ROBERT GORDON UNIVERSITY•ABERDEEN

كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY جامعة قطر

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث
حمد Hamad

Promoting Patient Safety through Pharmacovigilance

Dr Vibhu Paudyal
Dr Kerry Wilbur
Dr Mohamed Izham
Dr Anas Hamad

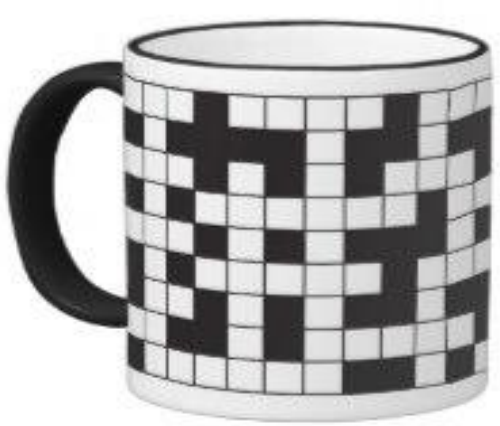
Reporting adverse drug reactions (ADRs)

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH
صحة • تعليم • بحوث

كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY جامعة قطر

ROBERT GORDON UNIVERSITY • ABERDEEN

Crossword puzzle



Workshop overview

- Pharmacovigilance: introduction
- International perspective
- Pharmacovigilance in Qatar
- Effective and efficient pharmacovigilance systems
- Barriers to effective pharmacovigilance
- Evidence based strategies in overcoming barriers to pharmacovigilance
- Better pharmacovigilance through research
- Summary

Reporting adverse drug reactions

- Have you ever
  - detected an ADR in a patient?
  - experienced an ADR as a patient?
- Did you document and report this ADR
  - in medical notes?
  - to other healthcare professionals?
  - to regulators, pharmacovigilance centres?

What is pharmacovigilance?

- **Adverse event** – 'any undesirable event experienced by a patient whilst taking a medicine, regardless of whether or not the medicine is suspected to be related to the event' (MHRA)

- **Adverse drug reaction** – 'an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use, which is suspected to be related to the drug' (MHRA)

- **Pharmacovigilance** - 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems' (WHO)

Which ONE of the following is the BEST estimate of the percentage of unplanned hospital admissions due to adverse drug reactions?

a.	1% - 2.5%
b.	3% - 4.5%
c.	5% - 6.5%
d.	7% - 8.5%
e.	9% - 10.5%

Which ONE of the following BEST describes the age group of patients at greatest risk of developing adverse drug reactions?

a.	1-12 years
b.	12-18 years
c.	18-40 years
d.	40-65 years
e.	65-85 years

ADRs account for

6% hospital admissions

4% of hospital bed capacity

ADRs occur in 10-20% of hospital in-patients

2% of patients admitted with an adverse drug reaction die

ADRs also impacts patients quality of life and trust in healthcare professionals or system

Aims of pharmacovigilance

1. improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions;

2. improve public health and safety in relation to the use of medicines;

3. contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use and;

4. promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public

Spontaneous ADR reporting

- Clinical trials involve a few thousand patients at most
  - Patients selected and carefully screened
  - Key patient groups under-represented
  - Unlikely to uncover all ADRs, especially rare
  - Limited ability to reveal long-term ADRs

Pharmacovigilance: international perspectives

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث
Hamad
كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY جامعة قطر
ROBERT GORDON UNIVERSITY • ABERDEEN

Yellow Card Scheme

- UK spontaneous ADR reporting process
    - 1964
    - significant impact
    - ensures that medicines are selected and used in the full light of up-to-date knowledge of harms
- Key limitation, **under-reporting**

What do you know?

