging participation. Such small details can have a motivating and transforming effect.

'Ah yes!' say officials, 'all very well and idealistic, but we don't have time for this stuff!' The question is 'what are our aims for a reporting system?' One that engages large numbers of health professionals and generates a lot of significant data and insight into patient experience? Or one that plods along an unimaginative and unproductive path, excluding the great majority of potential reporters and neglecting widespread harm to patients? One that just carries on as usual?

Are current resources being well used? Are the costs of personnel, administration, printing forms, generating commensurately decent results? Almost certainly not.

Pharmacovigilance suffers from bureaucratic sclerosis. Instead of the system being a lively, engaging, dynamic, collaborative, humane enterprise, sharply focused on improved therapy and the welfare and safety of patients, it is a sluggish routine that fails to excite and motivate. Forms are dispiriting, formality is alienating, distance is subversive. The dreadful forms produced in most places are potent symbols of the lack of imagination and creativity demonstrated by people, many of whom are passionate about their vocation in patient safety, but blind to the psychological, sociological, human relations, and marketing and design challenges of every aspect of the work. There is a risk that the new patient reporting initiatives will be stultified by the same disease, and that would be a tragic, lost opportunity. Surely we can do much, much better?

Acknowledgements

Thanks to Andrew Herxheimer for his comments on the first draft of this commentary, and to several colleagues for their assistance in sourcing references.

Bruce Hugman is a freelance writer and trainer, and has been Communications Consultant for the Uppsala Monitoring Centre (UMC) since 1995. He has published in the fields of literary criticism, sociology and law, criminal justice and biography, and written and taught extensively in pharmacovigilance and patient safety communications. *Healthcare Communication* was published by Pharmaceutical Press in 2009; *Expecting the Worst*, the second edition of the UMC's crisis management manual, was published by the UMC in 2010. He lives in Thailand and has no conflicts of interest.

References

1. Hazell L. Under-reporting of adverse drug reactions: a systematic review. Drug Saf 2006; 29 (5): 385-96
2. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf 2009; 32 (1): 19-31
3. Pushkin R, Frassetto L, Tsourounis C, et al. Improving the reporting of adverse drug reactions in the hospital setting. Postgrad Med 2010; 122 (6): 154-64
4. Vitillo JA. Adverse drug reaction surveillance: practical methods for developing a successful monitoring program [online]. Available from: http://www.medscape.com/viewarticle/408575 [Accessed 2011 Jun 1]
5. The Pharmaceutical Society of Ireland. Pharmacy Ireland 2020 Working Group. Interim report: April 2008. Advancing clinical pharmacy practice to deliver better patient care and added value services [online]. Available from URL: http://www.thepsi.ie/Libraries/Publications/Interim_Report_of_the_Pharmacy_Ireland_2020_Working_Group.sflb.ashx [Accessed 2011 Jun 1]
6. Coulter DM. The New Zealand intensive medicines monitoring programme. Pharmacoepidemiol Drug Saf 1998; 7: 79-90

Correspondence: *Bruce Hugman*, Communications Specialist, Healthcare Writer, Uppsala Monitoring Centre, Box 1051, SE 751 40, Uppsala, Sweden.
E-mail: mail@brucehugman.net