VOLUME 28 · NUMBER 27 · SEPTEMBER 20 2010

JOURNAL OF CLINICAL ONCOLOGY

SPECIAL ARTICLE

Rapid-Learning System for Cancer Care

Amy P. Abernethy, Lynn M. Etheredge, Patricia A. Ganz, Paul Wallace, Robert R. German, Chalapathy Neti, Peter B. Bach, and Sharon B. Murphy

"routinely collected real-time clinical data drive the process of scientific discovery, which becomes a natural outgrowth of patient care "

WHO Policy Perspectives on Medicines

9

Pharmacovigilance: ensuring the safe use of medicines

October 2004
World Health Organization
Geneva

Why pharmacovigilance is needed

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence con-

JOURNAL OF
Palliative
Medicine

Volume 15, Number 3, 2012

DOI: 10.1089/jpm.2012.9605

Special Report

An International Initiative To Create a Collaborative for Pharmacovigilance in Hospice and Palliative Care Clinical Practice

David C. Currow, M.P.H., B.Med.,[1] Debra Rowett, BPharm,[2] Matthew Doogue, MBBS,[3,4] Timothy H.M. To, MBBS,[1,5] and Amy P. Abernethy, M.D.[1,6]

Phase IV – RAPID Pharmacovigilance Sites

CANADA
-Bruyere Continuing Care
-Capital Health Integrated Palliative Care Service
-Foothills Hospital Calgary
-Fraser Health
-Grey Nuns Hospital
-Hamilton Health Sciences
-Providence Health Care

POLAND
-St Lazarus Hospice

ITALY
- Maria Teresa Chiantore Seràgnoli Hospice

HONG KONG
-Haven of Hope Hospital
-Our Lady of Maryknoll Hospital

JAPAN
-National Cancer Center Hospital East
-Seirei Hamamatsu Hospital
-Seirei Mikatahara Hospital

TAIWAN
- Hospice Palliative Care Centre Taipei

GERMANY
-University of Munich

FINLAND
-Tampere University Hospital

HUNGARY
-Pecs Medical School

USA
-Duke University
-Four Seasons Hospice
-Mayo Clinic Rochester
-San Diego Hospice
-University of California
-University of New Mexico

SINGAPORE
-National Cancer Centre
-Singapore General Hospital
-Singapore Palliative Care Service

MALAYSIA
-Hospis Malaysia Kuala Lumpur

CHINA
-West China Fourth Hospital of Sichuan University

IRAN
-Tehran University

NEW ZEALAND
-Arohanui Hospice
-Auckland palliative Care
-Mercy Hospice
-North Shore Hospice

UK
-Bradford Royal Infirmary
-Dove House Hospice
-Hayward House Macmillan Specialist Palliative Care
-Humber NHS Foundation Trust
-Kings College London
-Leeds Teaching Hospital
-Lindsey Lodge Hospice
-Marie Curie Hospice
-Pennine Acute Hospitals NHS
-St Catherine's Hospice
-St Gemma's Hospice
-St James's Hospital
-St Leonard's Hospice
-Sue Ryder Leckhampton Court Hospice
-Teesside Hospice
-Wheatfields Hospice Trust

INDIA
-Bangalore Institute of Oncology
-Bhagwan Mahaveer Cancer Hospital & Research Centre

AUSTRALIA
-Barwon Health
-Braeside Hospital
-Broken Hill Palliative Care
-Calvary Health Care Kogarah
-Calvary Mater Newcastle
-Calvary North Adelaide
-Gold Coast Hospital
-Greenwich Hospital
-Hope Health Care
-Illawarra Palliative Care
-Ipswich Hospital
-Liverpool Hospital
-Maitland Palliative Care Service
-Modbury Hospital
-Monash Palliative Care Unit
-Orange Health Service
-Peter MacCallum Cancer Centre
-Port Kembla Hospital
-Prince Charles Hospital
-Prince of Wales Hospital
-Redcliffe Hospital
-Royal Adelaide Hospital
-Prince Charles Hospital
-Prince of Wales Hospital
-Redcliffe Hospital
-Royal Adelaide Hospital
-Royal Brisbane Hospital
-Royal Hobart Hospital
-Royal Melbourne Hospital
-Royal North Shore Hospital
-Sacred Heart Hospice
-Sir Charles Gairdner Hospital
-South West Health Warrnambool
-Southern Adelaide Palliative Services
-St Vincent's Hospital Brisbane
-St Vincent's Hospital Melbourne
-Sunshine Coast Hospital
-Tasmanian Palliative Care Service
-The Alfred Hospital
-The Austin Hospital
-The Queen Elizabeth Hospital
-Wantirna Palliative Care
-Westmead Hospital
-Wolper Jewish Private Hospital

