Promoting Patient Safety through Pharmacovigilance

Dr Vibhu Paudyal
Dr Kerry Wilbur
Dr Mohamed Izham
Dr Anas Hamad
Reporting adverse drug reactions (ADRs)
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?

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<tbody>
<tr>
<td><strong>a.</strong></td>
<td>1% - 2.5%</td>
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<td><strong>b.</strong></td>
<td>3% - 4.5%</td>
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<td><strong>c.</strong></td>
<td>5% - 6.5%</td>
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<td><strong>d.</strong></td>
<td>7% - 8.5%</td>
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<td><strong>e.</strong></td>
<td>9% - 10.5%</td>
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Which ONE of the following BEST describes the age group of patients at greatest risk of developing adverse drug reactions?

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<tbody>
<tr>
<td>a.</td>
<td>1-12 years</td>
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<td>b.</td>
<td>12-18 years</td>
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<td>c.</td>
<td>18-40 years</td>
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<td>d.</td>
<td>40-65 years</td>
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<td>e.</td>
<td>65-85 years</td>
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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:
Completing a Yellow Card

Do you **suspect** an ADR?

- Yes
  - Is it a **serious** reaction?
    - Yes → Report
    - No
  - Is it a **black triangle** drug or is the patient a **child**?
    - Yes → Report
    - No
  - Are you **unsure** whether to report?
    - Yes → Report
Completing a Yellow Card

https://yellowcard.mhra.gov.uk/
Puzzle
ADR reporters

Proportion of ADR reports made by group (2011-2012)

Total number of “suspected” adverse drug reaction (ADR) reports made in the UK

2003: 19,190
2012: 26,014
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

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.
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)
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
Evidence based strategies in overcoming barriers to pharmacovigilance

Theoretical domains framework

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<td>Knowledge</td>
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<td>Skills</td>
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<tr>
<td>Social/professional role</td>
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<tr>
<td>Beliefs about capabilities</td>
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<tr>
<td>Beliefs about consequences</td>
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<tr>
<td>Reinforcement</td>
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<tr>
<td>Intentions</td>
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<td>Goals</td>
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<tr>
<td>Memory, attention and decision processes</td>
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<td>Environmental context and resources</td>
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<td>Social influence</td>
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<tr>
<td>Emotion</td>
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<tr>
<td>Behavioural regulation</td>
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“This probably won’t work, but we do have medications that will take care of the side effects.”
References and directed reading resources

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