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Electronic supplementary material

Article title: Knowledge of Adverse Drug Reaction Reporting and the Pharmacovigilance of Biological Medicines: A Survey of Healthcare Professionals in Ireland

Journal name: Biodrugs

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Questionnaire

Welcome to my survey on adverse drug reaction reporting

I am a pharmacist undertaking a MSc. in the School of Pharmacy, University College Cork. As part of my research I am conducting a survey on awareness, attitudes and practice behaviours of healthcare professionals relating to adverse drug reaction reporting. The questionnaire has a specific focus on biological medicines. This research is part of a Regulatory Science Ireland (RSI) project and involves a joint collaboration between the Health Products Regulatory Authority (HPRA) and University College Cork. RSI is a voluntary network of interested parties from the HPRA, Academia, Industry and Government Agencies.

Registered physicians, nurses and pharmacists working in the Republic of Ireland can contribute to this research by completing the multiple choice questions that follow.

The questionnaire is straightforward and should take no longer than10 minutes to complete. You are not required to look up any information. The questions focus on your awareness, attitudes and behaviours.

You may participate regardless of your previous experience with adverse drug reaction reporting or biological medicines.

Participation is of course voluntary. You can give your informed consent to participate in this research by completing the questionnaire online. You can withdraw from the questionnaire at any time before completion. You will not be asked to give your name or identifying information. For more information on the study and what is involved, please read the information sheet for survey respondents. If you have any questions about the survey please contact Joan O'Callaghan at joan.ocallaghan@hpra.ie.

Thank you for taking the time to read the above. Your input is highly valued and I hope you will participate.

Joan O'Callaghan BSc. Pharm. M.P.S.I.

Demographics

1. Are you a

- ◯ Consultant
- ◯ Non-consultant hospital doctor
- ◯ General practitioner
- ◯ Nurse/Midwife
- ◯ Pharmacist
- ◯ Other (please specify)

Physician Demographics

2. How many years are you registered as a medical practitioner?

- ◯ < 5 years
- ◯ 5 - 9 years
- ◯ 10 - 19 years
- ◯ 20 - 29 years
- ◯ > 30 years

3. Please indicate the therapeutic area in which you practice?

- ◯ Nephrology
- ◯ Rheumatology
- ◯ Gastroenterology
- ◯ Endocrinology
- ◯ Neurology
- ◯ Dermatology
- ◯ Oncology
- ◯ Haematology
- ◯ Haematology/Oncology
- ◯ Geriatric Medicine
- ◯ Other (please specify)

4. Do you ever prescribe medicines to patients under your care?

- ◯ Yes
- ◯ No
- ◯ Other (please specify)

Pharmacist Demographics

5. How many years are you registered as a pharmacist?

- ◯ < 5 years
- ◯ 5 - 9 years
- ◯ 10 - 19 years
- ◯ 20 - 29 years
- ◯ > 30 years

6. What is your main area of practice?

- ◯ Community
- ◯ Hospital
- ◯ Industry
- ◯ Other (please specify)

General Practitioner Demographics

7. How many years are you registered as a General Practitioner?

- ◯ < 5 years
- ◯ 5 - 9 years
- ◯ 10 - 19 years
- ◯ 20 - 29 years
- ◯ > 30 years

Other Demographics

8. How many years have you been in practice?

- ◯ < 5 years
- ◯ 5 - 9 years
- ◯ 10 - 19 years
- ◯ 20 - 29 years
- ◯ > 30 years

Nurse/Midwife Demographics

9. How many years has it been since you first entered practice?

- ◯ < 5 years
- ◯ 5 - 9 years
- ◯ 10 - 19 years
- ◯ 20 - 29 years
- ◯ > 30 years

10. Are you a (choose all that apply):

- ☐ Registered General Nurse
- ☐ Registered Midwife
- ☐ Registered Nurse Prescriber
- ☐ Registered Advanced Nurse Practitioner
- ☐ Registered Advanced Midwife Practitioner
- ☐ Registered Children's Nurse
- ☐ Registered Psychiatric Nurse
- ☐ Registered Nurse Intellectual Disability
- ☐ Registered Public Health Nurse
- ☐ Registered Nurse Tutor
- ☐ Other (please specify)

11. Please provide details of your practice area?

Adverse Drug Reaction Reporting

An adverse drug reaction is a response to a medicine which is noxious and unintended. An adverse drug reaction can be reported directly to the Health Products Regulatory Authority (formerly Irish Medicines Board) or to the manufacturer of the medicine.