Rapid Pharmacovigilance

- routinely used Rx
- prospective data at agreed time points
- std measures of clinical harms & benefits
- secure web- based technology
- build evidence of real-world net effect of Rx

PaCCSC

Palliative Care
Clinical Studies Collaborative
RAPID Pharmacovigilance

Site ..46/CDHA.. RN code: 03

Medication	GABAPENTIN/PREGABALIN Start date – September 2012
Indication	Neuropathic Pain
Time points	
Baseline	Commenced
Toxicity	1 week after baseline
Clinical benefit	3 weeks after baseline
Ad hoc toxicity	*ALSO* any other toxicity observed should be documented in the case-notes by the clinical team

*** Symptom Severity Score**

Grade Anorexia according to NCI criteria

	1	2	3	4	5
Anorexia	○	○	◉	○	○

NCI Criteria:

1: Loss of appetite without alteration in eating habits

2: Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated

3: Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tut

4: Life-threatening consequences; urgent intervention indicated

5: Death

***Medication of interest dosing**

	Please specify
Total dose given in the last 24 hours (mg)	4
Time of last dose (in 24-hour clock e.g. 2200)	0900

***Route of administration**

- ◉ Oral
- ○ Injectable

NCI Criteria (summary list of expected toxicities) - click here to download a pdf version

NCI Criteria V 4.03 (full list for all other toxicities) - click here to download a pdf version

*** Toxicities**

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	4	5	Un-gradable	No symptom
Hyperglycaemia	○	○	○	○	○	○	◉
Mania	○	○	○	○	○	○	◉
Euphoria	○	○	○	○	○	○	◉
Depression	◉	○	○	○	○	○	○
Insomnia	○	○	○	○	○	○	◉
Delirium	○	○	○	○	○	○	◉
Agitation	○	○	○	○	○	○	◉
Diarrhoea	○	○	○	○	○	○	◉
Other - please specify below	○	○	◉	○	○	○	○
Other - please specify below	○	◉	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	◉

CARESEARCH® palliative care knowledge network

www.caresearch.com.au

Table 4. Harms at Any Time in the 2 Weeks after Initiating Metoclopramide in Hospice/Palliative Care

			Response n=*40 people*				
	N *(%) harms*[a]	*Severity*[b] *median (range)*	*Cessation* n=*11*	*Other medication introduced* n=*7*	*Dose reduction* n=*0*	*No change in medication* n=*12*	*Other* n=*2*
Rigidity	0						
Akathisia	4 (10)	2.5 (1–4)	3	3		2	
Gait change	0						
Tremor	2 (5)	1 (1)	1	1		1	
Headache	4 (10)	2 (1–4)	2	1		2	
Dizziness	1 (3)	2 (2)	1	1			
Abdominal pain	4 (10)	2 (1–2)				4	
Vomiting	2 (5)	2 (1–2)				2	
Other	7 (18)	3 (1–3)	3	1		1	2

Pharmacovigilance in Hospice/Palliative Care: Rapid Report of Net Clinical Effect of Metoclopramide

JOURNAL OF PALLIATIVE MEDICINE
Volume 15, Number 10, 2012

BMJ Supportive & Palliative Care

Research

OPEN ACCESS

Pharmacovigilance in hospice/palliative care: net effect of gabapentin for neuropathic pain

BMJ

Sanderson C, *et al*. *BMJ Supportive & Palliative Care* 2014;**0**:1–8. doi:10.1136/bmjspcare-2014-000699

Design Multisite, prospective, consecutive cohort.

