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Promoting Patient Safety through Pharmacovigilance

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Reporting adverse drug reactions (ADRs)



Aberdeen



QU



WKH-HMC



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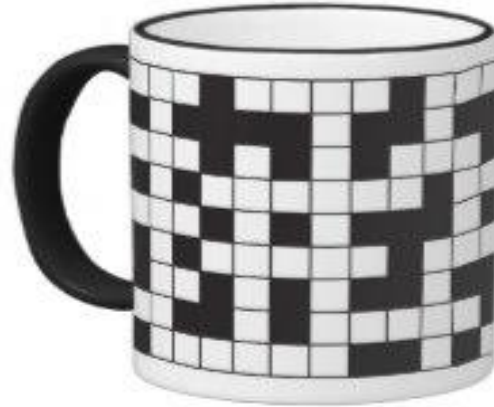


Doha



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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

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

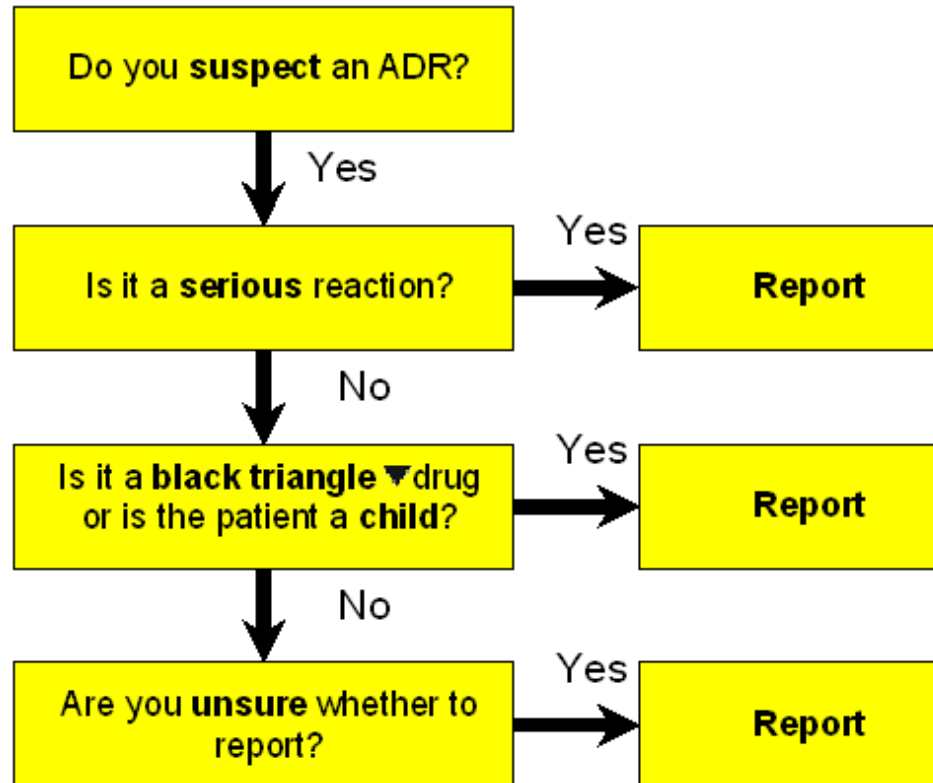
Issues in practice

- 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

YellowCard It's easiest to report online at www.yellowcard.gov.uk

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs/vaccines/complementary remedies, please complete this 'Yellow Card'. See 'Adverse reactions to drugs' section in BNF or www.yellowcard.gov.uk for guidance. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials: _____ Sex: M / F Ethnicity: _____ Weight (if known) (kg): _____
 Age (at time of reaction): _____ Identification number (e.g. Your Practice or Hospital): _____

SUSPECTED DRUG(S)/VACCINE(S)

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped

SUSPECTED REACTION(S) Please describe the reaction(s) and any treatment given:

Date reaction(s) started: _____ Date reaction(s) stopped: _____

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction Involved or prolonged inpatient hospitalisation
 Life threatening Involved persistent or significant disability or incapacity
 Congenital abnormality Medically significant; please give details: _____

OTHER DRUG(S) (including self-medication and complementary remedies)

Did the patient take any other medicines/vaccines/complementary remedies in the last 3 months prior to the reaction? If yes, please give the following information if known:

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed), interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the last month.