1. Only healthcare professionals can submit Yellow Cards
2. Yellow Cards can be submitted online
3. Black triangle drugs are new medicines which are under intensive monitoring for ADRs
4. All suspected ADRs in adults should be reported
5. All suspected ADRs in children should be reported
6. Serious reactions to over the counter and herbal medicines should be reported
7. Prior to reporting an ADR, it is essential to determine that the suspect drug is responsible for the reaction

Yellow Card Scheme

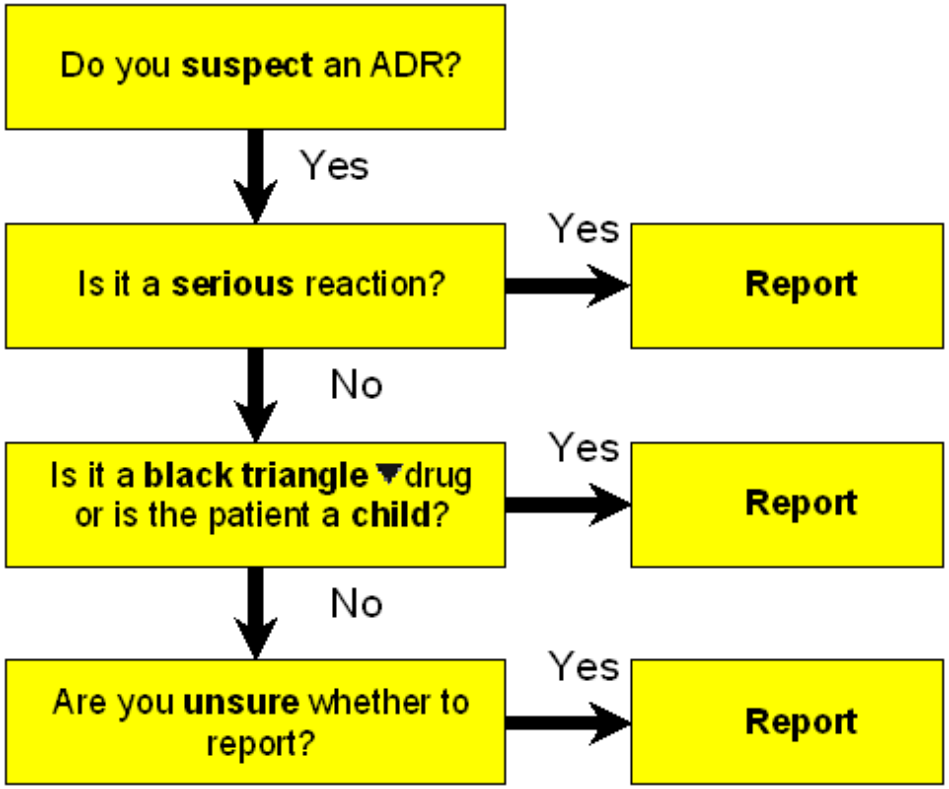
- Collects spontaneous reports of ADRs
- Prescribed, OTC medicines, blood products, and vaccines, herbal preparations, cosmetic treatments and unlicensed medicines
- **Not necessary to be certain that the drug has caused the ADR - a suspicion that it might be associated with the drug is sufficient**
- **Any** serious ADR thought associated should be reported
- Serious reactions - fatal, life-threatening, incapacitating or those that require hospitalisation (or prolong stay in hospitalised patients
- Health professionals and members of the public