12. Prior to this survey, did you know that an adverse drug reaction could be reported directly to the Health Products Regulatory Authority (HPRA)?

- ◯ Yes
- ◯ No

13. Have you ever reported an adverse drug reaction?

- ◯ No (0 times)
- ◯ Yes (1 time)
- ◯ Yes (2 or more times)
- ◯ Yes (> 3 times)

14. Do you think that:

	Yes	No	Don't know
You have adequate knowledge on how to report an adverse drug reaction?	○	○	○
Healthcare professionals should report serious adverse drug reactions even if uncertain that the medicine caused the event	○	○	○
Healthcare professionals should report serious adverse drug reactions even if they do not have all the details of the event (e.g. complete patient history, demographic data)	○	○	○
All serious adverse drug reactions are known before a medicine is marketed	○	○	○
HPRA will not disclose an adverse drug reaction reporters identity in response to a request from the public	○	○	○
One case reported by a healthcare professional **does not** contribute much to knowledge on medicine risks	○	○	○
Patients can report adverse drug reactions independent of a healthcare professional	○	○	○
Healthcare professionals should report adverse drug reactions associated with overdose, misuse or error	○	○	○

Additional Monitoring

The safety of all medicines is monitored on an ongoing basis. In some cases a medicine may be subject to additional monitoring. This is generally because there is less information available on it than on other medicines. It does not mean that the medicine is unsafe. Healthcare professionals are encouraged to report all adverse drug reactions, irrespective of severity, for medicines under additional monitoring.

15. Prior to this survey were you aware that some medicines are subject to additional monitoring?

- ◯ Yes
- ◯ No

Additional Monitoring

16. Prior to this survey did you know that when a medicine is subject to additional monitoring an inverted black triangle ▼ appears beside the name of the medicine in the summary of product characteristics and package leaflet?

- ◯ Yes
- ◯ No

17. Are you aware when medicines used in your practice are subject to additional monitoring?

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Frequently
- ◯ Always

18. Do you inform your patients when their medicines are subject to additional monitoring?

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Frequently
- ◯ Always
- ◯ Not applicable (I do not work directly with patients)

Biological Medicines: Awareness

19. How familiar are you with the term biological medicine?

- ◯ Never heard of the term
- ◯ Heard of the term - can't define it
- ◯ Familiar - I've a basic understanding
- ◯ Very familiar - I've a complete understanding

20. How familiar are you with the term biosimilar medicine?

- ◯ Never heard of the term
- ◯ Heard of the term - can't define it
- ◯ Familiar - I've a basic understanding
- ◯ Very familiar - I've a complete understanding

Biological Medicines: Awareness

Biological medicines are produced from biological sources, such as animals, human blood, or the cells of a living organism. Examples of biological medicines include monoclonal antibodies (e.g. infliximab), insulins, heparins, vaccines and blood products. A biosimilar is a biological medicine which is highly similar to an original biological medicine.

21. Do you think that:

	Yes	No	Don't know
Biosimilars are the same as generic medicines	○	○	○
In an adverse drug reaction report it is better to identify a biological medicine by its non-proprietary name (e.g. insulin glargine) instead of its brand name	○	○	○
In general, biological medicines pose a greater risk of immunogenicity than non-biological (chemical) medicines	○	○	○
Different batches of the same biological medicine are always idenitical	○	○	○
Rare adverse drug reactions resulting from changes to the manufacturing process of a biological medicine can always be predicted	○	○	○
It is more important to include batch numbers in adverse drug reaction reports for non-biological medicines than it is for biological medicines	○	○	○
Keeping a biological medicine outside its recommended storage conditions may introduce or alter immunogenicity	○	○	○
Adverse drug reactions associated with a patient changing between different brands of biological medicine should be reported	○	○	○

Biological Medicines: Experience

22. Are biological medicines prescribed/dispensed/administered in your practice?

- ◯ Yes
- ◯ No
- ◯ Don't know

Biological Medicines: Behaviours and Attitudes

23. In your practice how are the **names** of biological medicines that have been prescribed/dispensed/administered to patients generally recorded?