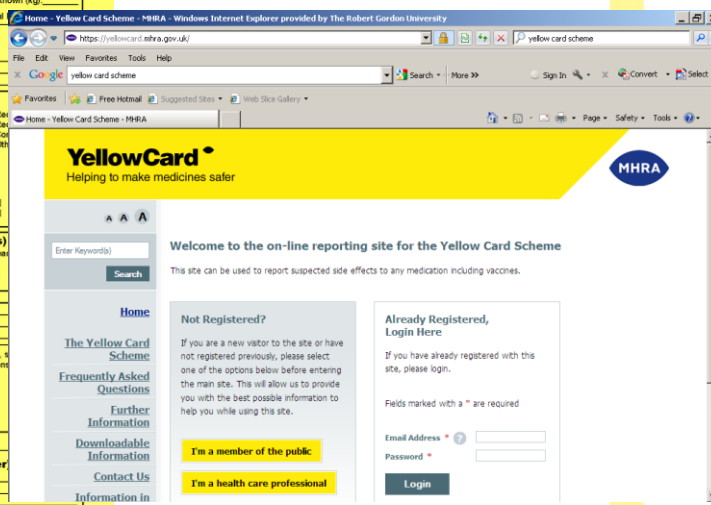
Please list any medicines obtained from the internet:

REPORTER DETAILS Name and Professional Address: _____
 Postcode: _____ Tel No: _____
 Email: _____
 Speciality: _____
 Signature: _____ Date: _____

CLINICIAN (if not the reporter) Name and Professional Address: _____
 Postcode: _____ Tel No: _____
 Email: _____
 Speciality: _____
 Date: _____

Information on adverse drug reactions received by the MHRA can be downloaded at www.mhra.gov.uk/daps
 Stay up-to-date on the latest advice for the safe use of medicines with our monthly bulletin *Drug Safety Update* at www.mhra.gov.uk/drugsafetyupdate

Please attach additional pages if necessary. Send to: FREEPOST YELLOW CARD (no other address details required)



YellowCard report Confidential

Use blue or black ink. Complete all the lines marked with * and give as much other information as you can

1 About the suspected side effect

* **What were the symptoms of the suspected side effect, and how did it happen?** If there isn't enough space here, attach an extra sheet of paper.

How did the suspected side effect feel? Tick the box that best describes how bad the symptoms were.
 Pleasant, but did not affect everyday activities Bad enough to affect everyday activities Bad enough to see doctor
 Be admitted to hospital Caused very serious illness Caused death Other _____

When did the suspected side effect start?

Are you still feeling now? Tick the box that best describes whether the person still has symptoms of the suspected side effect.
 Symptoms Getting better Still has symptoms More seriously ill Died Other _____

Any more details? For example, did the person take or receive any other treatment for the symptoms? Did they stop taking the medicine as a result of the side effect?

Who was the person who had the suspected side effect?