Issues in practice

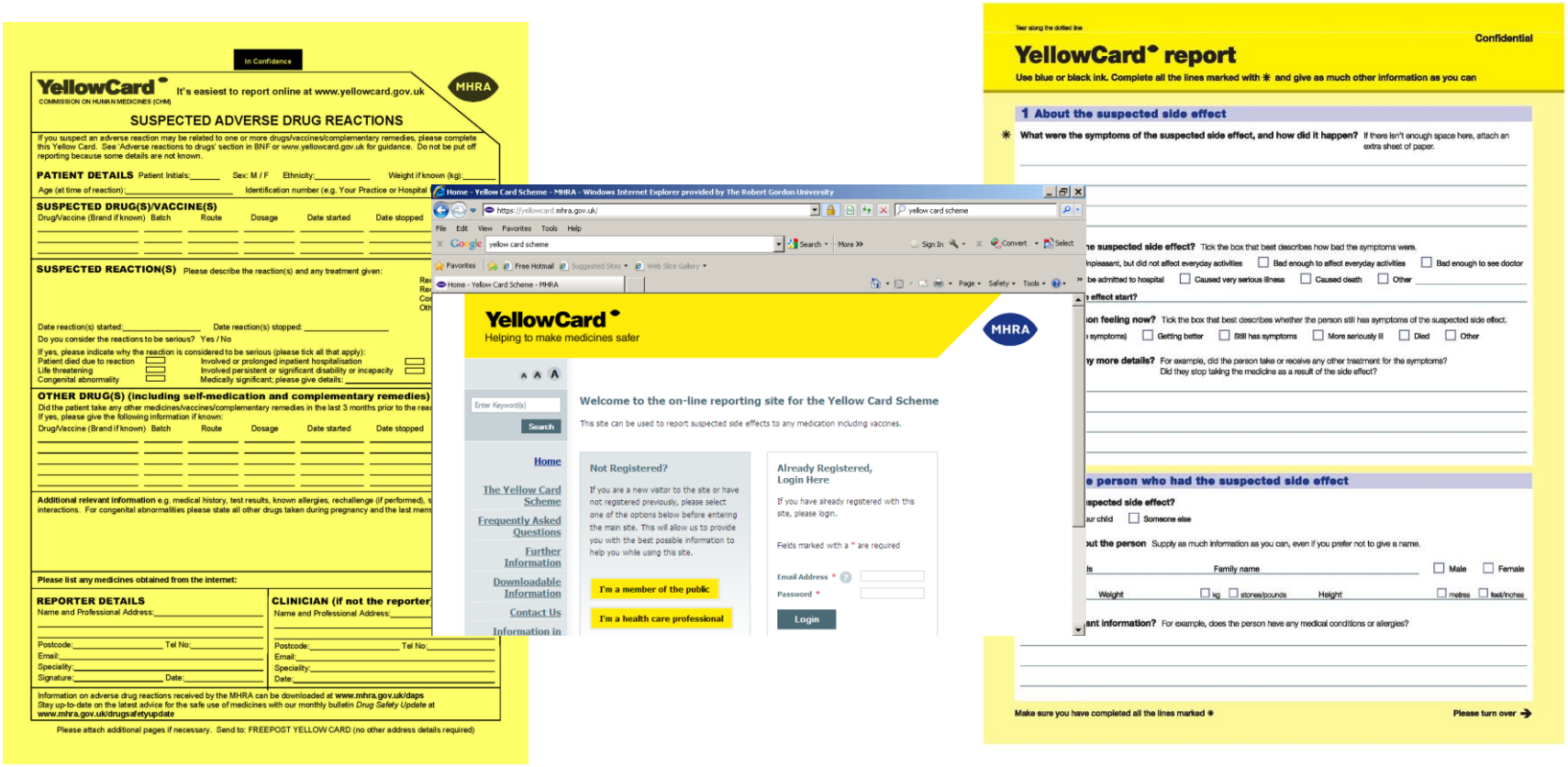
- Surveillance of ADRs of new medicines is more intensive
- An inverted black triangle (▼) is shown in the BNF
- All suspected ADRs in children should be reported, whether from established medicines or newly launched ones, whether from off-label use or from licensed use

Drug Analysis Prints:
http://www.mhra.gov.uk/drug-analysis-prints/drug-analysis-prints-a-z/index.htm

