

Drug Safety

Use of a patient-friendly terms list in the adverse drug reaction report form: A database study

Sieta T. de Vries, PhD¹; Judy Harrison, MD²; Patrick Revelle²; Alicia Ptaszynska-Neophytou³; Anna Radecka³; Gowthamei Ragunathan³; Phil Tregunno³; Petra Denig, PhD¹; Peter G.M. Mol, PhD^{1,4}

¹ *University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, Groningen, The Netherlands*

² *MedDRA Maintenance and Support Services Organization (MSSO)*

³ *Medicines and Healthcare products Regulatory Agency (MHRA)*

⁴ *Dutch Medicines Evaluation Board, Utrecht, The Netherlands*

✉ p.g.m.mol@umcg.nl

Supplemental Digital Content

This Supplemental Digital Content contains the appendix referred to in the full version of this article, which can be found at <http://adisonline.com/drugsafety>

Electronic Supplementary Material 1. Description of a small pilot study

In a small pilot study, 4 patients from the EURORDIS UK network or the Patient Group Consultative Forum (PGCF) completed a survey about their views on the use of patient-friendly terms in the adverse drug reaction (ADR) report form. The age of these patients ranged from 27 to 72 and three patients were male.

All patients indicated that they would prefer to describe the ADR in their own words rather than selecting a term from a list. They indicated that they can provide more accurate information when describing the ADR themselves and that this will not confront them with medical terms:

- *“I think by describing the side effects myself I can describe things better and more accurately”*
- *“I’d prefer to describe it in my own words as I’ve limited medical knowledge of terms and jargon”*
- *“Don’t see that a list would be helpful to me personally because I am capable of adequately explaining symptoms and expressing how I feel..... generally I know when I am feeling terrible and can figure out what could/might be a cause. Maybe some people can’t explain how they are feeling and prefer a list. This may be desirable where English isn’t first language and patients don’t know how to explain”*
- *“Side-effects can affect patients very differently, and there are so many variables that a tick-box multiple choice approach could be limiting at best, and inaccurate at worst”*

A patient indicated that the use of standard terms in the ADR report form could be a good idea for people who cannot express themselves. Other patients mentioned that the use of standard terms should be presented in non-medical terms and that there should be an option to fully describe the ADR and an option to report ADRs that are not in the list.

In the same survey, the patients evaluated the understandability of a sample of terms from the patient-friendly terms list. They were asked to indicate for each term whether the term was in their opinion clear/unclear and whether the term would be clear/unclear for other people they know. In addition, they could indicate any suggestions for improving each term or they could add any

comments. The selected terms were mainly terms considered by MSSO as *potentially difficult* terms for patients but contained also a sample of terms that were considered *probably understandable*. A total of 123 patient-friendly terms (i.e. 114 potentially difficult and 9 probably understandable terms) were evaluated by a patient:

Of the 114 potentially difficult terms:

- 60 terms were *unclear* for the patient and considered to be *unclear* for other people;
- 36 terms were *clear* for the patient and considered to be *clear* for other people;
- 17 terms were *clear* for the patient but considered to be *unclear* for other people;
- 1 term was *unclear* for the patient and an evaluation for other people was lacking.

		Other people	
		Unclear	Clear
Patient him-/herself	Unclear	60	0
	Clear	17	36

A)¹

Of the 9 probably understandable terms:

- 2 terms were *unclear* for the patient and considered *unclear* for other people;
- 7 terms were *clear* for the patient and considered *clear* for other people.

		Other people	
		Unclear	Clear
Patient him-/herself	Unclear	2	0
	Clear	0	7

B)

Figure. Patients' evaluation of a selection of **A)** potentially difficult terms, and **B)** probably understandable terms. ¹ One term is missing since there was an evaluation for the patient him-/herself but not for other people.

A few suggestions for improving the terms were given (see Table below).

In conclusion, patients seem to prefer to describe an experienced ADR in their own words rather than selecting a term from a list. The currently available patient-friendly terms list needs to be further improved to better represent lay-terms.

Overview of evaluated potentially difficult terms

LLT	LLT code	Your opinion		For other people		Suggestions for improvement
		Unclear	Clear	Unclear	Clear	
Abdominal abscess	10060921	x		x		
Abnormal liver function tests	10000158	x		x		Wouldn't know how you know this without a test
Accidental overdose	10000381		x	x		Taken too many by mistake
Acute myeloid leukaemia	10000880	x		x		
ADHD	10064104		x		x	
Agoraphobia	10001502		x		x	
Alcohol interaction	10001597		x	x		Had alcohol with medication
Alertness decreased	10049875		x		x	
Application site papules	10049043	x		x		
Atrial flutter	10003662	x		x		Heart flutter/palpitations
Auditory hallucinations	10003785		x		x	
Axillary pain	10048750	x		x		
Blood glucose increased	10005557		x		x	
Blood sugar decreased	10005808	x		x		Don't know how I would know blood sugar decreased
Bone density decreased	10049470		x	x		
Bone fragile	10005966		x		x	
Bone loss	10065687		x		x	
Breakthrough pain	10064556	x		x		
Candida infection	10074170	x		x		
Cardiopulmonary failure	10051093	x		x		Could be indigestion?
Cholesterol levels raised	10008663		x		x	
Clavicle fracture	10009245	x		x		
Clot blood	10009667	x		x		