Who reported the suspected side effect? Your child Someone else _____

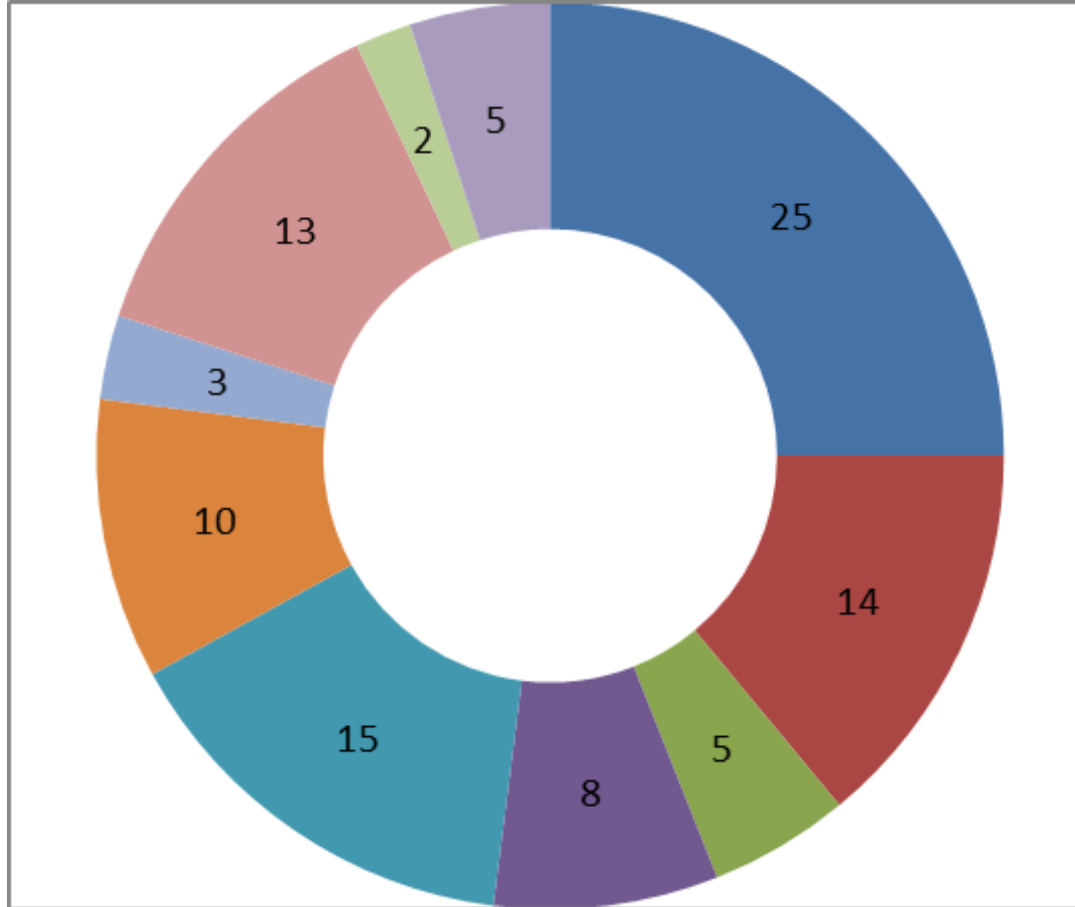
What is the person's name? Supply as much information as you can, even if you prefer not to give a name.
 Is _____ Family name _____ Male Female
 Weight _____ kg _____ stones/pounds Height _____ metres _____ feet/inches

Any other information? For example, does the person have any medical conditions or allergies?

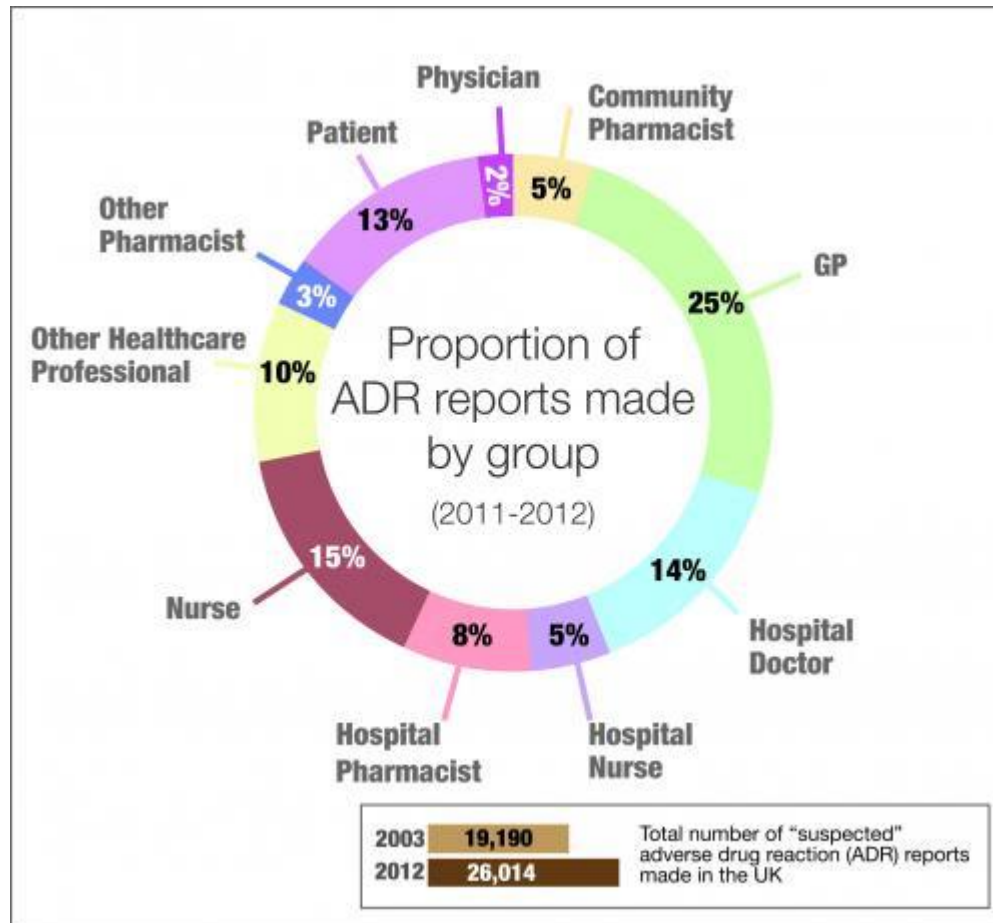
Make sure you have completed all the lines marked * Please turn over →