Completing a Yellow Card



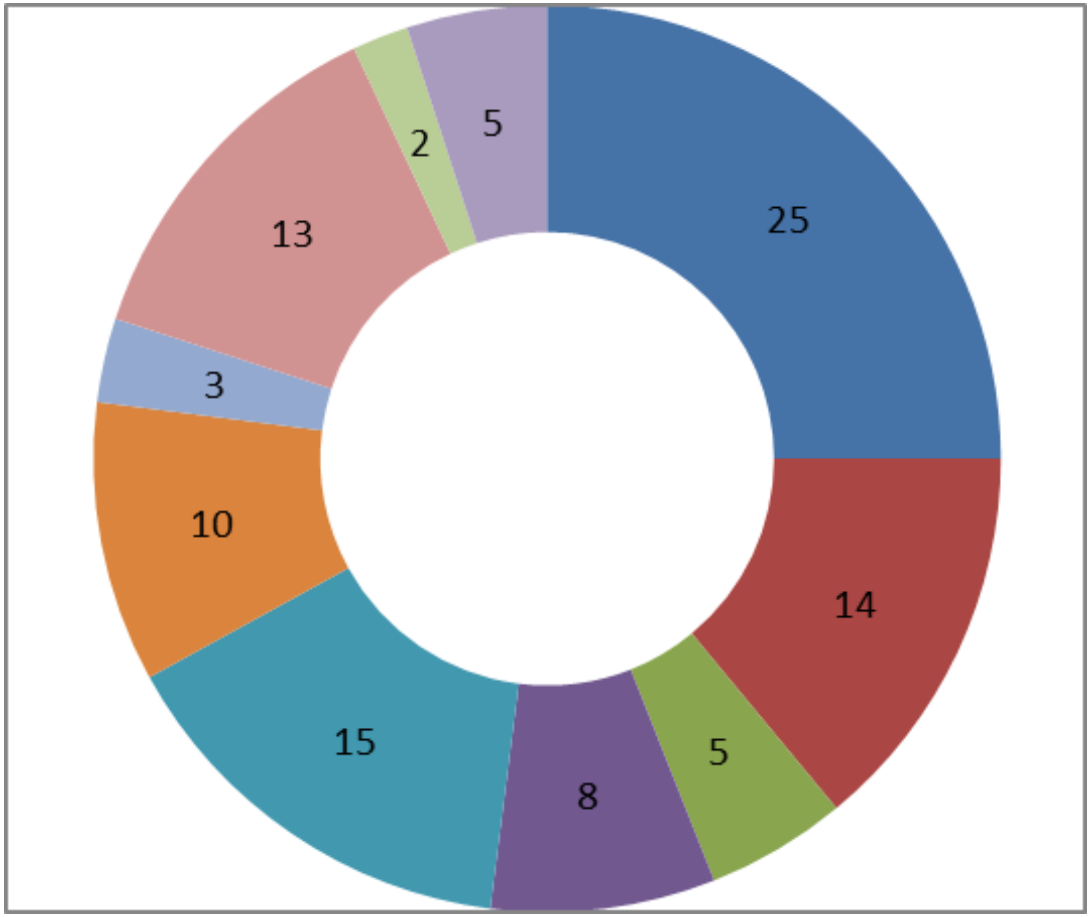
Completing a Yellow Card



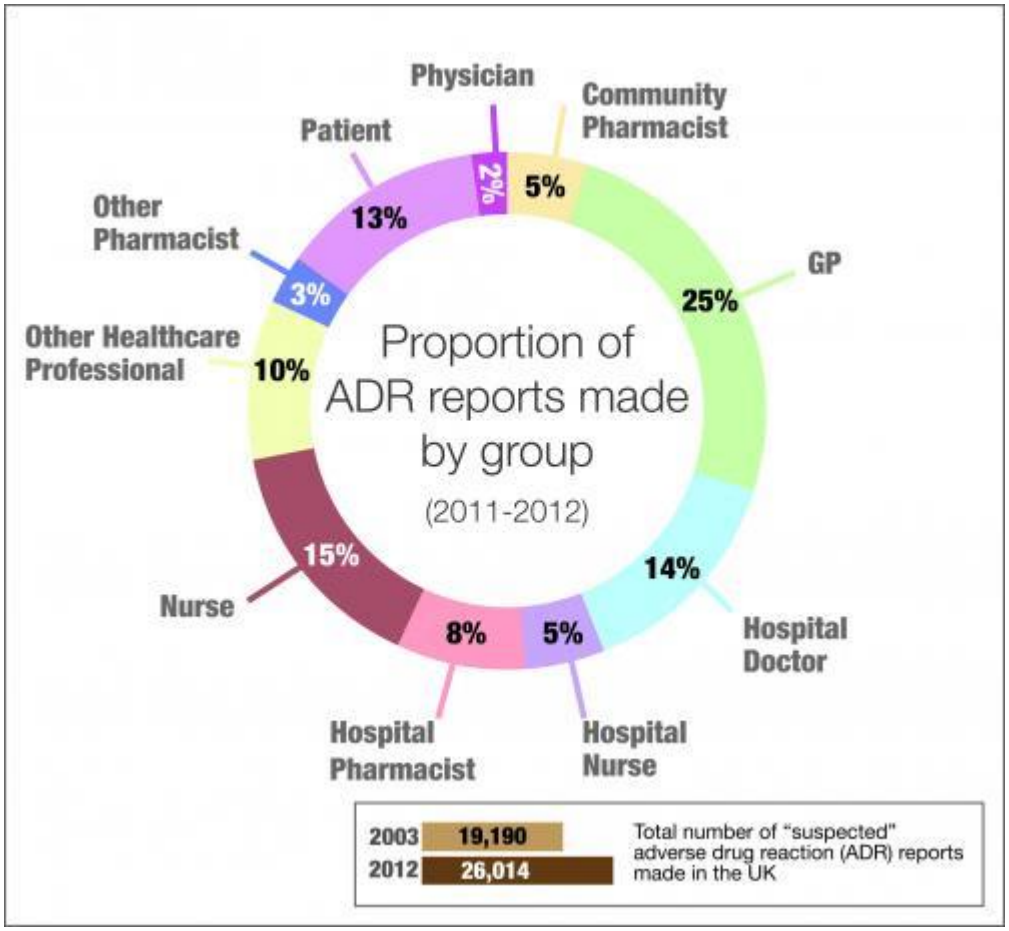
https://yellowcard.mhra.gov.uk/

Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH
College of Pharmacy
QATAR UNIVERSITY
ROBERT GORDON UNIVERSITY•ABERDEEN

