



Medicines & Healthcare products Regulatory Agency

Board Meeting

Adverse Drug Reaction (ADR) reporting by patients

16 December 2019

<p><u>Issue/ Purpose:</u> Patient Reporting to the Yellow Card Scheme</p>
<p><u>Summary:</u> Patient reporting to the Yellow Card Scheme was introduced in 2008 with an overall increase in the number of reports in recent years. Patient reports have made a valuable contribution in the identification of signals and have also supported the evidence base for decision making. This paper details statistics on patient reporting and describes strategic efforts to increase awareness of the Yellow Card Scheme.</p>
<p><u>Resource implications:</u> None</p>
<p><u>EU Referendum implications:</u> None</p>
<p><u>Implications for patients and the public:</u> Public stakeholder engagement as part of ongoing Yellow card strategy initiatives</p>
<p><u>Timings:</u> N/A</p>
<p><u>Action required by Board:</u> To note levels of patient reporting including efforts made to increase awareness of the scheme. To contribute ideas where we can build on our strategy to improve patients' contribution to pharmacovigilance.</p>
<p><u>Links:</u> N/A</p>
<p><u>Author(s):</u> Kendal Harrison, Charlotte Goldsmith</p>
<p><u>FOI/publication issues:</u> N/A</p>
<p><u>Which of the themes in the Corporate Plan 2018/2023 does the paper support?</u></p>

If relevant, which Business Plan strategic activity does it support? N/A

CET Sponsor: Dr Sarah Branch

Purpose

1. To update the Agency Board on patient reporting of Adverse Drug Reactions (ADRs) to the Yellow Card Scheme.

Background

2. The Yellow Card Scheme began in 1964 to enable reporting of suspected side effects and was initially limited to healthcare professionals. Following a successful pilot in 2005, patient reporting was formally launched in 2008 and patients now account for the largest reporting group and make a significant contribution to the Scheme.
3. In 2011, an MHRA sponsored review of patient reporting was published by Avery et al¹, and concluded that patient reports added value because the reports related to different types of drugs and reactions compared to healthcare professional reports and described the impact of symptoms in more detail, all leading to an enhanced ability to detect new potential safety concerns.

Patient, parent and carer data

4. Since 2008, patients (including parents and carers) have reported over 50,000 ADRs to the Yellow Card Scheme and the total per year has been increasing since 2011 (see figure one).

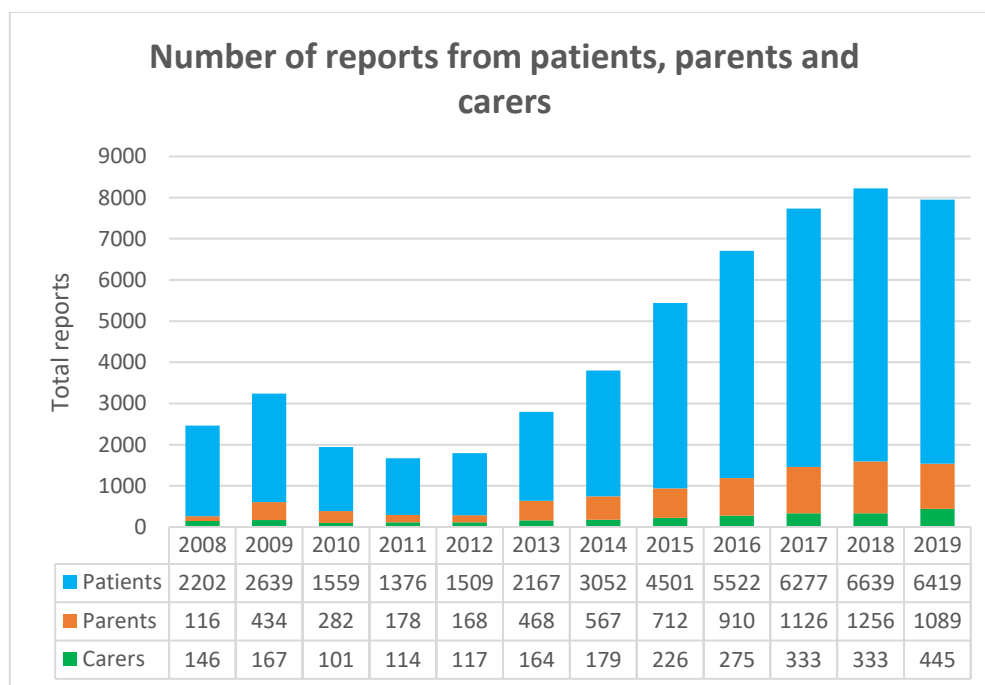


Figure 1. Yearly patient, parent and carer reports up to 10th December 2019

¹ Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess.* 2011;15(20):1–234, iii–iv. <https://doi.org/10.3310/hta15200>

