

Adverse drug reactions in children

Case study

Aim

To develop an Adverse Drug Reaction (ADR) form that would be useful and acceptable to children and young people (CYP) of various ages to help encourage an increase in reporting ADRs by this age group

Methods

Five workshops and engagement work with the Medicines and Healthcare products Regulatory Agency (MHRA) and Alder Hey Research Ambassador Scheme.

- **Workshop one** (GenerationR Liverpool YPAG): 20 CYP (aged 12-18 years) – presentation and discussion on how to increase CYP reporting of ADRs, and development of a CYP ADR reporting form.
- **Workshop two:** (Royal College of Paediatrics and Child Health Quality Improvement (QI) group): 56 CYP (aged 12-18 years) – presentation and discussion on how to increase CYP reporting of ADRs, and development of a CYP ADR reporting form.
- **Workshop three:** (Primary school): 40 CYP (aged 9-11 years) – presentation and discussion on how to increase CYP reporting of ADRs, and development of a CYP ADR reporting form
- **Workshop four:** (GenerationR Liverpool YPAG): 21 CYP (aged 12-18 years) – presentation and iterative improvement of the reporting form for different age groups.
- **Workshop five:** ICAN conference: 200 CYP (aged 12-18 years) from across the Globe - presentation and iterative improvement of the reporting form for different age groups.
- **Engagement work with MHRA:** The national drug regulator then undertook an anonymous survey of young people on a Department of Health email list, and received 234 responses, further refining the information
- **Alder Hey Research Ambassador Scheme:** Follow professional graphic design of the finalised information, it was used as the lead project in the 2023/4 Alder Hey research ambassador scheme, involving >20 schools and getting feedback from nearly 3000 more young people.

What difference did it make?

**Workshop one:** the Liverpool YPAG were clear that a single source of information would not be sufficient. They suggested that there should be two versions of the information, one for older children (12+ years) and one for younger (<12 years). Additionally, when reviewing existing adult-orientated information, it was stated that these contained too much information, and re-working them into 'bite-sized' chunks for CYP was requested.



The YPAG suggested specific information should be part of both the older and younger CYP information included (i) the ways you can make a yellow card report; (ii) what to report; (iii) protection of personal information; (iv) where to get more information; and (v) the potential benefits to reporting.

**Workshops two–four:** Refinement of the language used, and topics covered in two versions of the information for different age groups.

**ICAN Workshops:** Updates to the information were obtained regarding the format, language, and structure of the forms.

**MHRA:** The MHRA has now used the information (see pictures below) as part of targeted information for young people about the COVID vaccine side effects, demonstrating national impact.

**National Curriculum:** The team, supported by University of Liverpool, and the MHRA, have responded to a Department of Education consultation about the National Curriculum and are waiting for the results.

**Reporting a possible side effect to a medicine  
A guide for Children and Young People**

To report a side effect go to [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  
or use the QR code below



**What is a side effect?**  
If you are prescribed a medicine, it is meant to help you feel better. Sometimes medicines can also cause other problems, which are called 'side effects'. Your medicine comes with information in the packet (Patient Information Leaflet) that tells you about the known side effects. It can be difficult to know if you have a problem from a medicine, as there are lots of possible side effects, and they can happen anytime, even if you have been taking the same medicine for a long time. You may need to ask a doctor, nurse, pharmacist, or an adult you trust to help you.



**Who are the MHRA and why do they want to know about side effects?**  
The Medicines and Healthcare products Regulatory Agency (MHRA) keeps a watch over medicines to make sure they are safe, are used properly, and don't harm people. They collect information about side effects of medicines (called "Yellow Card reports") from people of all ages who get side effects. This means that if you think you may have had a side effect, and want to help keep medicines safe, the MHRA would like you to send in a Yellow Card report. It is important for the MHRA to work out which medicines are giving children and young people side effects and learn about new side effects, as it may be possible to change something to help others in the future.



