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Yellow Card: please help to reverse the decline in reporting of suspected adverse drug reactions

2018 saw a fall in reporting of suspected adverse drug reactions (ADRs) to the Yellow Card Scheme from key reporter groups, including GPs, pharmacists, and hospital doctors. Every Yellow Card report counts, and a few minutes taken by you or your patient to report can make a lifetime of difference for others – don't delay, report today!

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Decrease in reporting in 2018

Reporting suspected adverse drug reactions (also termed ADRs) to the Yellow Card Scheme helps the MHRA to monitor the safety of medicines and improve patient safety.

Between 2009 and 2017, the number of reports we received from UK healthcare professionals doubled. However, in 2018, there was a significant decrease in reports from some healthcare professional groups.

Figure 1 (https://assets.publishing.service.gov.uk/media/5cde9181ed915d2d4cf7dda3/Figure_1.pdf) shows how reports from you and your colleagues have changed over time.

In 2018, a decrease in reports was seen in the following groups, which are self-designated when a reporter submits a Yellow Card:

Healthcare professional group	Decrease in number of reports	Decrease in 2018 compared with 2017
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Healthcare professional group	Decrease in number of reports	Decrease in 2018 compared with 2017
Hospital pharmacists	-380	–11%
General practitioners (GPs)	-280	-4%
Community pharmacists	-226	-14%
Hospital doctors	-161	-7%
Physicians	-142	-46%
Nurses	-122	-5%
Healthcare professionals in hospitals	-53	-7%

Reporting improves medicines safety

The MHRA continually reviews the safety of all medicines. Some adverse drug reactions can only be identified when medicines are used for a long time in a wide range of different people, so it is very important that suspected adverse drug reactions are reported to the Yellow Card Scheme.

Every report has a vital role in understanding the benefits and risks of medicines in clinical use, allowing action to be taken to minimise risks (see Figure 2 (https://assets.publishing.service.gov.uk/media/5cde918eed915d2d46b718b4/figure_2.pdf) for how your report makes medicines safer).

Reporting results in better tailored prescribing advice, which can help improve adherence to treatment and minimise the risk of avoidable harm. The value of the Scheme has been demonstrated many times and has helped identify numerous safety issues

(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/396811/Contribution_of_Yellow_C ards to identifying safety issues.pdf).

What should I report?

The effectiveness of the Yellow Card Scheme to detect new drug safety signals is dependent upon your reporting of your suspicions and observations.

Yellow Cards can be used for reporting suspected adverse drug reactions to medicines, vaccines, herbal or complementary products, whether for self-medication or prescribed. This includes suspected adverse drug reactions associated with misuse, overdose, or medication errors, or from use of unlicensed and off-label medicines.

You should report all suspected adverse drug reactions that are:

- serious, medically significant, result in harm, associated with medication errors where harm occurs. Serious events are fatal, life-threatening, a congenital abnormality, disabling or incapacitating, or resulting in hospitalisation
- associated with newer drugs and vaccines (▼); irrespective of whether they are serious or not; the most up-to-date list of black triangle medicines is available on the MHRA website.

If in doubt whether to report or not, please complete a Yellow Card.

How can I complete a Yellow Card?

You can report:

- online at www.mhra.gov.uk/yellowcard (http://www.mhra.gov.uk/yellowcard)
- via the Yellow Card app available in the Apple App Store (https://itunes.apple.com/us/app/apple-store/id990237487?pt=117756671&ct=EYC&mt=8) or Google Play Store
 (https://play.google.com/store/apps/details?
 id=uk.org.mhra.yellowcard&referrer=utm_source%3DEYC%26utm_medium%3Dcpc%26anid%3Dadmob)
- through SystmOne, Vision, and MiDatabank clinical IT systems
- by emailing yellowcard@mhra.gov.uk or by downloading printable forms
 (https://yellowcard.mhra.gov.uk/downloadable-information/) from the Yellow Card website and sending
 them freepost to 'Yellow Card'
- by completing Yellow Card forms in the BNF, NPF, MIMS, or PAGB OTC directory
- by calling the Yellow Card reporting line on 0808 100 3352.

You can also report Yellow Cards for all medicines, medical device adverse incidents, defective medicines, counterfeit or fake medicines or medical devices, and safety concerns with e-cigarettes or their refill containers on the Yellow Card website (https://yellowcard.mhra.gov.uk/).

Remember it is good practice if you have completed a Yellow Card to inform your patient that you have done so and discuss with them how reporting contributes to improving the safe use of medicines.

Don't wait for someone else to report it

It is estimated that only 10% of serious reactions and between 2 and 4% of non-serious reactions are reported. Under-reporting coupled with a decline in reporting makes it especially important to report all suspicions of adverse drug reactions to the Yellow Card Scheme.

This article was published in response to a decline in Yellow Card reporting in 2018. The reporting rate for adverse drug reactions is variable and can depend on a multitude of factors. These estimates should not be used as indicators of the reporting rate for COVID-19 vaccines, for which there is high public awareness of the Yellow Card scheme and the reporting of suspected reactions. For more information see the COVID-19 vaccine weekly report (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting).

Please complete a Yellow Card even if you think someone else may have reported one – the system can detect duplicate reports and we can use information to add to details about the case.

What can healthcare professionals and their organisations do to raise awareness of the Yellow Card Scheme?

• Download our animation (http://www.medextranet.com/categories/awareness-campaigns.html? view=document&id=156:adverse-drug-reactions&catid=21:awareness-campaigns) and add it to the screens in your patients' waiting area

- Encourage dialogue regularly between your colleagues and patients, parents, and caregivers about the importance of reporting suspected adverse drug reactions to the Yellow Card Scheme and new Drug Safety Updates
- Discuss suspected adverse drug reactions that you have reported and how you've kept up to date with emerging safety issues with Drug Safety Update in your professional revalidation, annual appraisals and for continuing professional development (CPD) purposes
- Engage locally with your regional Yellow Card Centre (https://bnf.nice.org.uk/guidance/adverse-reactions-to-drugs.html) or your local Medication Safety Officer (MSO) in England at your hospital trust
- See the dedicated guidance on the Yellow Card Scheme for healthcare professionals including accredited CPD e-learning modules (https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals#further-guidance-and-online-learning) and downloadable materials (https://yellowcard.mhra.gov.uk/downloadable-information/) to share on social media
- Want to add the Yellow Card logo to supporting information on your website, intranet, e-mail signatures or screensavers? Get in touch with us.

Talking to your patients about side effects and the Yellow Card Scheme

Patient reports, including those from parents and carers, now account for the highest reporting group compared to any specific group of healthcare professionals, for example compared to GPs or hospital pharmacists (see Figure 3

(https://assets.publishing.service.gov.uk/media/5cde919b40f0b652b980a8aa/Figure_3.pdf) for a comparison).

Next time you are talking to your patients or even producing or providing health information for patients, remember to mention the potential for side effects and how to report them to the Yellow Card Scheme (http://www.mhra.gov.uk/yellowcard). Providing and discussing the Patient Information Leaflet that accompanies all licensed medicines forms an ideal basis for this discussion.

Every report counts, and a few minutes taken by you or your patient to report can make a lifetime of difference for others. Don't delay, report (http://www.mhra.gov.uk/yellowcard) today.

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