



**ANNUAL REPORT
2012/13**

ANNUAL REPORT OF THE YELLOW CARD CENTRE WALES TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

1. STAFF

Dr A M Thomas	Medical Director
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Dr J P Thompson	Senior Lecturer in Clinical Pharmacology
Dr C V Krishna	Consultant Clinical Pharmacologist/Toxicologist
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Mrs F J Woods	Director, Welsh Medicines Information Centre
Mrs A Adams	Senior Information Pharmacist
Mrs J E Houghton	Regional Pharmacovigilance Pharmacist
Mrs E Carey	Specialist Information Pharmacist

2. SUMMARY

There have been many changes within YCC Wales in 2012/13. We have said goodbye to our longstanding pharmacovigilance pharmacist Jane Houghton and wish her well in retirement. Furthermore, we welcome Emma Carey to our team.

YCC Wales celebrated its 30th anniversary on 1st March 2013 with the launch of our new Yellow Card Hospital Champion Scheme and an anniversary lunch event. Yellow card reporting was initiated as a 'Local comparator' by the All Wales Prescribing Advisory Group (AWPAG) for 2012/13.

Members of YCC Wales have continued to encourage the spontaneous reporting of suspected adverse drug reactions from healthcare professionals and patients throughout Wales. We have developed many new ways to encourage reporting and continue to present lectures, workshops and seminars on pharmacovigilance to a variety of cohorts.

In 2012/13 the number of reports received from reporters within Wales decreased by 9% compared with the previous year. The number of reports from community pharmacists rose for the second year and the number of reports from GPs stayed the same as the previous year. However, reporting rates from other reporters fell.

Several strategies are planned for the next financial year to target individual reporter groups with the aim of improving reporting rates.

3. YELLOW CARD DATA

A total of 649 reports of suspected adverse drug reactions originated from the YCC Wales region in 2012/2013. Comparative data for the previous four years are shown in Table 1. Unfortunately, there was a 9% decrease in the total number of reports over the previous year.

Table 1. Number of reports received 2012-13 with previous 4 years for comparison

Year	Total number of reports	Percentage change on previous year
2012/13	645	-9
2011/12	711	- 26
2010/11	963	+7
2009/10	898	-11
2008/09	1013	+15

Chart 1 indicates that there is a considerable variation in the reporting rates throughout Wales. There was increased reporting from Abertawe Bro Morgannwg UHB and Hywel Dda Health Board but a reduction in reporting rates for all other Health Boards.

