



SHORT REPORT

Public awareness in Wales of the UK Yellow Card scheme for reporting suspected adverse drug reactions

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We used the HealthWise Wales (HWW) platform to explore public knowledge about the UK Yellow Card scheme (YCS), the spontaneous reporting scheme for suspected adverse drug reactions (ADRs) and whether a short information video could improve awareness. Members of the public in Wales ($n = 1606$) completed a questionnaire about the YCS, watched the information video and then completed a follow-up questionnaire. Almost half (46.5%) of respondents said they had previously experienced an ADR (>90% of the ADRs involving prescribed medicines). Before the video, 18% of respondents knew how to report an ADR via the YCS and of these, 34% were from allied-health professions. Immediately after watching it, 71% participants reported knowing how to report and 82% reported being confident to report. If this awareness were maintained, such an approach could contribute to improved reporting of suspected ADRs by the public.

KEYWORDS

adverse drug reactions, public awareness, Yellow Card scheme

1 | INTRODUCTION

Following the thalidomide tragedy almost 60 years ago, the UK Yellow Card scheme (YCS) was introduced for health professionals to report suspected adverse drug reactions (ADRs). Since 2008, the public have also been encouraged to report. Fewer than 3000 patients on average are exposed to a medicine prior to marketing authorisation (licensing), so ADRs rarer than 1 in 10 000, chronic or delayed ADRs and interactions with other medicines and foods may remain undetected at launch.¹ As case reports most commonly provide the supporting evidence for withdrawal of medicines on safety concerns within the EU,² it is important to improve rates of reporting individual cases via systems such as the YCS.

A previous study showed most patients find the current methods of reporting relatively straightforward and would recommend the YCS to others.³ However, a recent study revealed a mean weekly reporting rate of only 0.005 per 10 000 patients,⁴ so improved public knowledge of the YCS is required.⁵ This study, the first part of a quality improvement activity to explore public awareness of the YCS, was designed to assess current understanding and a possible association between watching the Medicines and Healthcare Products Regulatory Agency (MHRA) patient information video and increased awareness of the YCS.

2 | METHODS

A pre-post methodology was developed and following ethical approval from the Wales Research Ethics Committee (Ref

There is no Principal Investigator as this study did not include a medical intervention and was not implemented on patients.

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15/WA/0076), the HealthWise Wales (HWW) platform was used to recruit participants and host data collection. HWW is an online, longitudinal, health study of the population of Wales which is funded by Health and Care Research Wales.⁶ It currently includes 40 000 participants and is open to all individuals aged ≥ 16 years who live in or access their healthcare in Wales.

Half of the existing participants were selected using their randomly allocated odd versus even study ID number. A prestudy recruitment target of 1000 subjects was agreed to ensure that the sample was reasonably likely to have demographic characteristics similar to the population of Wales (population 3.139 million; mid-year 2018). This sample of HWW members was asked to complete a questionnaire. They then watched the 86-second MHRA video (<https://www.youtube.com/watch?v=3et5LdYLc8M&feature=youtu.be>) and were given links to the Yellow Card Centre Wales website. The animation was developed from the Joint Action project as part of the first EU-wide social media campaign led by the MHRA in 2016, with the Welsh sub-titled version being provided by MHRA. Finally, participants were asked to complete another questionnaire concerning factors that might contribute to awareness of the YCS, areas for improvement of the video and their communication preferences.

In this study, ADRs were defined in the questionnaire as: “any unwanted symptoms caused by medical treatment” (see Supplementary Material). Demographic characteristics assessed included age, sex and area deprivation, based on the Welsh Index of Multiple Deprivation,⁷ with areas grouped on the quintile level from most (1) to least (5) deprived area.

The questionnaire was made available to HWW participants from October 2018 until April 2019 with 1606 HWW members participating. No question was mandatory. Data drawn from HWW questionnaires are stored on the Secure Analysis Portal and Protected HWW Information Repository (SAPHIRE), through which all data are accessed by approved researchers on a project basis.⁸

3 | RESULTS

3.1 | Cohort characteristics

Of the 1606 respondents, 68% were female, with 68% being older than 50 years. Among 1570 respondents with known area deprivation data, 26% lived in the least deprived, and 10% in the most deprived areas.