Clotting disorder	10064732		x		x	
Condition						
aggravated	10010264		x		x	
Deafness unilateral	10048812	x			x	
Deep vein thrombosis						Never having had something like this I'm not sure I would distinguish it with cramp?
	10051055	x			x	
Dermatitis	10012431		x			x
Diabetic neuropathy	10012680	x			x	
Diverticulitis	10013538		x		x	
Drug effect decreased	10013678		x			x
Ectopic pregnancy	10014166	x			x	
Edema	10014210	x			x	
Endometriosis	10014778	x			x	
Esophagitis	10015461	x			x	
Facial bones fracture	10016042		x		x	Face bone broken
Fatty liver	10016261	x			x	
Femur fracture	10016454	x			x	
Fistula	10016717	x			x	
Gastric disorder	10056819		x		x	
Gastric perforation	10017815	x			x	
GERD	10018203	x			x	
Grand mal convulsion	10018659	x			x	
Guillain-Barre syndrome	10018767	x			x	
Hand deformity	10061194		x			x
Hepatitis C	10019744	x			x	
Hypertension	10020772		x		x	
Hyperthyroidism	10020850	x			x	
Hyperventilation	10020910		x		x	
Impaired liver function	10021520		x			x
Increased urinary frequency	10021692		x		x	Older people more likely to be aware of this
Infusion site swelling	10053505		x			x
Injection site inflammation	10022078		x			x
Iron low	10022982		x		x	Only know this following a blood test
Laceration	10023572	x				
Libido decreased	10024419		x			x
Lip disorder	10048470		x			x
Lumbar pain	10024998		x			x

Lung cancer					
metastatic	10050017	x		x	
Lymphedema	10025233	x		x	
Lymphoedema	10025282	x		x	
Macular					
degeneration	10025409	x		x	
Metastases to lung	10027458	x		x	
Metastases to					Wouldn't know symptoms of this
lymph nodes	10027459	x		x	
Metastasis	10062194	x		x	
Movements					
abnormal	10028039		x		x
Mucous membrane					
disorder	10028133	x		x	
Multiple myeloma	10028228	x		x	
Myalgic					
encephalomyelitis	10028414	x		x	
Myelodysplastic					
syndrome	10028533	x		x	
Necrosis	10028851	x		x	
Nerve damage					Again wouldn't be able to distinguish this from bruising?
	10029177	x		x	
Neuropathy	10029328	x		x	
Nicotine addiction	10056478		x		x
Oedema	10030095	x		x	
Oesophageal pain	10030180		x		x
Osteoporosis	10031282		x		x
Patella fracture	10034122		x	x	Broken kneecap
Pelvic inflammatory					
disease	10034254	x		x	Not sure of symptoms
Pharyngitis	10034835	x		x	
Polycystic ovaries	10036049	x		x	
Polyp	10061529	x		x	
Postmenopausal					
bleeding	10036399		x		x
Product quality					
issue	10069327	x		x	
Product size issue	10069249	x		x	
Product taste					
abnormal	10069227		x		x
Psychosis	10037234	x		x	
Radius fracture	10037802	x		x	
Raynaud's syndrome					Would have to look it up on google
	10037914	x		x	
Shoulder bursitis	10040611	x		x	
Skin abrasion	10064990		x		x
Skin depigmentation	10040825		x		x
Skin pigmentation	10040910		x		x

Soft tissue disorder	10061366		x	x		
Sore oesophagus	10041365	x		x		
Substance abuse	10066169		x		x	
Tenderness	10043224		x		x	
Tendinitis	10043232	x		x		Could be other causes
Thrombosis leg	10043623		x	x		Swollen leg
Tibia fracture	10043827	x		x		
Type 1 diabetes mellitus	10067584		x		x	
Underdose	10057362	x		x		
Unilateral vision loss	10059679		x	x		
Urinary retention	10046555		x		x	
Urticaria	10046735		x	x		
Uterine prolapse	10046814	x		x		
Vaccination site inflammation	10068878		x		x	
Venous thrombosis						I might know but could confuse it with something else...
	10047249		x	x		
Visual hallucinations	10047570		x		x	
Vulvovaginal pain	10069055	x		x		
Weakness left or right side	10047866		x		x	
Whitlow	10059856	x		x		
Wound healing delayed	10048036		x		x	
Writing impaired	10048053		x		X	

LLT = Lowest level term

Overview of evaluated probably understandable terms

LLT	LLT code	Your opinion		For other people		Suggestions for improvement
		Unclear	Clear	Unclear	Clear	
Scoliosis	10039722	x		x		
Shingles	10040555		x		x	
Ache	10000424		x		x	
Cold feet	10009859		x		x	
Dizziness	10013573		x		x	
Eye burns	10015911	x		x		
Flu	10016790		x		x	
Hand rash	10019117		x		x	
Increased tendency to bruise	10021688		x		X	

LLT = Lowest level term