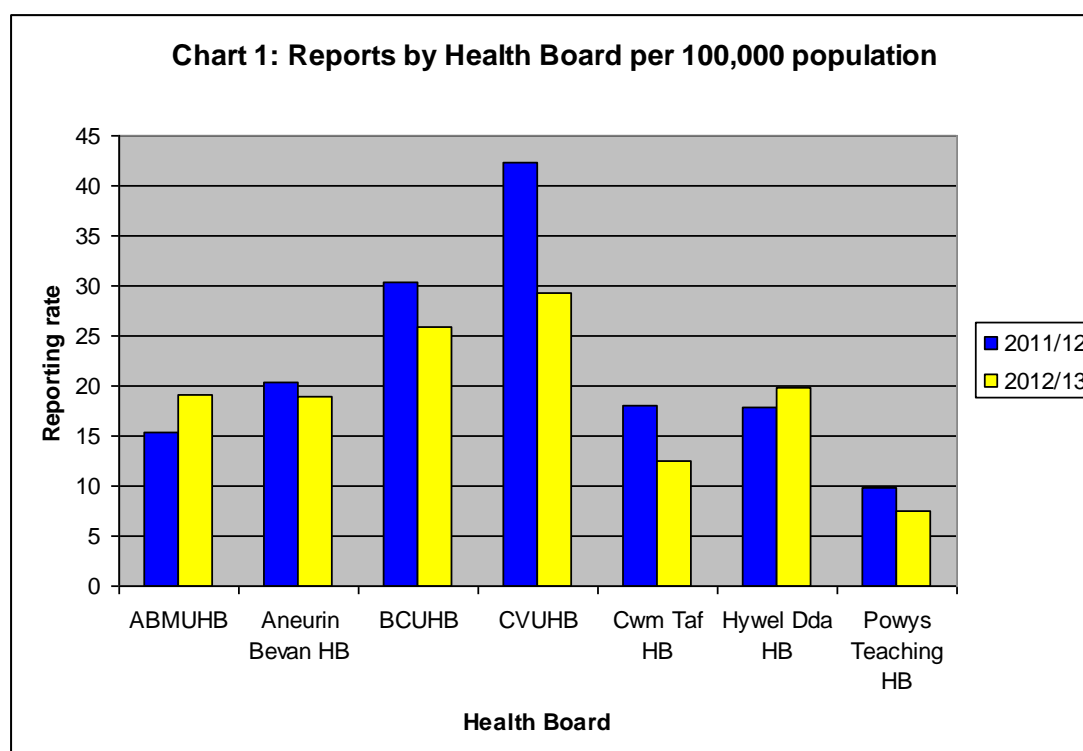


Table 2 highlights the total number and percentage of reports from reporter groups in 2012/13 with comparative data for 2011/12. Hospital pharmacists represent the highest percentage of reporters as in previous years.

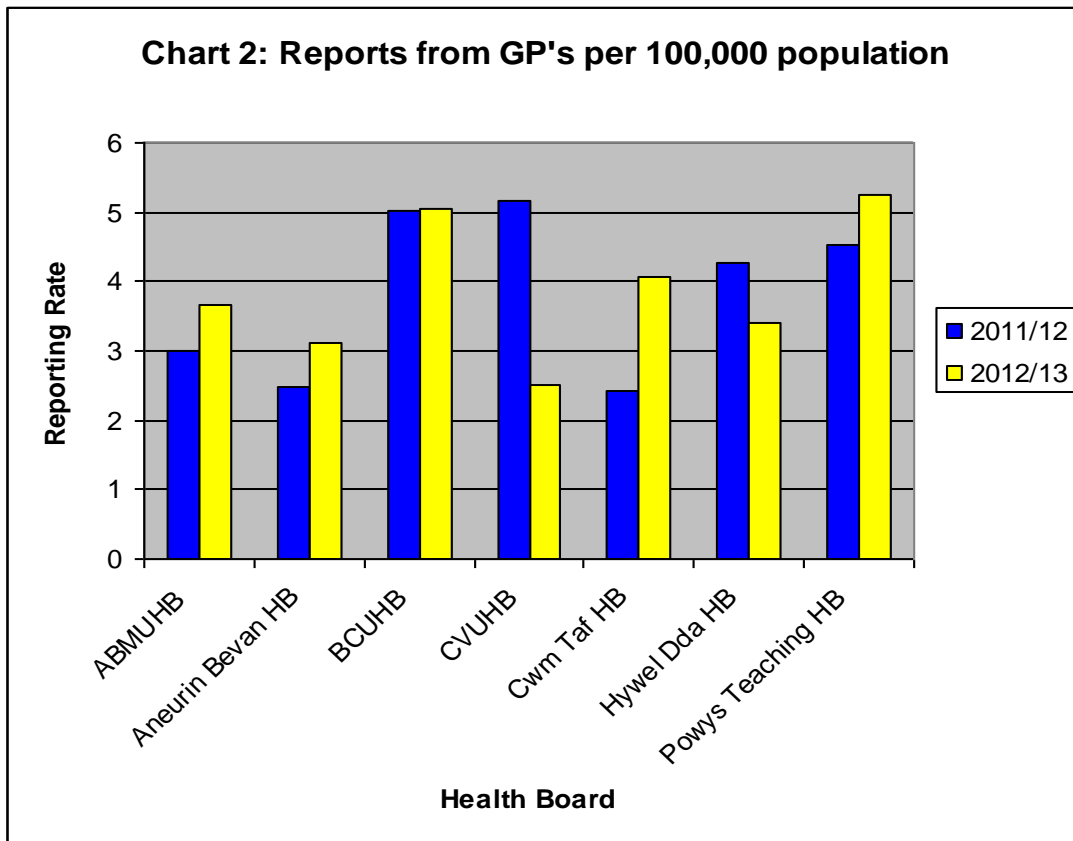
Table 2 Total number and percentage of reports from reporter groups in 2012/13 with comparative percentage changes compared with 2011/12.