- ◯ Brand name
- ◯ Non-proprietary name (e.g. insulin glargine)
- ◯ Both brand name and non-proprietary name
- ◯ Don't know
- ◯ Varies by medicine (please specify)

24. In your practice are the **batch numbers of biological medicines** that have been administered/dispensed to patients generally recorded?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Yes, but only for some medicines (please specify)

Please mark your response to the following questions on each scale ranging from 1 to 7

25. Do you believe that recording the brand names of **all** biological medicines prescribed/administered/dispensed to patients is:

	1	2	3	4	5	6	7
Worthless (1) - Valuable (7)	◯	◯	◯	◯	◯	◯	◯
Easy (1) - Difficult (7)	◯	◯	◯	◯	◯	◯	◯

Any other comments

26. Do you believe that recording batch numbers of**all** biological medicines administered/dispensed to patients is

	1	2	3	4	5	6	7
Worthless (1) - Valuable (7)	◯	◯	◯	◯	◯	◯	◯
Easy (1) - Difficult (7)	◯	◯	◯	◯	◯	◯	◯

Any other comments

Supplementary Tables

Table S1

Hospital doctor specialities

Specialty	**Percentage**	**Number**
Cardiology	3.4%	3
Cardiology and internal medicine	1.1%	1
Dermatology	3.4%	3
Endocrinology	6.8%	6
Gastroenterology	15.9%	14
General Medicine	4.6%	4
Geriatric Medicine	2.3%	2
Geriatrics	3.4%	3
Geriatrics and general medicine	1.1%	1
Geriatrics and internal medicine	1.1%	1
Haematology	1.1%	1
Histopathology	1.1%	1
Infectious diseases	1.1%	1
Internal medicine	3.4%	3
Neonatology	1.1%	1
Nephrology	5.7%	5
Neurology	3.4%	3
Obstetrics and gynaecology	11.4%	10
Oncology	2.3%	2
Paediatrics	8.0%	7
Palliative	3.4%	3
Psychiatry	1.1%	1
Rehabilitation	1.1%	1
Respiratory and internal medicine	1.1%	1
Respiratory medicine	2.3%	2
Rheumatology	9.1%	8
	100.0%	88

Table S2

Nurse registration details

Registration status*	**Percentage**	**Number**
Registered general nurse	68.3%	71
Registered midwife	11.5%	12
Registered nurse prescriber	13.5%	14
Registered advanced nurse practitioner	4.8%	5
Registered children's nurse	4.8%	5
Registered psychiatric nurse	18.3%	19
Registered nurse intellectual disability	9.6%	10
Registered public health nurse	6.7%	7
Registered nurse tutor	2.9%	3
Other*	9.6%	10

Other clinical nurse specialist (n=2), nurse manager (n=4), Director of nursing (n=1), candidate advanced nurse practitioner (n=1), candidate advanced nurse prescriber (n=1), tissue viability nurse (n=1)

** Nurses could choose more than one option*

Table S3

Details of suspected new adverse reaction reports for human medicines received by Health Products Regulatory Authority (HPRA) from 2012 to 2016. Information obtained from annual reports published on the HPRA website (www.hpra.ie).

Year	2012	2013	2014	2015	2016	Average
Total number of new adverse reaction reports received	2757	2835	2884	2810	3264	2910
Percentage reports received						
Pharmaceutical company	69%	64%	67%	67%	69%	67%
Patient/consumer	2%	1%	3%	8%	10%	5%
Community pharmacist	4%	4%	4%	4%	4%	4%
General practitioner	5%	5%	4%	4%	3%	4%
Nurse	3%	5%	4%	4%	3%	4%
Community care doctor	8%	9%	7%	4%	3%	6%
Hospital pharmacist	4%	4%	4%	4%	3%	4%
Hospital doctor/specialist	5%	4%	4%	3%	2%	4%
Other	<2%	4%	1%	1%	2%	2%
Clinical trial reports	0%	-	2%	1%	1%	1%

Table S4

Adverse Drug Reaction reporting. Responses to individual knowledge items by each healthcare professional group