3.2 | Pre-video assessment

Before watching the video, 46.5% of respondents stated that they had “*experienced a side effect (also called an adverse drug reaction or ADR) to a medicine*”. Of those who had experienced an ADR, approximately 7 out of 10 were aged ≥ 50 years (68%). When asked to rate the most recently experienced ADR as mild, moderate or severe, 20.9% reported that the ADR was severe, 42.4% moderate and 36.7%

What is already known about this subject

- Spontaneous reporting of suspected adverse drug reactions using the Yellow Card scheme (YCS) helps to identify possible medicines safety issues.
- Although the YCS has encouraged reporting by the public since 2008, awareness of the scheme is limited.

What this study adds

- It provides new observational data on public awareness of the YCS.
- It provides evidence on the impact of a concise, public information, video intervention in improving awareness of the importance of reporting adverse drug reactions and confidence in using the YCS.

mild. Among those experiencing an ADR, 93.7% reported having an ADR to a prescribed medication 2.3% to a vaccine and 3.9% to an over the counter medicine. Over half (57%) were aware of the possible ADR they experienced beforehand.

In response, 44.5% said they stopped the medicine, 36.4% contacting their general practitioner (GP) who advised them to either stop the medicine or change the dose, whilst 15.2% consulted other health professionals (in a community or hospital setting). When asked if they would stop taking the medicine if they were advised by their GP to do so, 61% said they would not have complied with their GP's advice.

Asked if they knew how to report ADRs to the YCS, only 18.4% of respondents answered yes (see Table 1). When questioned about what side effects or problems they think they can report to the YCS (using a multiple-choice question), almost all (98.5%) thought the scheme applied to prescribed medicines while 29.8% felt that it applied to homeopathic and herbal medicines and 39.5% believed it applied to fake or counterfeit medicines. Participants were asked about their preferred method of reporting to the YCS. Around 3/4 (75.1%) indicated online reporting as their first preference, 12.9% suggested a paper form from a pharmacy or GP, 9.6% a mobile app, and 2.4% preferred a postal return.

Figure 1 shows that across all ages, the highest preference is to use the internet. A preference for a mobile app is highest in the under 30s (21%) and falls off steadily to 5.1% in the 60+ age group whereas a preference for the paper forms increases with age, with 19.9% of 60 + year-old respondents preferring this format.

Of those who had experienced an ADR, 18.4% reported knowing how to report it while, of those who had not had an ADR, 19.1% knew how to report it. A χ^2 test of independence was performed to examine the association between these 2 variables. This was not significant, χ^2 ($df = 1, n = 1411$) = 0.109, $P = .742$ (excluding *do not know* and missing responses), suggesting that the experience of having an ADR might not