Source of reports

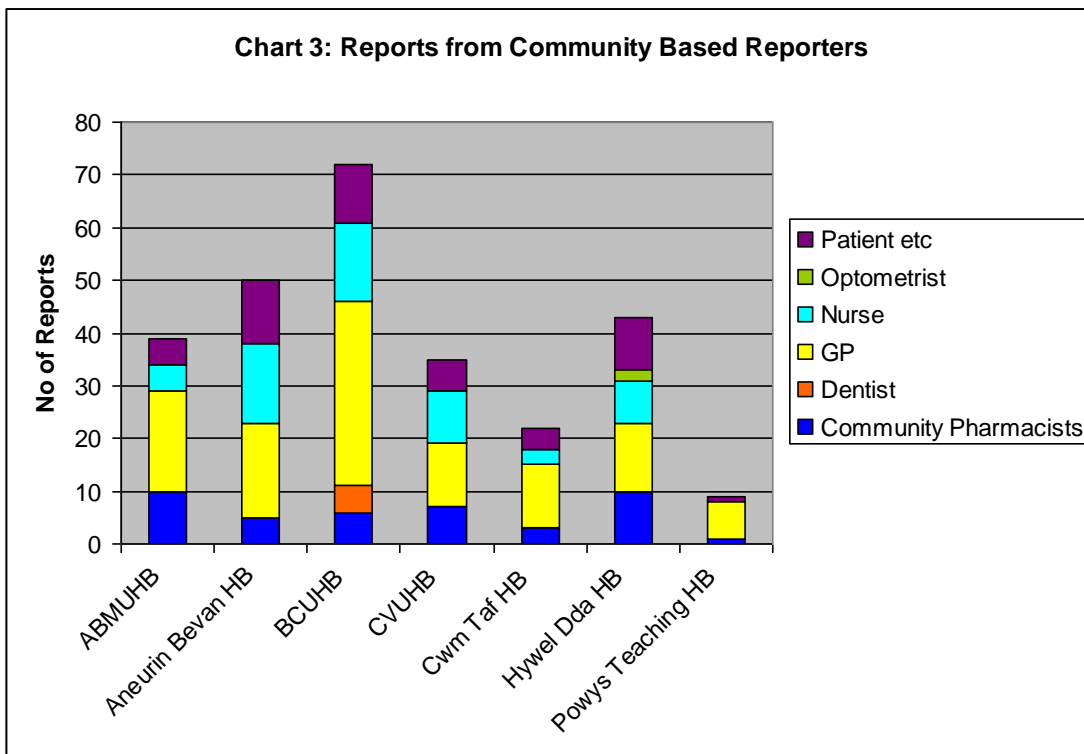
Reporter qualification	Number of reports 12/13	Number of reports 11/12	% of total reports 12/13	% change
Hospital Pharmacist	144	179	22	-20
Hospital Doctor	104	119	16	-13
General Practitioners	116	117	18	-1
Patient/Parent/Carer	49	77	8	-36
Hospital Nurse	46	68	7	-32
Nurse/Midwife	61	62	9	-2
Hospital Health Professional	30	36	5	-17
Community Pharmacist	42	32	6	+31
Other Health Professional	15	10	2	+50
Dentist	5	5	1	0
Physician	1	4	<1	-75
Pharmacist	19	2	3	-
Pre-reg pharmacist	12	0	2	-
Optometrist	2	0	<1	-
Medical student	2	0	<1	-
Total	649	711	100	

The following charts show the differing reporting patterns geographically throughout Wales. A map of the Health Boards is also given for reference.

