

Volume 3 (2022) Issue 2. July 2022

**MEDwatch** is the ebulletin for all NHS Grampian Staff who are involved with patients and medicine management.

Its aim is to improve the safety of medicines by sharing learning, and encouraging adverse event reporting from all staff groups.

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# **MHRA Drug Safety Updates**

Latest MHRA Drug Safety Updates

- May 2022
- June 2022

## World Patient Safety Day - 17th September 2022

The World Health Organisation (WHO) have announced that the theme for World Patient Safety Day 2022 is "medication safety" and their slogan is "medication without harm".

Objectives of World Patient Safety Day 2022 are:

- 1. RAISE global awareness of the high burden of medicine-related harm due to medication errors and unsafe practices, and ADVOCATE urgent action to improve medication safety.
- 2. ENGAGE key stakeholders and partners in the efforts to prevent medication errors and reduce medication-related harm.
- 3. EMPOWER patient and families to be actively involved in the safe use of medication.
- 4. SCALE UP implementation of the WHO Global Patient Safety Challenge: Medication Without Harm.

It would be great to see teams across NHS Grampian getting involved in this day. Contact lindsay.cameron2@nhs.scot if you have plans for your area that you would like to share.

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## Yellow Cards - Everyone's Responsibility

Run by the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Cards are an easy way for anyone to submit reports of adverse drug reactions (ADR) to the MHRA. An ADR is a response to a medicinal product which is noxious and unintended, commonly known as a side effect. This includes adverse reactions which arise from:

- Use of a medicinal product within the terms of the marketing authorisation
- Use outside the terms of the marketing authorisation, including overdose, misuse, abuse, and medication errors
- Occupational exposure

The <u>Yellow Card Centre (YCC) Scotland</u> aim to increase and improve the quality of adverse drug reactions (ADR) reporting in Scotland using the Yellow Card Scheme. The more information that is submitted about ADRs the more the MHRA can understand about medicines when in across the population and the safer medicines become.

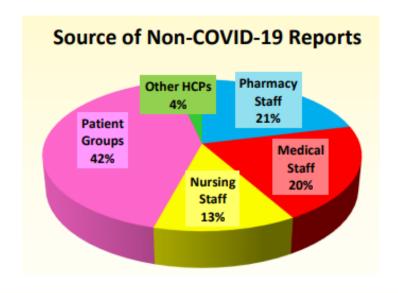
The majority of reports are submitted by patients but anyone; healthcare professional, patient, relative or carer, can report an adverse reaction to a medicine using the yellow card. We shouldn't assume that someone else has done it already and the Yellow Card Centre Scotland would rather get duplicate reports than no report at all so if you think your patient has suffered an ADR report it using the Yellow Card in any of the following formats.

Online - Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

App – Yellow Card App is free to download via Apple or Android, you will also find useful information on medicines within the app.

Phone – You can phone the yellow card scheme free on 0800 731 6789 Post – Print out, complete and post the Healthcare Professional Paper Yellow Card

The <u>YCC Annual Report April 2020 – March 2021</u> was published earlier this year and is shared here for interest. Reporting trends in Scotland and previous years' annual reports can be found <u>here</u>. Specific NHS Grampian data is expected later in the year but below are a couple of key charts and tables from the 2020-2021 report (Scotland wide data).



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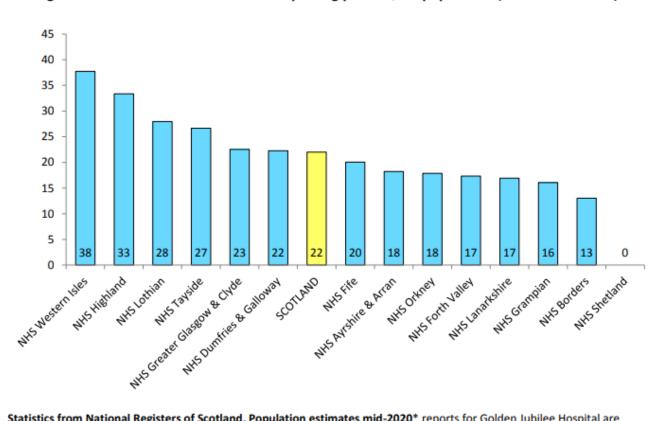


Figure 2 - Health Board Yellow Card Reporting per 100,000 population (Scotland 2020/21)

<u>Statistics from National Registers of Scotland, Population estimates mid-2020</u>\* reports for Golden Jubilee Hospital are included in NHS Greater Glasgow and Clyde. Reports for the State Hospital are included in NHS Lanarkshire.

YCC Scotland recently delivered learning sessions to acute pharmacy staff via teams and plans are being made to run sessions for primary care pharmacists and community pharmacies. If you would like YCC Scotland to deliver a session to your team their contact details can be found on their <u>website</u>.

There are also ADR eLearning modules, developed by the Yellow Card Centre (YCC) Scotland in conjunction with NHS Education for Scotland (NES), available on <u>Turas</u> covering the following topics:

- 1. Basic principles of ADR
- 2. Categorisation
- 3. Drug Allergy classification
- 4. Diagnosis, interpretation and management
- 5. Avoiding adverse drug reactions
- 6. Pharmacovigilance.

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## The Professional Duty of Candour

A small project undertaken within NHS Grampian, looking at whether professional duty of candour had been applied where adverse events involving insulin had occurred, showed that only 18% of patients had it documented anywhere (patient notes and/or Datix report) that an explanation had been given and only 9% of patients had it documented that they were apologised to.

This project focused on adverse events that did not trigger Organisational Duty of Candour and while numbers in the project were small, it does highlight that improvements should be made in openness and honesty with our patients when things go wrong or "Professional Duty of Candour".

Organisational Duty of Candour is a statutory requirement that organisations must adhere to when there has been an unexpected event or incident that has resulted in death or harm that is not related to the course of the condition for which the patient is receiving. More information on Organisational Duty of Candour within NHS Grampian can be found <a href="https://example.com/here/beta/here/be

Where Organisational Duty of Candour is not triggered following an adverse event we still have a professional duty to be open and honest with our patients when things go wrong and to apologise for this.

Professional Bodies have guidance on Professional Duty of Candour which should be followed by registrants. The Nursing Midwifery Council (NMC) and General Medical Council (GMC) have joint guidance Openness and honesty when things go wrong: the professional duty of candour and other professional bodies such as the General Pharmaceutical Society (GPhC) have similar guidance Keeping patients safe: being open and honest when things go wrong for their registrants.

The main principles of Professional Duty of Candour are:

- Tell the patient when something has gone wrong
- Apologise to the patient
- Offer an appropriate remedy or support to put matters right
- Explain fully to the patient the short and long-term effects of what has happened.

The professional bodies' guidance also gives its registrants advice on how to apologise and to document the apology.

This <u>animation</u> from NHS Resolution (a part of NHS England) explains duty of candour with the first 3-4 minutes focusing on Professional Duty of Candour and individual responsibilities. Please be aware that the second part of the animation focuses on Statutory Duty of Candour and its legislation in England. Information on Organisational (statutory) Duty of Candour within Scotland can be found here.