	n	% correct*	% incorrect	% don't know
All serious ADRs are known before a medicine is marketed (No)				
Hospital doctor	88	94.3%	3.4%	2.3%
General practitioner	196	83.7%	9.2%	7.1%
Nurse	104	61.5%	21.2%	17.3%
Community pharmacist	168	92.3%	5.4%	2.4%
Hospital pharmacist	87	95.4%	3.4%	1.1%
Other pharmacist	53	98.1%	1.9%	0%
HCPs should report serious ADRs even if uncertain that the medicine caused the event (Yes)				
Hospital doctor	88	92.0%	2.3%	5.7%
General practitioner	197	87.3%	2.5%	10.2%
Nurse	104	89.4%	3.8%	6.7%
Community pharmacist	169	83.4%	3.6%	13.0%
Hospital pharmacist	87	95.4%	0%	4.6%
Other pharmacist	53	96.2%	0%	3.8%
You have adequate knowledge on how to report ADRs (Yes)				
Hospital doctor	88	46.6%	40.9%	12.5%
General practitioner	197	48.7%	43.7%	7.6%
Nurse	103	48.5%	40.8%	10.7%
Community pharmacist	169	63.3%	24.3%	12.4%
Hospital pharmacist	87	88.5%	6.9%	4.6%
Other pharmacist	53	88.7%	7.5%	3.8%
One case reported by a HCP does not contribute much to knowledge on medicine risks (No)				
Hospital doctor	88	85.2%	6.8%	8%
General practitioner	197	83.8%	6.1%	10.2%
Nurse	103	80.6%	9.7%	9.7%
Community pharmacist	168	75.6%	12.5%	11.9%
Hospital pharmacist	87	87.4%	4.6%	8.0%
Other pharmacist	53	90.6%	5.7%	3.8%
HCPs should report serious ADRs even if they do not have all the details of the event (e.g. complete patient history, demographic data) (Yes)				
Hospital doctor	88	75.0%	15.9%	9.1%
General practitioner	196	75.5%	12.2%	12.2%
Nurse	103	70.9%	14.6%	14.6%
Community pharmacist	169	78.1%	7.1%	14.8%
Hospital pharmacist	87	86.2%	5.7%	8.0%
Other pharmacist	53	94.3%	3.8%	1.9%
HCPs should report ADRs associated with overdose, misuse or error (Yes)				
Hospital doctor	88	52.3%	20.5%	27.3%
General practitioner	195	47.2%	17.9%	34.9%
Nurse	103	78.6%	9.7%	11.7%
Community pharmacist	169	63.9%	11.8%	24.3%
Hospital pharmacist	87	58.6%	19.5%	21.8%
Other pharmacist	53	83.0%	7.5%	9.4%
Patients can report ADRs independent of a HCP (Yes)				
Hospital doctor	88	47.7%	11.4%	40.9%
General practitioner	197	48.7%	4.1%	47.2%
Nurse	104	76.9%	6.7%	16.3%
Community pharmacist	169	66.9%	5.3%	27.8%
Hospital pharmacist	87	67.8%	9.2%	23.0%
Other pharmacist	52	94.2%	0%	5.8%
HPRA will not disclose and ADR reporters identity in response to a request from the public (Yes)				
Hospital doctor	88	52.3%	4.5%	43.2%
General practitioner	197	37.1%	7.1%	55.8%

Nurse	104	43.3%	12.5%	44.2%
Community pharmacist	167	43.7%	7.2%	49.1%
Hospital pharmacist	87	50.6%	6.9%	42.5%
Other pharmacist	53	69.8%	5.7%	24.5%

**Correct answer is shown in brackets*

ADR, Adverse drug reaction; HCP, Healthcare professional; HPRA, Health Products Regulatory Authority

Table S5

Pharmacovigilance considerations for biological medicines: Response to individual knowledge items from individual HCP groups

Question (*)	**n**	**% correct**	**%incorrect**	**% don't know**
ADRs associated with a patient changing between different brands of biological medicines should be reported (Yes)				
Hospital doctor	88	93.2%	2.3%	4.5%
General practitioner	194	85.1%	2.1%	12.9%
Nurse	104	93.3%	0%	6.7%
Community pharmacist	168	94.6%	0.6%	4.8%
Hospital pharmacist	87	97.7%	0%	2.3%
Other pharmacist	53	96.2%	0%	3.8%
In an ADR report it is better to identify a biological medicine by its non-proprietary name (e.g. insulin glargine) instead of its brand name (No)				
Hospital doctor	87	57.5%	35.6%	6.9%
General practitioner	195	56.9%	27.7%	15.4%
Nurse	104	25.0%	55.8%	19.2%
Community pharmacist	169	65.7%	18.3%	16.0%
Hospital pharmacist	87	86.2%	9.2%	4.6%
Other pharmacist	53	81.1%	15.1%	3.8%
Biosimilars are the same as generic medicines (No)				
Hospital doctor	88	73.9%	15.9%	10.2%
General practitioner	194	73.2%	9.8%	17.0%
Nurse	102	43.1%	23.5%	33.3%
Community pharmacist	169	82.8%	6.5%	10.7%
Hospital pharmacist	87	89.7%	5.7%	4.6%
Other pharmacist	53	98.1%	1.9%	0%
Rare ADRs resulting from changes to the manufacturing process of a biological medicine can always be predicted (No)				
Hospital doctor	88	94.3%	1.1%	4.5%
General practitioner	195	80.5%	0%	19.5%
Nurse	104	68.3%	2.9%	28.8%
Community pharmacist	169	79.3%	2.4%	18.3%
Hospital pharmacist	87	94.3%	0%	5.7%
Other pharmacist	53	94.3%	1.9%	3.8%
Keeping a biological medicine outside its recommended storage conditions may introduce or alter immunogenicity (Yes)				
Hospital doctor	88	83.0%	1.1%	15.9%
General practitioner	195	78.5%	0.5%	21.0%
Nurse	104	85.6%	0%	14.4%
Community pharmacist	169	78.1%	0%	21.9%
Hospital pharmacist	85	76.5%	4.7%	18.8%
Other pharmacist	53	83.0%	1.9%	15.1%
Different batches of the same biological medicine are always identical (No)				
Hospital doctor	87	89.7%	2.3%	8.0%
General practitioner	195	62.6%	8.2%	29.2%
Nurse	104	51.9%	9.6%	38.5%
Community pharmacist	169	69.8%	11.2%	18.9%
Hospital pharmacist	87	87.4%	5.7%	6.9%
Other pharmacist	53	90.6%	5.7%	3.8%
It is more important to include batch numbers in ADR reports for non-biological medicines than it is for biological medicines (No)				
Hospital doctor	87	52.9%	26.4%	20.7%
General practitioner	195	55.9%	11.8%	32.3%
Nurse	103	49.5%	25.2%	25.2%
Community pharmacist	168	62.5%	18.5%	19.0%
Hospital pharmacist	87	83.9%	12.6%	3.4%