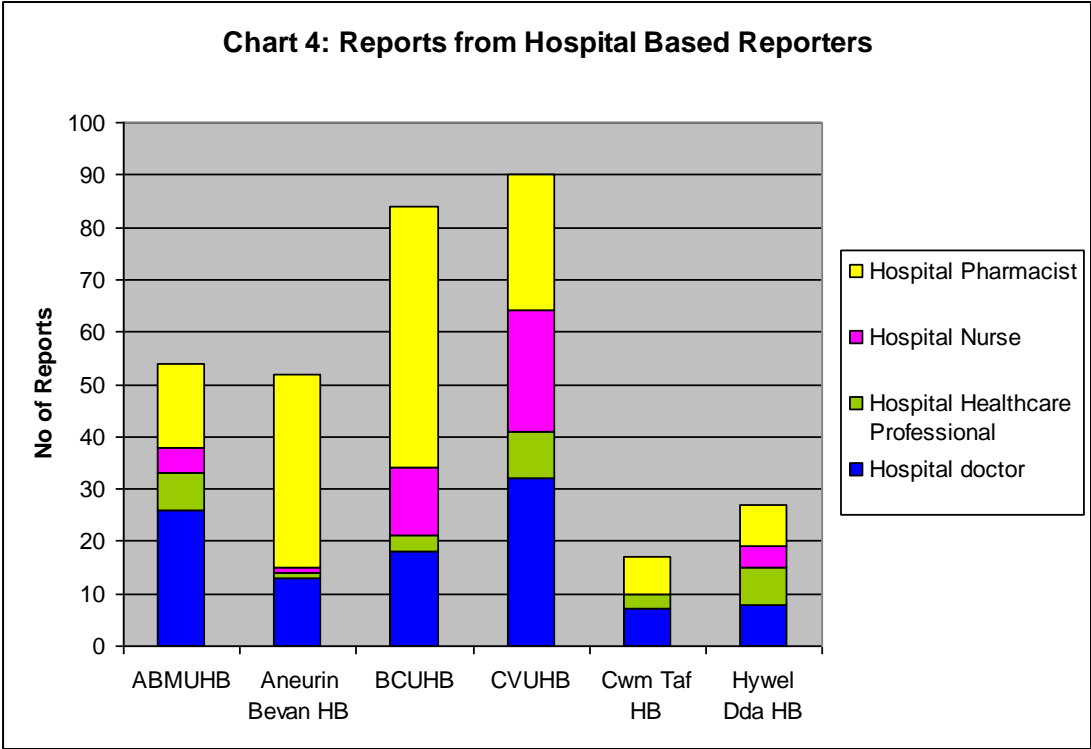




The highest community based reporting rate in 2012/13 was from the Betsi Cadwaladr University Health Board followed by Aneurin Bevan Health Board and Hywel Dda Health Board.



The highest hospital based reporting rate was from Cardiff & Vale UHB followed by Betsi Cadwaladr UHB. Powys Teaching Health Board has been omitted from this chart as the Health Board does not include an acute hospital in Wales.



4. Serious Reactions

The total number of reports of serious reactions received in 2012/13 and comparative data for the previous 4 years is shown in Table 3.

Table 3. The total number of reports of serious reactions received in 2011/12 and comparative data for the previous 4 years

Year	Number of Serious Reactions	% of Total Reports
2012/13	422	65
2011/12	468	66
2010/11	588	61
2009/10	413	56
2008/9	514	51

Table 4. The number and percentage of serious reactions per reporter group in 2012/13 with comparative percentage data in 2011/12

Reporter Qualification	Number of Serious Reports	Percentage of Serious Reports/Total Reports by reporter type 2012/13	Percentage of Serious Reports/Total Reports by reporter type 2011/12
Hospital Pharmacist	130	90	86
Hospital Doctor	81	78	73
General Practitioners	63	54	79
Patient/Parent/Carer	41	84	46
Hospital Nurse	23	50	54
Nurse/Midwife	18	30	67
Hospital Health Professional	18	60	37
Community Pharmacist	17	40	47
Other Health Professional	4	27	56
Dentist	5	100	60
Physician	0	0	100
Pharmacist	11	58	50
Pre-reg pharmacist	6	55	-
Optometrist	0	0	-
Medical student	2	100	-

5. Reports of reactions to Black Triangle Drugs

Medicines that are being monitored particularly closely by regulatory authorities in the European Union (EU) are described as being under 'additional monitoring'. These were previously known as 'black triangle drugs'. All medicines are carefully monitored after they are placed on the market. If a medicine carried the Black Triangle symbol, this means that it is subject to intensive monitoring.

Table 5. The total number of reports concerning black triangle drugs received in 2012/13 together with comparative data from the previous 4 years

Year	Number of reactions to ▼ drugs	Percentage of total reports	% Change (on previous year)
2012/13	153	24	0
2011/12	168	24	-22
2010/11	216	22	-11
2009/10	243	33	-34
2008/9	370	37	+90

6. Fatal Reports

The number of fatal reports received in 2012/13 with comparative data from the previous 4 years are shown in Table 6. There was an 18% decrease in the number of fatal reports reported in 2012/13. It is important to note that suspected ADRs are associations only and there is not necessarily a causal link between any of the medicines reported on a particular yellow card and the fatal outcome. It is also important to note that the fatal reports are a very small proportion of the total yellow card reports.