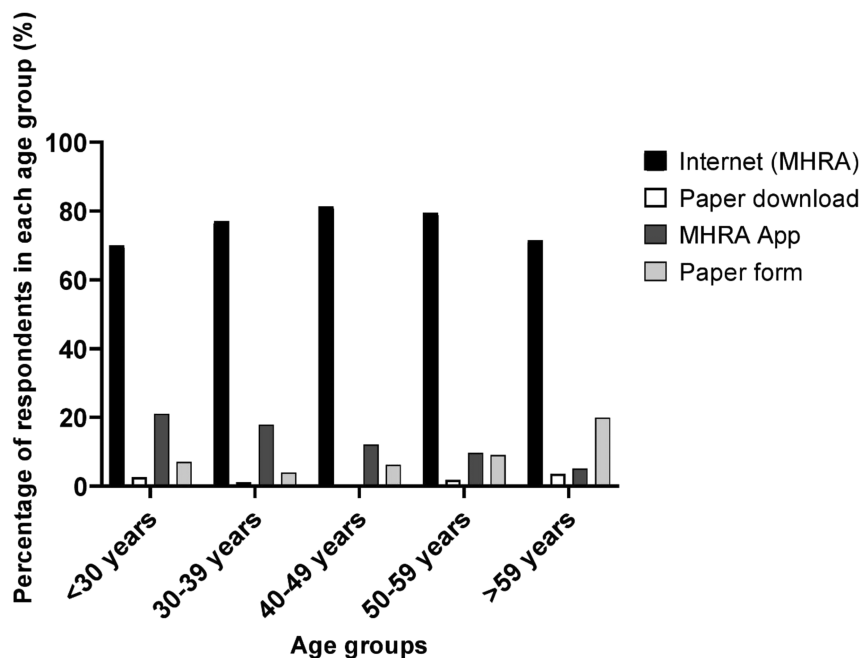


FIGURE 1 Preferred method of reporting suspected adverse drug reactions in each age group. MHRA, Medicines and Healthcare Products Regulatory Agency

sufficiently prompt individuals to seek relevant information on how to report it. In addition, there was no discernible relationship between the severity of the ADR experienced and knowledge of ADR reporting.

3.3 | Post-video assessment

Overall, 1531 respondents (95.3%) indicated that they watched the video, and 99.4% of viewers reported that they now understood the meaning of the term *side-effect* (ADR). Before watching the video, 81.6% said they did not know how to report a suspected ADR. After watching it, 84.5% indicated that they knew what the YCS was and 70.8% said they would know how to report an ADR to the YCS. This represents a significant change in knowledge of the scheme from only 18.4% of respondents who knew about ways of reporting to the YCS prior to watching the video (χ^2 (df = 1, n = 1514) = 103.109, P < .0001 (excluding missing responses). Change was also observed in participants' intention to report ADRs in the future, with 81.8% saying that they would feel confident reporting an ADR to the YCS and 81.5% saying they would report a suspected ADR to their GP.

Feedback on the video showed that 87.3% found it informative and 83.6% suggested that it had encouraged them to report a suspected ADR in the future. Furthermore, it was indicated that they would prefer: (i) more information on how to report to the YCS; (ii) clarification on whether all ADRs should be reported or only serious, or new ones should be reported; and (iii) more detail about the YCS. Finally, around half of respondents (54.2%) said that they were likely to seek further information about the YCS via the Yellow Card (MHRA) website. Alongside the study's implementation stage and following feedback, the MHRA developed a longer information video (232 seconds) on how to report an ADR via the YCS website (<https://www.youtube.com/watch?v=TrUHlgVAE4&feature=youtu.be>).

4 | DISCUSSION

We have found that a patient information video significantly increased their short-term knowledge on how to report a suspected ADR via the YCS from 18.4 to 70.8%. Around 8 out of 10 viewers who had watched the MHRA video reported being aware of the YCS and the same proportion felt confident they could report a suspected ADR to the YCS. Over half of respondents indicated that they were likely or very likely to seek further information about the YCS. We are not aware of any previous studies using video to increase awareness of the YCS among the public; however, a video intervention improved the perceived knowledge and attitudes of medical trainees to incident reporting.⁹

The introduction of patient reporting of suspected ADRs in 2008 aimed to complement healthcare professional reporting.¹⁰ Patient reporting of suspected ADRs and their impacts, especially when these differ from reports by healthcare professionals has been suggested as a key step towards improving pharmacovigilance.⁵ However, a telephone poll conducted in 2009 showed that only 172 of 2028 respondents (8.5%) had heard of the YCS, and only 3 individuals had self-reported to the scheme.¹¹ The attitudes to YCS observed in this study after watching the information video confirm lay-user assessments of the scheme, reported elsewhere.¹² Exposure to this video by the public may also reinforce the intentions of health professionals to report suspected ADRs in the future.