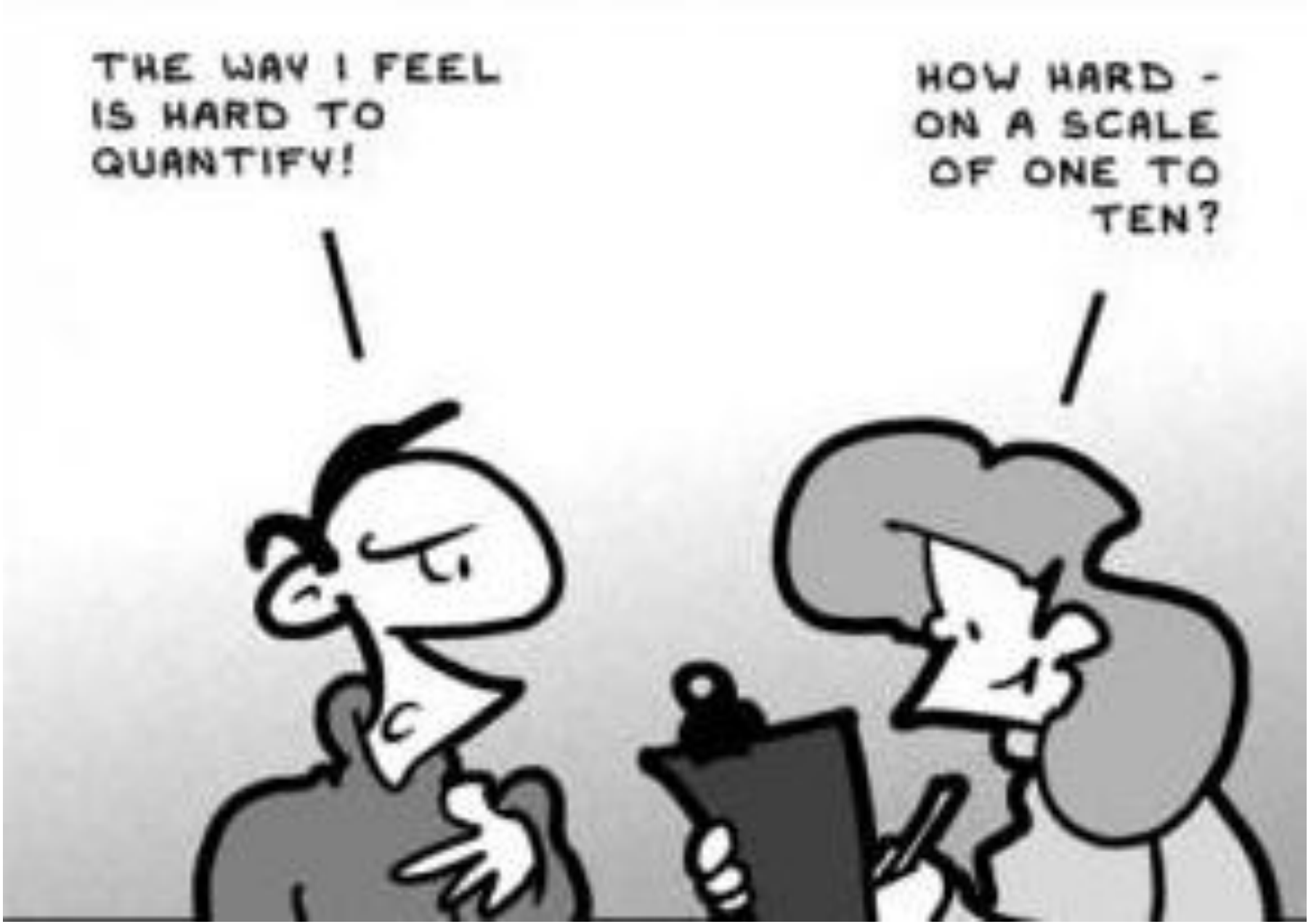
Population 127 patients, 114 of whom had cancer, who started gabapentin for neuropathic pain as part of routine clinical care.

Settings 42 centres from seven countries. Data were collected at three time points—at baseline, at day 7 (and at any time; immediate and short-term harms) and at day 21 (clinical benefits).

Results At day 21, the average dose of gabapentin for those still using it (n=68) was 653 mg/24 h (range 0–1800 mg) and 54 (42%) reported benefits, of whom 7 (6%) experienced complete pain resolution. Harms were reported in 39/127 (30%) patients at day 7, the most frequent of which were cognitive disturbance, somnolence, nausea and dizziness. Ten patients had their medication ceased due to harms. The presence of significant comorbidities, higher dose and increasing age increased the likelihood of harm.

Conclusions Overall, 42% of people experienced benefit at a level that resulted in continued use at 21 days.

Acknowledgements Thanks go to all the clinicians and the clinical units who have contributed to this programme. This includes: Sunshine Coast Hospital and Health Service QLD, Braeside Hospital NSW, Calvary Mater Newcastle NSW, Calvary Healthcare NSW, Greenwich Hospital NSW, Wolper Private Hospital NSW, Peter MacCallum Cancer Institute VIC, St Vincent's Hospital Melbourne VIC, Barwon Health VIC, Royal Melbourne Hospital VIC, Sir Charles Gardiner Hospital WA, Fraser Health British Columbia Canada, Hamilton Health Sciences Ontario Canada, Capital Health Integrated Palliative Care Service Canada, Maria Teresa Chiantore Seràgnoli Hospice Italy, Arohanui Hospice New Zealand, Humber NHS Foundation Trust UK, Leeds Teaching Hospitals NHS Trust UK, Haven of Hope Hospital Hong Kong.


THE WAY I FEEL IS HARD TO QUANTIFY!
HOW HARD - ON A SCALE OF ONE TO TEN?