Table 6. Total number of fatal reports received in 2012/13 together with comparative data from the previous 4 years

Year	Number of fatal reports	Percentage of total reports	Percentage change on previous years
2012/13	9	1.4	-18
2011/12	12	1.7	-43
2010/11	21	2.1	31
2009/10	16	2.2	-43
2008/9	28	2.8	+155

7. Age Banding

Table 7. Number of reports per age band in 2012/13 and comparative data for the previous year

Age range	Number of reports 2012/13	Number of reports 2011/12
<18	73	82
18-24	25	39
25-34	38	49
35-44	52	65
45-54	81	81
55-64	80	100
65-74	146	127
75-84	83	81
>85	33	38
not specified	39	49
Total	649	711

8. Top Ten Medicines

Table 8. Ten most frequently reported suspected medicines in 2012/13 in Wales

Drug/Vaccine	Number of Reports
DTP vaccine	17
Influenza Vaccine	15
Dabigatran	15
Simvastatin	14
Human Papilloma virus vaccine	14
Clarithromycin	12
Varenicline	12
Nitrofurantoin	11
Exenatide	9
Naproxen	9

The five most frequently reported suspected medicines by General Practitioners are shown in Table 9. Not surprisingly, the majority of reports of suspected ADRs in association with varenicline (a smoking cessation treatment) were from General Practitioners

Table 9. Five most frequently suspected medicines in reports by General Practitioners

Drug/Vaccine	Number of Reports
Varenicline	9
Dabigatran	6
Clarithromycin	5
DTP vaccine	5
Influenza vaccine	4

Table 10. Six most frequently reported suspected medicines from Hospital Doctors

Drug/Vaccine	Number of Reports
DTP vaccine	5
Citalopram	3
Meningitis C vaccine	3
Naproxen	3
Patent Blue	3
Rocuronium	3

Table 11. Four most frequently reported suspected medicines from Hospital Pharmacists

Drug/Vaccine	Number of Reports
Nitrofurantoin	11
Dabigatran	5
Methotrexate	5
Naproxen	5

Table 12. Two most frequently reported suspected medicines from Carers/Patients/Parents

Drug/Vaccine	Number of Reports
Atorvastatin	3
Simvastatin	3

Table 13. Four most frequently reported suspected medicines from Community Pharmacists

Drug/Vaccine	Number of Reports
Finasteride	4
Mirtazapine	3
Atorvastatin	2
Ranolazine	2
Simvastatin	2

9. INTERPRETATION OF FINDINGS

There were a total of 649 reports from reporters within Wales in 2012/13, the lowest number of reports for over 10 years. There was a 9% decrease in the total number of reports, 65% of the reports were of serious reactions, and 24% were to black triangle drugs. The highest number of reports was from hospital pharmacists.

There was a 20% decrease in reports from hospital pharmacists, a 13% decrease from hospital doctors, a 32% decrease in hospital nurse reports and a 36% decrease in reports from patient/parent/carers. For the second year the number of reports from community pharmacists increased (31%) and we received two reports from optometrists.

Two Health Boards showed an increase in reporting rates: Abertawe Bro Morgannwg University Health Board and Hywel Dda Health Board. Of concern is the reduction in reporting rates for the other Health Boards in Wales. A targeted approach has been launched to reverse this trend.

The number of reports from GPs fell only by 1% and this could be explained by the inclusion of yellow card reporting as a local comparator in Wales. Encouragingly, reporting rates have increased for GPs in all Health Boards except Cardiff and Vale University Health Board and Hywel Dda Health Board. Initiatives are planned for the next financial year to further improve reporting rates.

The percentage of serious reports and reports for black triangle drugs remained the same as last year. The most frequently reported treatment was DTP virus vaccine. The highest number of reports was in the 65-74 age group.

10. PROMOTIONAL ACTIVITIES

Presentations on the Yellow Card Scheme, mechanisms and classification of ADRs have been given to medical students, dental students, nursing students and pharmacy undergraduates. Regular talks on drug safety have been given to dentists and nurses involved with medicines management. Presentations have been given to non medical prescribers, diploma pharmacists, pre-registration pharmacy graduates, primary and secondary care pharmacy technicians, health visitors and practice nurses.

Members of YCC Wales have presented at local Quality & Safety sessions, GP prescribing lead meetings, Royal Pharmaceutical Society conferences and Carers Association meetings.