5. In 2019, up to and including 10 December 2019, 20% of all reports came from patients which makes them the largest reporting group; when excluding industry reports they account for 27% of all direct reports (see figure two).

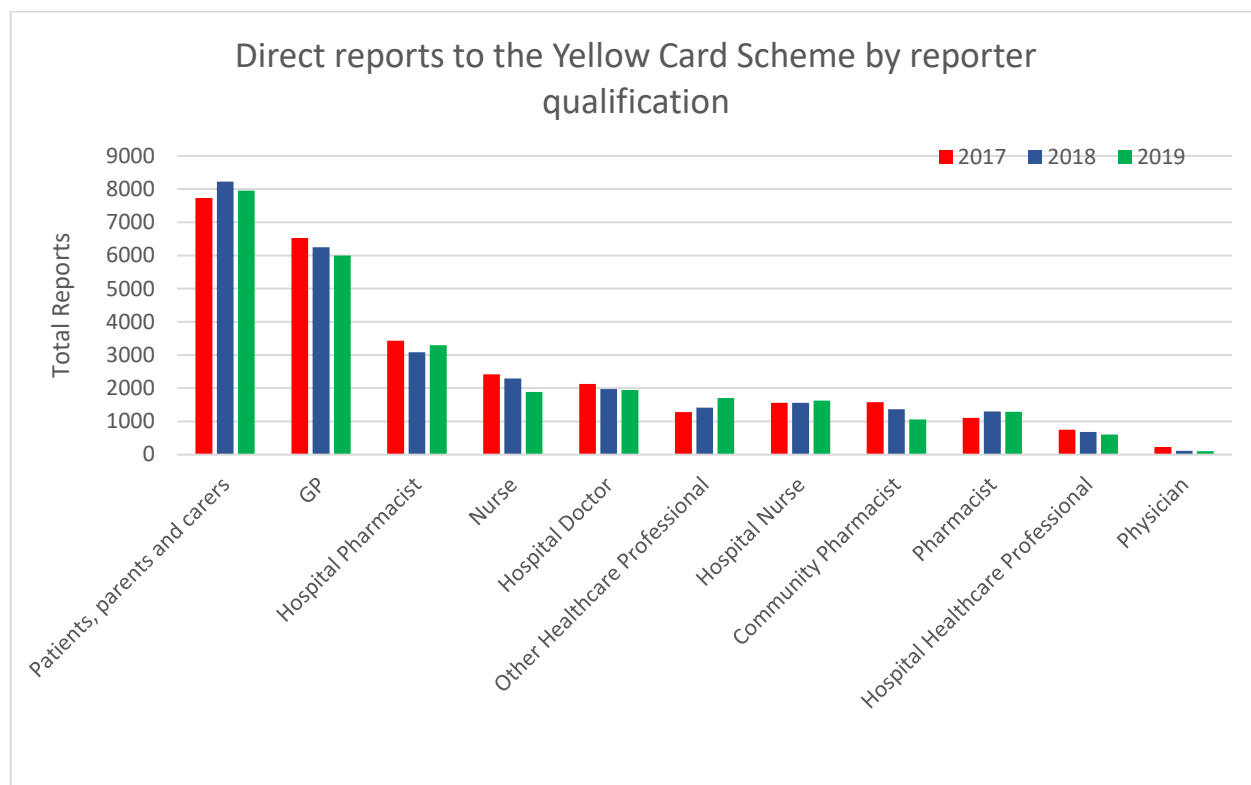


Figure 2. Yearly reports by reporter qualification (2017 to 10th December 2019)

Signals from patients

6. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.
7. Patient reports have made a valuable contribution to the identification of signals and have also supported the evidence base for decision making. We have seen an increase in the number of signals that patient reports contribute to, especially over the last few years. In 2018, patient reports triggered 16 signals which led to regulatory action and, in addition, patient reports contributed to the evidence base for 30 safety signals. Examples are provided below:
- a. A patient contacted us to ask whether other patients had reported an increase in weight after taking propranolol. We identified 9 other cases which showed good temporal association and also identified a plausible mechanism; this led to the addition of abnormal weight gain to the product information.