Puzzle



ADR reporters



Pharmacovigilance in the Middle East

A recent survey of key stakeholders from 13 Middle Eastern countries showed

- Qatar
- Bahrain
- Kuwait
- Palestine and
- Yemen

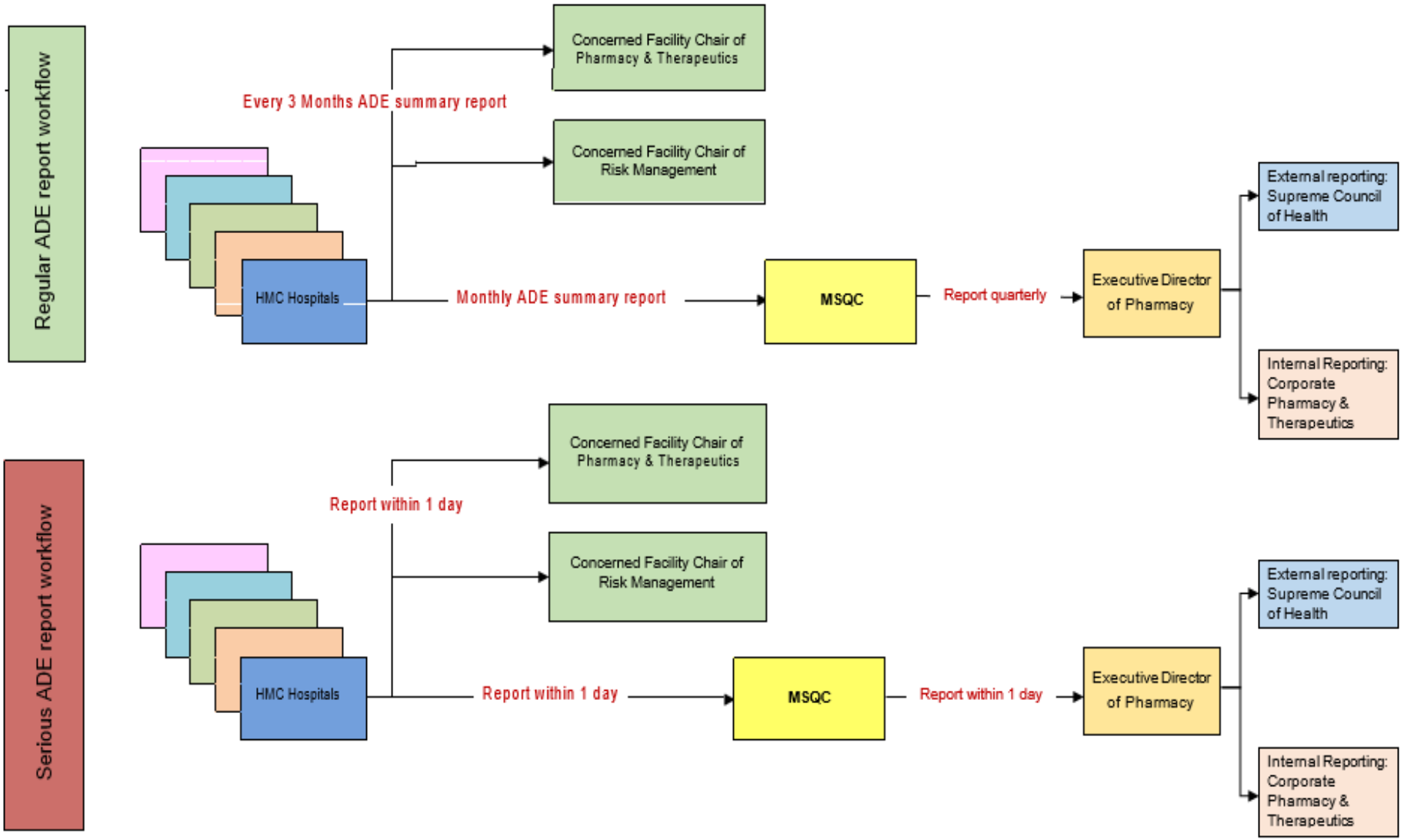
with no active pharmacovigilance programme or designated centre