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

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

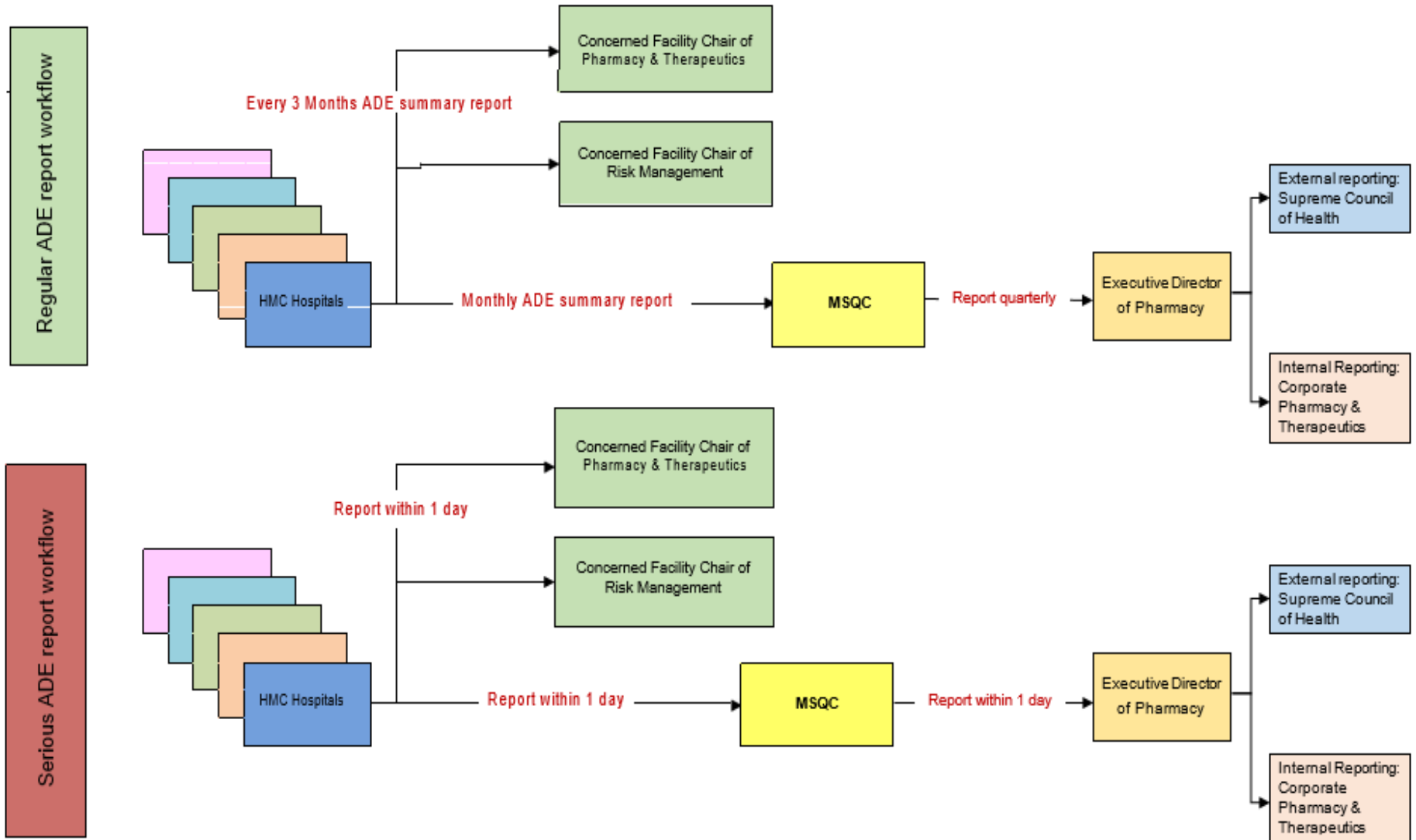
with no active pharmacovigilance programme or designated centre