Other pharmacist	53	77.4%	17.0%	5.7%
In general biological medicines pose a greater risk of immunogenicity than non-biological (chemical) medicines (Yes)				
Hospital doctor	88	81.8%	5.7%	12.5%
General practitioner	194	56.7%	2.6%	40.7%
Nurse	102	26.5%	13.7%	59.8%
Community pharmacist	169	61.5%	8.9%	29.6%
Hospital pharmacist	87	80.5%	11.5%	8.0%
Other pharmacist	53	86.8%	7.5%	5.7%

**Correct answer is shown in brackets*

ADR, Adverse drug reaction;

Table S6

Recording of biological medicines by brand name among healthcare professionals who use biological medicines in their practice. Survey question: In your practice are the brand names of biological medicines that have been administered/dispensed to patients generally recorded?

Profession	**n**	**Brand name***	**Non-proprietary name**	**Varies by medicine**	**Don't know**
Hospital doctor	69	75.3%	15.9%	5.8%	2.9%
General practitioner	144	87.5%	5.6%	3.5%	3.5%
Nurse	54	77.8%	13.0%	3.7%	5.6%
Community pharmacist	149	96.0%	0%	4.0%	0%
Hospital pharmacist	73	87.7%	5.5%	6.8%	0%
Other pharmacist	15	100%	0%	0%	0%
Total	504	87.7%	6.0%	4.4%	2.0%

** Respondents indicated that biological medicine was recorded by either 'Brand name' or 'Brand name and non-proprietary name'.*

Table S7

Attitudes to brand name and batch number recording among healthcare professionals who use biological medicines in their practice

Profession	**n**	**Mean score**	**Standard deviation**
Worthless (1) - Valuable (7)			
Brand name recording	489	5.98	1.44
Batch number recording	496	5.47	1.65
Easy (1) – Difficult (7)			
Brand name recording	496	3.60	2.25
Batch number recording	492	4.61	2.04

Survey questions: Please mark your response on each scale ranging from 1 to 7. ***Q1****. Do you believe that recording the brand names of biological medicines prescribed/administered/dispensed to patients is worthless (1) to valuable (7) and (ii) easy (1) to difficult?* ***Q2****. Do you believe that recording batch numbers of biological medicines administered/dispensed to patients is (i) worthless (1) to valuable (7) and (ii) easy (1) to difficult?*

Table S8

Proportions of healthcare professionals aware of additional monitoring who inform their patients about the additional monitoring status of a medicine

Profession	n*	Never/Rarely	Sometimes	Frequently/Always
Hospital doctor	73	58.9%	19.2%	22.0%
General Practitioner	132	57.6%	17.4%	25.0%
Nurse	62	41.9%	11.3%	46.8%
Community pharmacist	153	59.5%	24.8%	15.7%
Hospital pharmacist	66	68.2%	13.6%	18.2%
'Other' pharmacist	20	60.0%	30.0%	10.0%
Total	506	57.9%	19.2%	23.0%

** Excludes those who answered 'Not applicable (I do not work directly with patients)'*

Survey question: Do you inform your patients when their medicines are subject to additional monitoring?