- b. A pregnant patient reported crippling nipple pain which lasted for 20 minutes after taking labetalol. A review identified six similar reports in pregnant women, two of which were reported by patients. These symptoms were associated with the recognised risk of Raynaud's phenomenon and subsequently the patient information leaflet was strengthened to reflect nipple manifestations of Raynaud's phenomenon.

Engagement strategy

8. As with all reporting, patients' knowledge of the Yellow Card Scheme is low and so sustained engagement activities are needed to increase awareness and reporting.
9. Avery¹ recommended approaches to help improve the timeliness and value of patient reporting as well as the number of reports and an improved patient experience. Recommended strategies included increasing publicity, improving guidance, changing the design of reporting forms, including the online form, and providing feedback to patients, both generally and in relation to their specific medicines and suspected reactions.
10. Our Yellow Card strategy aims to address these recommendations, and other feedback received since, by publicising the importance of reporting to the Scheme and raising awareness amongst healthcare professionals and patients. Alongside this we are improving the ease of reporting, for example with mobile apps, and increasing transparency through publishing our data². Recent examples are provided below.
 - a. The MHRA are part of a group established to look at raising awareness and improve the quantity of Yellow Card reports in children and young people. This will be done by engaging stakeholders to raise awareness and develop appropriate information materials. The project will focus on children and young people that can report a Yellow Card themselves and children where a suspected ADR report would be made on their behalf. This project is in its early stages and will continue to progress into 2020.
 - b. The Yellow Card website was redesigned in 2012 following the Avery Report recommendations and has had continuous improvements since, including enhancements related to usability, transparency of information and data protection.
 - c. In 2015 the MHRA launched a Yellow Card mobile App through the WEB-RADR project³ which simplifies reporting as well as provides news and reporting statistics to engage the public. To date, over 15,000 patients and healthcare professionals have downloaded the app. A planned enhancement to enable push notifications will support delivery of targeted messages to users.

² <https://yellowcard.mhra.gov.uk/iDAP/>

³ <https://web-radr.eu/>

- d. Following review of medicines taken in pregnancy we introduced new pregnancy specific questions to the website form, including due dates, to enhance our collection of data in this under studied group as well as to enable us to follow up with patients after the baby has been born. In parallel we are piloting more comprehensive questions related to pregnancy in the Yellow Card App. We hold weekly pregnancy review meetings to focus on signals specifically in this population as well as take advice from an independent Medicines for Women's Health Expert advisory group.
- e. Since 2017, the MHRA, together with the Uppsala Monitoring Centre, have led an EU awareness campaign aimed at the public using social media channels, which included distributing infographics and animations which reached millions internationally. The campaign in 2018 focused on reporting of ADRs that occur in babies, children and pregnant women and breastfeeding mothers. The key message demonstrated that the reporting of suspected side effects helps the safe use of medicines to protect public health. The campaign week of the 16-25 November 2018 saw an overall increase of 24% in direct Yellow Card reports, with an 11% increase in reports from patients, parents and carers. MHRA will be undertaking a further national campaign in early 2020.
- f. We also formed a partnership with the National Association for Patient Participation (N.A.P.P.) - a UK umbrella organisation for patient-led groups in general practice. MHRA together with the West Midlands Yellow Card regional centre promoted and presented to the Patient Participation Groups in England at their annual conference which included the importance of reporting to the Yellow Card Scheme.

11. Responses to the recent Patient and Public Engagement consultation are currently being analysed and will provide valuable information to feed into our Yellow Card Strategy.

Conclusion

12. Patients provide a valuable contribution to pharmacovigilance which we should build on moving forwards. Through continued activities to simplify reporting and increase awareness we hope to continue increasing the trend in patient engagement.

Questions for the Board and attendees to consider

13. Do the activities described in the paper align with patient expectations?
14. What activities should we be focussing on in 2020 to support patient engagement and contribution further?
15. Have you been aware of our social media campaigns, if not how can we ensure we reach a wider audience?

VRMM
December 2019