If advised by their GP to stop a medicine due to a suspected ADR, 61% of respondents said they would not have complied with the GP's advice. This finding contrasts with a report commissioned by MHRA prior to the introduction of patient ADR reporting, which found that 41% of patients seeking advice on the risks and benefits of medicines would consult their pharmacist and 61% their doctor, 64% of people would trust their pharmacist to give this information

TABLE 1 Pre- and post-video comparison of adverse drug reaction (ADR) awareness

Question no.	Pre-video assessment	Yes (%)	Positive/total responses
1.	Have you ever experienced a side effect (also called an adverse drug reaction or ADR) to a medicine?	46.5	744/1599
7.	Do you know how to report a side effect to the Yellow Card scheme?	18.4	294/1600
8.	If yes to Q7, where did you hear about how to report side effects? (please tick all that apply)		
	Hospital pharmacy	5.5	16/293
	Hospital	9.9	29/293
	Internet	12.6	37/293
	Community pharmacy	16.7	49/293
	GP	18.8	55/293
	Poster or leaflet	23.5	69/293
	Other	43.0	126/293
11.	If you reported a side effect to the Yellow Card scheme, would you like to get a response to your report?	89.6	1394/1556
Post-video assessment			
1.	Do you understand what is meant by the term side effect?	99.4	1512/1521
2.	If you had a side effect from medication who would you report it to? (please tick all that apply)		
	Your GP	81.5	1246/1528
	Your pharmacist	47.1	719/1528
	Your consultant	36.0	550/1528
	Your nurse	27.5	420/1528
	The manufacturer	5.0	77/1528
	The Yellow Card scheme	73.8	1128/1528
4.	After watching the video, do you feel you know what the Yellow Card scheme is?	84.5	1282/1518
5.	Do you know how to report a side effect to the Yellow Card scheme?	70.8	1073/1516
6.	Would you feel confident reporting a side effect to the Yellow Card scheme?	81.8	1237/1512

whereas 87% would trust their doctor.¹³ Further, qualitative investigation of the reasons for continued use of medicines despite contrary advice from a health professional is required.

Overall, the most popular way of reporting was via the internet, but different age groups expressed a preference for other methods. Continued availability of several methods may therefore be useful in ensuring that reporting is optimised across all age groups.

The HWW platform has provided an opportunity to test the short-term effectiveness of a patient information video on raising awareness on the YCS but it is important to consider potential methodological limitations, such as the representativeness of the sample. The membership of HWW represents adults living or receiving their healthcare in Wales (age ≥ 16 years)⁶ and may not be reflective of other UK regions. As is typical of other population health studies¹⁴ across the UK,¹⁵ a greater proportion of women, people aged >50 years and those living in less deprived areas than in the general population signed up.

Of the 18.4% HWW members who knew how to report ADRs using the YCS prior to seeing the video, 34% were healthcare professionals (current or retired) or from allied fields, accounting for 6.3% of participants in this project. This proportion could be higher within HWW than in the general population, due to the platform attracting members with specific interest in health-related research. The proportion of people with pre-existing awareness of YCS, who are not health professionals may be even lower than observed here. This suggests that the impact of wider dissemination of the video might be even greater in the lay public. HWW members are computer literate and completed the survey via the online HWW platform, potentially limiting the study generalisability, although the sample comprised a broad age range including older individuals who might be less familiar with digital technologies. We tested participant awareness of the system immediately after a single viewing of the video, so we cannot comment on how long this awareness might be retained by the respondents or the possible impact of reinforcement through repeated viewings or other interventions.

5 | CONCLUSION

This study demonstrates the benefit of a concise patient information video delivered via an online health context in increasing public awareness of the YCS and attitude towards reporting suspected ADRs after a single viewing. If shown widely to members of the public, it may lead to improved awareness of the YCS and thus promote the safer use of medicines.

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COMPETING INTERESTS

The authors declare no conflict of interest.

CONTRIBUTORS

R.B., P.A.R., A.T., A.A., F.W., J.W. and M.J. contributed to designing the Yellow Card material. L.C. (formerly HWW) and P.A.W. worked with the lead author to implement the video and develop the pre/post video survey methodology on the HWW platform. P.A.W. and M.A. processed and interpreted the data, and F.T. and R.B. drafted the manuscript. All authors reviewed the manuscript prior to submission.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The full data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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