**What should I do if I am worried that I may have had a side effect?**  
If you are worried, then talking to a doctor, nurse, pharmacist, or another adult you trust may help. You can contact NHS 111 in England, Wales, Scotland and Northern Ireland by visiting [www.111.nhs.uk](http://www.111.nhs.uk) or call 111

**SCAN ME**

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**Reporting a possible side effect to a medicine  
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**What side effects can be reported on a Yellow Card?**  
You can report any side effect you think you may have had on a Yellow Card even if you are taking multiple medicines or with food/drink. The side effect you are worried about may not be on the leaflet that comes with the medicine (Patient Information Leaflet). That is ok, it might be a new effect and you can still report it.

**When should I report the side effect?**  
You can report a side effect anytime, even if you are no longer using the medicine. The medicine may have come from a doctor, pharmacy, or a shop, it doesn't matter, all can be reported. If you take more than one medicine and are not sure which one caused the side effect, you can put the names of all the medicines on the report.



**How do I report the side effect?**  
You can fill out a Yellow Card report in different ways:

- Using a computer or smart phone (with permission), go to [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- Using the Yellow card app on a mobile phone or tablet
- You can ask a doctor, nurse, pharmacist, or adult you trust to complete a Yellow Card with you

The MHRA may need to ask some more questions about your side effect, so they will need a way of contacting you or an adult you trust if you give their details. The MHRA will not share your personal information, or those of your trusted adult, with anyone else.



**Yellow Card**

## Discussion and conclusions

The workshops and engagement work with CYP created the first ever tailored information for CYP to report their own suspected ADRs. The output of this work has the potential to be used nationally to positively influence CYP's behaviours with regard to healthcare.

## Reflections/critical perspective

The research team work very closely with the PPI team on a variety of research projects and understand the value of PPI with CYP. A big criticism of PPI in general is that it often lacks diversity in the people who get involved (i.e., it tends to be white middle-class people from a particular age group). To tackle the issue of diversity this project developed a PPI plan that involved activities with 1000s of CYP from various settings including schools, and existing YPAGs over several years. Adopting such an approach takes time but has the potential to have more impact because of the diverse views sought. However, although some of the cohort of CYP had various learning difficulties or physical impairments these were only in small numbers. Additional PPI activities with these populations may have generated different outputs and this needs to be explored if further iteration of the reporting forms are to be developed. Developing relationships and undertaking PPI activities with specialist schools with skilled staff may have been useful to overcome this challenge.

### Contact information

[Jennifer.preston@liverpool.ac.uk](mailto:Jennifer.preston@liverpool.ac.uk)

[Jenny.ainsworth@liverpool.ac.uk](mailto:Jenny.ainsworth@liverpool.ac.uk)

[dhawcutt@liverpool.ac.uk](mailto:dhawcutt@liverpool.ac.uk)

### Social media

[@CRFalderhey](https://twitter.com/CRFalderhey)

[@PMRUalderhey](https://twitter.com/PMRUalderhey)

## Publications

Bhoombala, N., Preston, J., Ainsworth, J. et al. Pharmacovigilance Reports Received from Children and Young People, and Development of Information to Aid Future Reporting from this Age Group. *Pediatr Drugs* 22, 335–341 (2020). <https://doi.org/10.1007/s40272-020-00391-6>

Hawcutt DB, Jadeja M, Bhoombala N, Smith S, McWilliam SJ. Information for children and young people about reporting suspected adverse drug reactions. *Arch Dis Child*. 2022 Jul;107(7):681–685. doi: [10.1136/archdischild-2021-323400](https://doi.org/10.1136/archdischild-2021-323400). Epub 2022 Mar 15. PMID: 35292430.

Bioletti L, Alder Hey Research Ambassadors, Woodward C, Jadeja M, Hawcutt DB. Assessing and further developing age-appropriate information for young people about reporting suspected adverse drug reactions. *Br J Clin Pharmacol*. 2024; 90(3): 863–870. doi:[10.1111/bcp.15971](https://doi.org/10.1111/bcp.15971)