YCC Wales has continued to attend conferences to mount table displays thus promoting reporting of side effects to both healthcare professionals and members of the general public. We have continued to work closely with the British Lung Foundation, Age Concern, Crossroads and Parkinsons Disease and Dementia patient groups and have given talks in centres throughout Wales. Promotional literature has been supplied by YCC Wales for inclusion in delegate packs when high conference fees prevent the attendance of YCC Wales staff.

As part of the 30th anniversary celebrations, YCC Wales launched its new logo and the YCC website is currently being updated with this new branding and will be re-launched shortly.

In March 2013, to coincide with the 30th anniversary, YCC Wales launched its latest initiative to encourage reporting. Each health board in Wales was asked to nominate a hospital pharmacist to act as a Yellow Card Champion. These champions are to act as local promoters and educators on the yellow card scheme on behalf of YCC Wales and we hope to see a positive impact on reporter rates as a result of this scheme over the next year.

Selected communications on drug safety and related issues by members of the YCC Wales team.

Dr AM Thomas

Presentation on ADR classification to Hospital Champions Cardiff, March 2013

Professor PA Routledge

'Safe Prescribing: a Titanic Challenge' to RCPI/BPS joint Symposium. Rational and Safe Prescribing- the way forward, Dublin, May 2012.

'Safety of Herbal Medicines' to the MSC in Experimental Therapeutics, University of Oxford, May 2012.

'Safety of herbal medicines, a toxicologist's perspective' at a Celebration of the life and work of Professor Gabrielle Hawksworth, Aberdeen, Feb 7-8th 2013

'Yellow Card Centre Wales: The first thirty years' at the 30th anniversary Celebration of the Regional Pharmacovigilance Centre in Wales, Cardiff, March 4th 2013

Dr R Bracchi

Lecture on ADRs to Diploma in Therapeutics Cardiff, September 2012

Presentation & Workshop on ADRs to Hospital Champions Cardiff, March 2013

Mrs A Adams

Presentation to Parkinsons Disease nurses on ADRs, Cardiff Dec 2012

Presentation on completing a yellow card to hospital champions, Cardiff, March 2013

Mrs E Carey

Presentation to Nurse Prescribers on ADRs and YC scheme, Cardiff, Oct 2012

Training sessions x 3 to Hospital Pharmacists at UHW, Cardiff, Nov 2012

Presentation to Parkinsons Disease and Dementia conference, Cardiff, Nov 2012

Training session to Crossroads Carers, Cardiff, Jan 2012

Training sessions x 12 to Quality and Safety sessions at UHW, Jan-Mar 2012

Presentation to Nurse Prescribers on ADRs and YC scheme, Cardiff, March 2013

Presentation x2 on YC scheme to GP prescribing leads, Cardiff & Vale, Feb 2013

Presentations and workshops to hospital champions, Cardiff, March 2013

Mr J Hayes

Information Mastery, Cardiff University Diploma in Palliative Medicine, Sept 2012

Evidence Based Practice, Bangor University, Non-medical prescribing course, Sept 2012

Drug Development, Cardiff University, November 2012

Interprofessional Learning, Cardiff University, November 2012

Evidence Based Medicine/Practice, Cardiff University, non-medical prescribing, November 2012

Improving medication review through multidisciplinary working. Royal Pharmaceutical Society, Medicines Safety Conference, November 2012

Interprofessional Learning, Cardiff University, February 2013

Evidence Based Medicine/Practice, Cardiff University, non-medical prescribing (nurses), February 2013

Prescribing and the world at large. Cardiff University Post Graduate, dentists, March 2013

Prescribing and the world at large. Cardiff University Post Graduate, dentists, March 2013

Publications by members of the YCC Wales team.

Routledge PA. Safe prescribing: a titanic challenge. Br J Clin Pharmacol. 2012. 2012 Oct;74(4):676-84. doi: 10.1111/j.1365-2125.2012.04367.x.

Hughes D and **Routledge PA.** A Prescribing Partnership. Public Service Review: Health and Social Care 2013; 35: 65-67

Routledge PA. A national inpatient prescription chart: the experience in Wales 2004-12. Br J Clin Pharmacol. 2012 Oct;74(4):561-5. doi: 10.1111/j.1365-2125.2012.04283.x

Routledge PA and Hutchings AD. Therapeutic Drug Monitoring in *"The Immunoassay Handbook, Fourth Edition: Theory and applications of ligand binding, ELISA and related techniques"*. D Wild (ed) Elsevier Science 2013 (pages 945-962)