Wilbur (2013)a

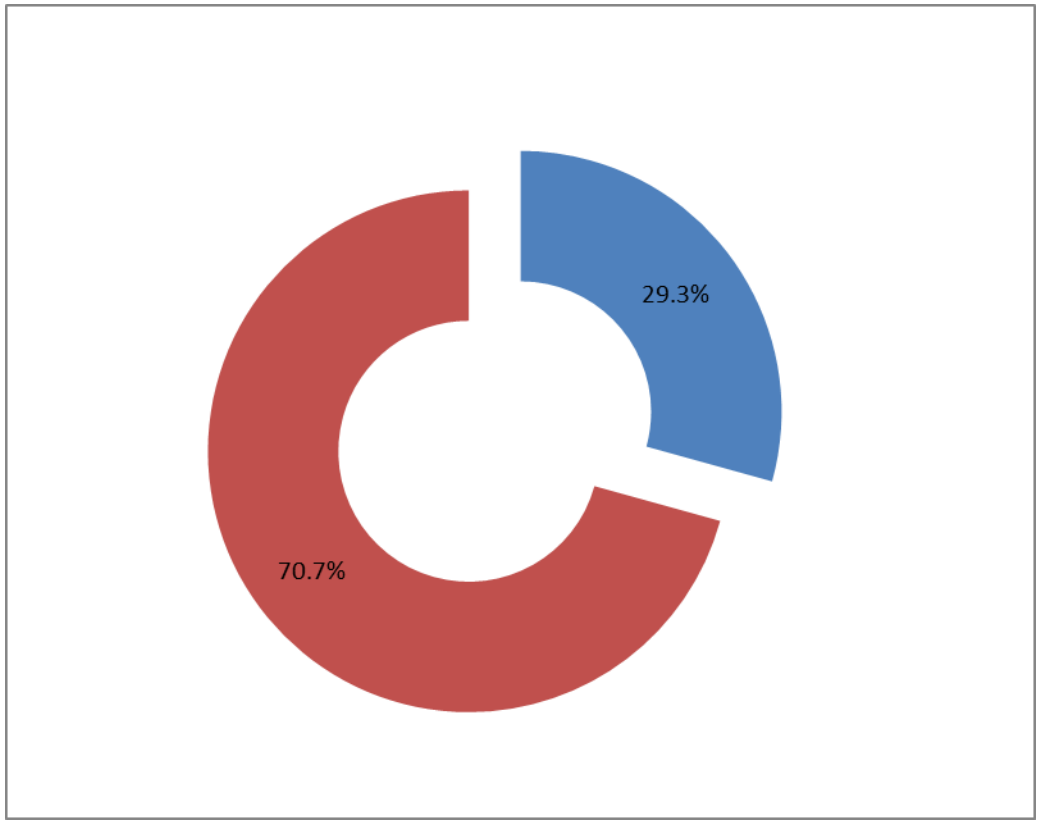
Qatar: Pharmacovigilance in HMC

- 65% of drug consumption in Qatar occurs in HMC
- Electronic and paper ADR reporting forms
- Medication Safety & Quality Center of HMC established in Sept 2015
- Analysis of ADR reports in HMC
  - Preventability (Schumock &Thorntons Scale)
  - Causality/Probability (Naranjo Scale)
  - Severity (Hartwig's Scale)
- Initiatives to improve ADR reporting in HMC

Qatar: Pharmacovigilance workflow in HMC



Qatar: Proportion of pharmacists ever reporting an ADR



?Ever reported

?Never reported

Wilbur (2013)b

Under-reporting: international context

94% Under-reporting rate of ADRs

Barriers to reporting ADRs

Can you discuss in your groups what are the biggest barriers to reporting ADRs?

Research findings

A cross-sectional survey of UK non-medical prescribers' perceptions of their pharmacovigilance training and roles

Aim was to determine non-medical prescriber perceptions of their training, contribution, and potential for enhancement of their pharmacovigilance role

Pharmacovigilance and non-medical prescribers: are they fulfilling their potential?

An MHRA funded collaborative research project

Research into adverse drug reaction reporting

Pharmacovigilance plays a key role in defining the safety of modern healthcare practice. This UK wide study explores the attitudes and awareness of nurses and pharmacists practising as supplementary or independent prescribers to ADR reporting.

How you can take part - please only complete the survey once

Participation in research is voluntary and confidential. Contact the Principal Investigator or Research Assistant if you require further information or a paper copy of the survey. After reading the **information sheet** please click on the button to access the **survey:**

Thank you

Every response contributes to the evidence base which guides and supports best practice. Your feedback and suggestions for further research are always greatly appreciated so do please get in touch with the research team.

Queen's University Belfast · University of Aberdeen · University of Surrey · Robert Gordon University Aberdeen

THE RESEARCH TEAM

Derek Stewart
Principal Investigator
Robert Gordon University

James McLay
University of Aberdeen

Carmel Hughes
Queen's University, Belfast

Molly Courtenay
University of Surrey

Contact
Research Assistant
K.M.MacLure@rgu.ac.uk
01224 262556

Stewart, Paudyal et al. 2011

Hamad Medical Corporation · HEALTH · EDUCATION · RESEARCH · مؤسسة حمد الطبية · صحة · تعليم · بحوث

College of Pharmacy · QATAR UNIVERSITY · كلية الصيدلة · جامعة قطر

ROBERT GORDON UNIVERSITY•ABERDEEN

Research findings

- Web-based survey of: demographics; pharmacovigilance training; experience of Yellow Card reporting; attitudes towards reporting; and suggestions to encourage reporting

- Sample was nurse and pharmacist prescribers

- Nurse prescribers who were members of the Association of Nurse Prescribers (n=912)