Wilbur (2013)a

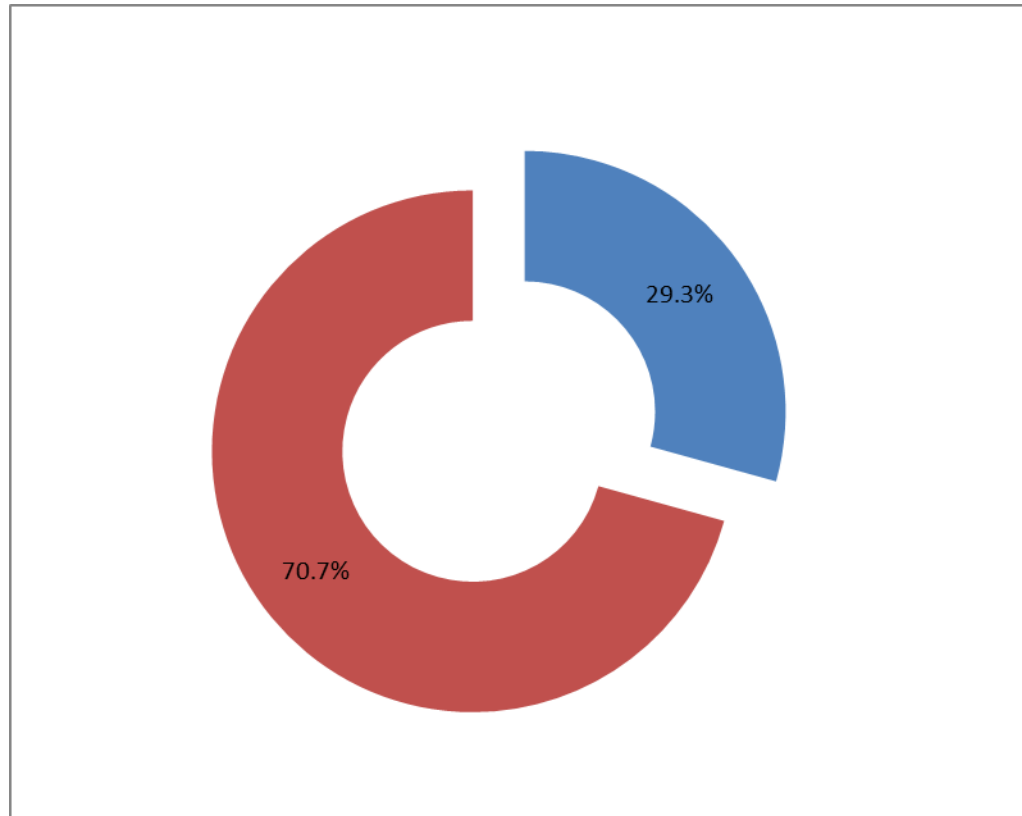
Qatar: Pharmacovigilance in HMC

- 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.

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Stewart, Paudyal et al. 2011

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?



dreamstime.com

ADR reporting systems: features

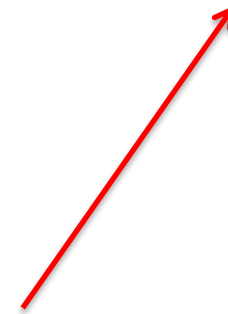
Efficient? achieving maximum productivity with minimum wasted effort or expense

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

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

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