- All pharmacist prescribers (n=2439)

Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH
College of Pharmacy
QATAR UNIVERSITY
ROBERT GORDON UNIVERSITY•ABERDEEN

Research findings

- Responses received from 32.2% nurses and 13.1% pharmacists
- A third ‘couldn’t remember’ if pharmacovigilance covered in NMP training
- Although the majority of respondents felt competent in pharmacovigilance, a third said they needed further training
- 41.4% had never submitted a Yellow Card
- Respondents reported a positive attitude toward and awareness of ADR reporting, yet only a minority correctly answered all seven questions about the Yellow Card Scheme
- Most commonly suggested to enhance reporting were publicity and education

Research findings

- *'not a deliberate omission. Usually comes about in the consult and you are so busy doing everything else you don't register that you need to report it.'*

- *'my previous experiences of reporting have been time consuming - the information needed is not always readily available and easy to obtain. Also sometimes more information is requested and the process puts increased pressure on an already stressful and busy workload.'*

- *'it was a clear ADR but I felt it was not my position to report it and felt not as capable as others to do so as I was less experienced and not prescribing at that time.'*

ADR reporting systems: features

Efficient?

Effective?

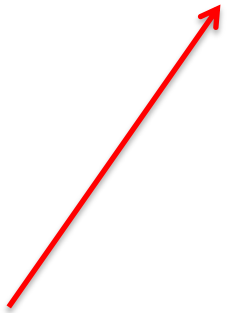
ADR reporting systems: features

Efficient? achieving maximum productivity with minimum wasted effort or expense

Effective? Successful in producing a desired or intended result

Source: Oxford Dictionary

Discuss in your groups three most important features each of an _____ pharmacovigilance system



A- Efficient
B- Effective

Pharmacovigilance in Qatar: informed by research

Research current practice

Behavioural aspects of pharmacovigilance

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث
Hamad
كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY جامعة قطر
ROBERT GORDON UNIVERSITY•ABERDEEN

Evidence based strategies in overcoming barriers to pharmacovigilance

Theoretical domains framework

Behavioural determinants of reporting or not reporting an ADR

TDF domain
Knowledge
Skills
Social/professional role
Beliefs about capabilities
Beliefs about consequences
Reinforcement
Intentions
Goals
Memory, attention and decision processes
Environmental context and resources
Social influence
Emotion
Behavioural regulation

"This probably won't work, but we do have medications that will take care of the side effects."

References and directed reading resources

1.World Health Organisation (WHO). Pharmacovigilance: Available: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/ . Accessed 14 April 2016

2.Medicines and Healthcare Regulatory Agency. Adverse drug reactions. Available https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals. Accessed 14 Apr 2016.

3.European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/05/WC500143294.pdf. Accessed 14 Apr 2016.

4.Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, Pirmohamed M. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS One 2009;4(2):e4439.

5.McLernon DJ, Bond CM, Hannaford PC, Watson MC, Lee AJ, Hazell L, Avery A. Drug Safety 2010;33(9):775-88.

6.Adverse drug reaction reporting in the UK: a retrospective observational comparison of yellow card reports submitted by patients and healthcare professionals.

7.Biswas P. Pharmacovigilance in Asia. Journal of Pharmacology and Pharmacotherpeutics 2013:4: Suppl S1:7-19.

8.Lopez-Gonzalez E, Herdeiro MT, Figueiras A: Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Safety 2009;32:19-31.

9. Stewart D, MacLure K, **Paudyal V**, Hughes C, Courtenay M, McLay J. Non-medical prescribers and pharmacovigilance: participation, competence and future needs. International Journal of Clinical Pharmacy 2013;35:268-274.

10. **Wilbur K**. Pharmacovigilance in the Middle East; A survey of 13 Arabic-speaking countries. Drug Safety 2013;36:25-30.

11. **Wilbur, K**. Pharmacovigilance in Qatar: a survey of pharmacists. Eastern Mediterranean Health Journal. 2013:11: 931–936.